

**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, 2022

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37977

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland

(State or Other Jurisdiction of Incorporation)

98-1341933

(I.R.S. Employer Identification No.)

10 Earlsfort Terrace

Dublin 2 D02 T380

Ireland

(Address of Principal Executive Office and Zip Code)

+353-1-901-5201

(Registrant's telephone number, including area code)

N/A

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

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

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

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 7, 2022, 61,778,732 ordinary shares, nominal value \$0.01 each, of the Company were outstanding.

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NOTE REGARDING TRADEMARKS

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

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

Cautionary Disclosure Regarding Forward-Looking Statements

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

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

- Our reliance on a single lead product candidate, LUMRYZ, also known as FT218;
- Our ability to obtain final regulatory approval and full authorization from the U.S. Food and Drug Administration (“FDA”) to commercialize LUMRYZ, including any delays in a final approval and/or authorization to launch;
- The ability of LUMRYZ, if granted final approval by the FDA, to be successfully commercialized and gain market acceptance;
- Our ability to enter into strategic partnerships for the commercialization, manufacturing and distribution of LUMRYZ;
- Our dependence on a limited number of suppliers for the manufacturing of LUMRYZ and certain raw materials used in LUMRYZ and any failure of such suppliers to deliver sufficient quantities of these raw materials, which could have a material adverse effect on our business;
- Our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;
- Our expectations about the potential market size and market participation for LUMRYZ, if granted final approval by the FDA;
- Our expectations regarding litigation related to LUMRYZ, including the potential delisting of U.S. Patent No. 8731963 from the Orange Book;
- Our expectations regarding the timing and results of our cost structure optimization efforts, including the estimated charges and costs expected to be incurred and projected cost savings in connection with such cost structure optimization efforts;
- Our expectations regarding our cash runway lasting to a potential final FDA approval of our New Drug Application (“NDA”) for LUMRYZ;
- Our ability to continue to service our exchangeable senior notes due February 2023 (the “February 2023 Notes”) and our exchangeable senior notes due October 2023 (the “October 2023 Notes”, together with the February 2023 Notes, the “2023 Notes”), including making the ongoing interest payments on the 2023 Notes, settling exchanges of the 2023 Notes in cash or completing any required repurchases of the 2023 Notes;
- The potential impacts of COVID-19, inflation and rising interest rates on our business and future operating results;
- Our ability to hire and retain key members of our leadership team and other personnel; and
- Competition existing today or that will likely arise in the future.

These forward-looking statements are neither promises nor guarantees of future performance due to a variety of risks and uncertainties and other factors more fully discussed in the “Risk Factors” section in Part I, Item 1A of the Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (“SEC”) on March 16, 2022 and the risk factors and cautionary statements described in our subsequent filings with the SEC. Given these uncertainties, readers should not place undue reliance on our forward-looking statements. These forward-looking statements speak only as of the date on which the statements were made and are not guarantees of future performance. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this Quarterly Report, even if new information becomes available in the future.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development expenses	\$ 2,933	\$ 4,380	\$ 14,465	\$ 14,994
Selling, general and administrative expenses	14,096	21,283	57,535	47,469
Restructuring (income) expense	(69)	—	3,523	(53)
Total operating expense	16,960	25,663	75,523	62,410
Operating loss	(16,960)	(25,663)	(75,523)	(62,410)
Investment and other income, net	448	489	503	1,531
Interest expense	(3,564)	(1,929)	(9,087)	(5,788)
Gain from release of certain liabilities	—	—	33	166
Loss before income taxes	(20,076)	(27,103)	(84,074)	(66,501)
Income tax provision (benefit)	70	(5,101)	25,940	(11,473)
Net loss	\$ (20,146)	\$ (22,002)	\$ (110,014)	\$ (55,028)
Net loss per share – basic	\$ (0.33)	\$ (0.38)	\$ (1.85)	\$ (0.94)
Net loss per share – diluted	(0.33)	(0.38)	(1.85)	(0.94)
Weighted average number of shares outstanding - basic	60,201	58,585	59,359	58,506
Weighted average number of shares outstanding - diluted	60,201	58,585	59,359	58,506

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,	
	2022	2021	2022	2021
Net loss	\$ (20,146)	\$ (22,002)	\$ (110,014)	\$ (55,028)
Other comprehensive loss, net of tax:				
Foreign currency translation loss	(647)	(237)	(1,489)	(839)
Net other comprehensive loss, net of income tax benefit of \$—, \$59, \$— and \$220, respectively	(934)	(157)	(2,480)	(854)
Total other comprehensive loss, net of tax	(1,581)	(394)	(3,969)	(1,693)
Total comprehensive loss	<u>\$ (21,727)</u>	<u>\$ (22,396)</u>	<u>\$ (113,983)</u>	<u>\$ (56,721)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	September 30, 2022	December 31, 2021
	<i>(Unaudited)</i>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 60,715	\$ 50,708
Marketable securities	45,760	106,513
Research and development tax credit receivable	2,077	2,443
Prepaid expenses and other current assets	4,670	32,826
Total current assets	<u>113,222</u>	<u>192,490</u>
Property and equipment, net	896	285
Operating lease right-of-use assets	1,947	2,652
Goodwill	16,836	16,836
Research and development tax credit receivable	1,137	1,225
Other non-current assets	11,720	33,777
Total assets	<u>\$ 145,758</u>	<u>\$ 247,265</u>
LIABILITIES AND SHAREHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Current portion of long-term debt	\$ 26,299	\$ —
Current portion of operating lease liability	1,011	900
Accounts payable	2,479	7,679
Accrued expenses	7,965	7,151
Other current liabilities	3,757	5,270
Total current liabilities	<u>41,511</u>	<u>21,000</u>
Long-term debt	109,934	142,397
Long-term operating lease liability	1,026	1,707
Other non-current liabilities	5,727	3,917
Total liabilities	<u>158,198</u>	<u>169,021</u>
Shareholders' (deficit) equity:		
Preferred shares, nominal value of \$0.01 per share; 50,000 shares authorized; 488 issued and outstanding at September 30, 2022 and 488 issued and outstanding at December 31, 2021	5	5
Ordinary shares, nominal value of \$0.01 per share; 500,000 shares authorized; 60,885 issued and outstanding at September 30, 2022 and 58,620 issued and outstanding at December 31, 2021	608	586
Additional paid-in capital	572,626	549,349
Accumulated deficit	(557,770)	(447,756)
Accumulated other comprehensive loss	(27,909)	(23,940)
Total shareholders' (deficit) equity	<u>(12,440)</u>	<u>78,244</u>
Total liabilities and shareholders' (deficit) equity	<u>\$ 145,758</u>	<u>\$ 247,265</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Ordinary shares		Preferred shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total shareholders' (deficit) equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2021	58,620	\$ 586	488	\$ 5	\$ 549,349	\$ (447,756)	\$ (23,940)	\$ 78,244
Net loss	—	—	—	—	—	(26,424)	—	(26,424)
Other comprehensive loss	—	—	—	—	—	—	(1,102)	(1,102)
Exercise of stock options	275	3	—	—	1,903	—	—	1,906
Vesting of restricted shares	119	1	—	—	(1)	—	—	—
Employee share purchase plan share issuance	18	—	—	—	103	—	—	103
Share-based compensation expense	—	—	—	—	2,505	—	—	2,505
Balance, March 31, 2022	59,032	\$ 590	488	\$ 5	\$ 553,859	\$ (474,180)	\$ (25,042)	\$ 55,232
Net loss	—	—	—	—	—	(63,444)	—	(63,444)
Other comprehensive loss	—	—	—	—	—	—	(1,286)	(1,286)
Vesting of restricted shares	6	—	—	—	—	—	—	—
Change in fair value of October 2023 Notes conversion feature	—	—	—	—	5,508	—	—	5,508
Share-based compensation expense	—	—	—	—	658	—	—	658
Balance, June 30, 2022	59,038	\$ 590	488	\$ 5	\$ 560,025	\$ (537,624)	\$ (26,328)	\$ (3,332)
Net loss	—	—	—	—	—	(20,146)	—	(20,146)
Other comprehensive loss	—	—	—	—	—	—	(1,581)	(1,581)
Exercise of stock options	14	—	—	—	64	—	—	64
Vesting of restricted shares	8	—	—	—	—	—	—	—
Issuance of common stock under at-the-market offering program, net of issuance costs	1,768	17	—	—	10,515	—	—	10,532
Amortization of deferred issuance costs	—	—	—	—	(19)	—	—	(19)
Employee share purchase plan share issuance	57	1	—	—	118	—	—	119
Share-based compensation expense	—	—	—	—	1,923	—	—	1,923
Balance, September 30, 2022	60,885	\$ 608	488	\$ 5	\$ 572,626	\$ (557,770)	\$ (27,909)	\$ (12,440)

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

	Ordinary shares		Preferred shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total shareholders' equity
	Shares	Amount	Shares	Amount				
Balance, December 31, 2020	58,396	\$ 583	488	\$ 5	\$ 566,916	\$ (384,187)	\$ (21,051)	\$ 162,266
Impact of the adoption of ASU 2020-06	—	—	—	—	(26,699)	13,760	—	(12,939)
Net loss	—	—	—	—	—	(13,445)	—	(13,445)
Other comprehensive loss	—	—	—	—	—	—	(1,255)	(1,255)
Exercise of stock options	23	—	—	—	106	—	—	106
Vesting of restricted shares	61	1	—	—	(1)	—	—	—
Employee share purchase plan share issuance	8	—	—	—	43	—	—	43
Share-based compensation expense	—	—	—	—	1,728	—	—	1,728
Balance, March 31, 2021	<u>58,488</u>	<u>\$ 584</u>	<u>488</u>	<u>\$ 5</u>	<u>\$ 542,093</u>	<u>\$ (383,872)</u>	<u>\$ (22,306)</u>	<u>\$ 136,504</u>
Net loss	—	—	—	—	—	(19,581)	—	(19,581)
Other comprehensive loss	—	—	—	—	—	—	(44)	(44)
Share-based compensation expense	—	—	—	—	2,001	—	—	2,001
Balance, June 30, 2021	<u>58,488</u>	<u>\$ 584</u>	<u>488</u>	<u>\$ 5</u>	<u>\$ 544,094</u>	<u>\$ (403,453)</u>	<u>\$ (22,350)</u>	<u>\$ 118,880</u>
Net loss	—	—	—	—	—	(22,002)	—	(22,002)
Other comprehensive loss	—	—	—	—	—	—	(394)	(394)
Exercise of stock options	25	1	—	—	62	—	—	63
Vesting of restricted shares	94	1	—	—	(1)	—	—	—
Employee share purchase plan share issuance	9	—	—	—	51	—	—	51
Share-based compensation expense	—	—	—	—	2,359	—	—	2,359
Balance, September 30, 2021	<u>58,616</u>	<u>\$ 586</u>	<u>488</u>	<u>\$ 5</u>	<u>\$ 546,565</u>	<u>\$ (425,455)</u>	<u>\$ (22,744)</u>	<u>\$ 98,957</u>

AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2022	2021
Cash flows from operating activities:		
Net loss	\$ (110,014)	\$ (55,028)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	907	614
Amortization of debt discount and debt issuance costs	4,147	937
Change in deferred taxes	25,916	(11,322)
Share-based compensation expense	5,086	6,088
Gain from release of certain liabilities	(33)	(166)
Other adjustments	1,539	1,056
Net changes in assets and liabilities		
Prepaid expenses and other current assets	27,948	(54)
Research and development tax credit receivable	27	3,079
Accounts payable & other current liabilities	(11,629)	(201)
Accrued expenses	4,277	2,421
Other assets and liabilities	(3,109)	(2,228)
Net cash used in operating activities	<u>(54,938)</u>	<u>(54,804)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(716)	(26)
Proceeds from the disposition of the hospital products	—	16,500
Proceeds from sales of marketable securities	59,873	83,726
Purchases of marketable securities	(2,334)	(58,591)
Net cash provided by investing activities	<u>56,823</u>	<u>41,609</u>
Cash flows from financing activities:		
Payments for debt issuance costs	(4,803)	—
Proceeds from issuance of shares off the at-the-market offering program	10,532	—
Proceeds from stock option exercises and employee share purchase plan	2,192	263
Net cash provided by financing activities	<u>7,921</u>	<u>263</u>
Effect of foreign currency exchange rate changes on cash and cash equivalents	201	(621)
Net change in cash and cash equivalents	10,007	(13,553)
Cash and cash equivalents at January 1,	50,708	71,722
Cash and cash equivalents at September 30,	<u>\$ 60,715</u>	<u>\$ 58,169</u>
Supplemental disclosures of cash flow information:		
Interest paid	\$ 9,660	\$ 6,469
Income taxes (refund) paid	\$ (32,323)	\$ 68

See accompanying notes to unaudited condensed consolidated financial statements.

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

NOTE 1: Summary of Significant Accounting Policies

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

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

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

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

Liquidity and Going Concern

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 Company has a recent history of generating losses and negative cash flows from operations, an accumulated shareholders’ deficit as of the date of these unaudited condensed consolidated financial statements and approximately \$60,715 of cash and cash equivalents and \$45,760 of marketable securities available for use to fund its operations, debt service and capital requirements. The Company’s ability to generate revenue is expected to start following the launch of LUMRYZ, which is dependent, in part, on final approval of LUMRYZ by the FDA. As of September 30, 2022, the Company has \$26,375 aggregate principal amount of its 4.50% exchangeable senior notes due February 2023 (the “February 2023 Notes”) and \$117,375 aggregate principal amount of its 4.50% exchangeable senior notes due October 2023 (the “October 2023 Notes”) (together, the “2023 Notes”). The Company does not currently have sufficient available liquidity to repay the outstanding balance of the October 2023 Notes. These conditions and events raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that these unaudited condensed consolidated financial statements are issued.

In response to these conditions and events, the Company is evaluating various financing strategies to obtain sufficient additional liquidity to meet its operating, debt service and capital requirements for the next twelve months following the date of this Quarterly Report. The potential sources of financing that the Company is evaluating include one or any combination of royalty financing, secured or unsecured debt, convertible debt and equity. In addition, the Company’s financing strategy could also include refinancing or negotiating new terms for the 2023 Notes. The Company also currently has authorized and available the use of its at-the-market offering program (“ATM Program”), described in more detail below, which could provide the Company up to approximately \$135,000 (as of September 30, 2022), net of commissions, if fully utilized. While the Company has the ability to utilize the ATM Program, it intends to pursue the other financing strategies described above. Based on the Company’s ability to raise funds through the ATM Program, the Company has determined that it is probable that such proceeds would provide sufficient additional capital to meet the Company’s operating, debt service and capital requirements for the next twelve months following the date of this Quarterly Report. As a result, the Company has concluded that management’s plans are probable of being achieved to alleviate the substantial doubt about the Company’s ability to continue as a going concern.

The sources of financing described above that could be available to the Company and the timing and probability of obtaining sufficient capital depends, in part, on obtaining final FDA approval of LUMRYZ, resolving any legal and regulatory matters that could preclude the Company from launching LUMRYZ and future capital market conditions. If the Company’s current assumptions regarding timing of potential final approval, the timing of the launch of LUMRYZ or if there are any other changes or differences in our current assumptions that negatively impact our financing strategy, the Company may have to further

reduce expenditures or significantly delay, scale back or discontinue the development or commercialization of LUMRYZ in order to extend its cash resources.

At-the-Market Offering Program

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

As of September 30, 2022, the Company had issued and sold 1,768 ADSs, resulting in net proceeds to the Company of approximately \$10,532, pursuant to the 2020 Prospectus. The Company may offer and sell up to an additional \$39,142 of ADSs under the ATM Program that remain available for sale pursuant to the 2020 Prospectus and also up to \$100,000 of ADSs available for sale under the ATM Program pursuant to the 2022 Prospectus.

Basis of Presentation. The unaudited condensed consolidated balance sheet as of September 30, 2022, which is derived from the prior year 2021 audited consolidated financial statements, and the interim unaudited condensed consolidated financial statements presented herein, have been prepared in accordance with U.S. GAAP, the requirements of Form 10-Q and Article 10 of Regulation S-X and, consequently, do not include all information or footnotes required by U.S. GAAP for complete financial statements or all the disclosures normally made in an Annual Report on Form 10-K. Accordingly, the unaudited condensed consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company’s 2021 Annual Report on Form 10-K filed with the United States Securities and Exchange Commission (“SEC”) on March 16, 2022.

The unaudited condensed consolidated financial statements include the accounts of the Company and subsidiaries, and reflect all adjustments (consisting only of normal recurring adjustments) that are, in the opinion of management, necessary for a fair presentation of the Company’s financial position, results of operations and cash flows for the dates and periods presented. All intercompany accounts and transactions have been eliminated. Results for interim periods are not necessarily indicative of the results to be expected during the remainder of the current year or for any future period.

NOTE 2: Fair Value Measurement

The Company is required to measure certain assets and liabilities at fair value, either upon initial recognition or for subsequent accounting or reporting. For example, the Company uses fair value extensively when accounting for and reporting certain financial instruments, when measuring certain contingent consideration liabilities and in the initial recognition of net assets acquired in a business combination. Fair value is estimated by applying the hierarchy described below, which prioritizes the inputs used to measure fair value into three levels and bases the categorization within the hierarchy upon the lowest level of input that is available and significant to the fair value measurement.

ASC 820, *Fair Value Measurements and Disclosures*, defines fair value as a market-based measurement that should be determined based on the assumptions that marketplace participants would use in pricing an asset or liability. When estimating fair value, depending on the nature and complexity of the asset or liability, the Company may generally use one or each of the following techniques:

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

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

- Level 1 - Quoted prices for identical assets or liabilities in active markets.

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

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

Fair Value Measurements:	As of September 30, 2022			As of December 31, 2021		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Marketable securities (see Note 3)						
Mutual and money market funds	\$ 31,481	\$ —	\$ —	\$ 78,098	\$ —	\$ —
Corporate bonds	—	9,178	—	—	16,479	—
Government securities - U.S.	—	3,458	—	—	9,471	—
Other fixed-income securities	—	1,643	—	—	2,465	—
Total assets	\$ 31,481	\$ 14,279	\$ —	\$ 78,098	\$ 28,415	\$ —

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain financial assets or liabilities. During the periods ended September 30, 2022 and December 31, 2021, respectively, there were no transfers in and out of Level 3. During the three and nine months ended September 30, 2022 and 2021, respectively, the Company did not recognize any allowances for credit losses.

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

Debt

The Company estimates the fair value of its \$26,375 aggregate principal amount of its February 2023 Notes and its \$117,375 aggregate principal amount of its October 2023 Notes based on interest rates that would be currently available to the Company for issuance of similar types of debt instruments with similar terms and remaining maturities or recent trading prices obtained from brokers (a Level 2 input). The estimated fair values of the February 2023 Notes and the October 2023 Notes at September 30, 2022 are \$25,584 and \$101,970, respectively. See Note 4: Long-Term Debt for additional information regarding the Company's debt obligations.

NOTE 3: Marketable Securities

The Company has investments in available-for-sale debt securities which are recorded at fair market value. The change in the fair value of available-for-sale debt investments is recorded as accumulated other comprehensive loss in shareholders' (deficit) equity, net of income tax effects. As of September 30, 2022, the Company considered any decreases in fair value on its marketable securities to be driven by factors other than credit risk, including market risk.

The following tables show the Company's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of September 30, 2022 and December 31, 2021, respectively:

Marketable Securities:	September 30, 2022			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value
Mutual and money market funds	\$ 32,922	\$ 220	\$ (1,661)	\$ 31,481
Corporate bonds	9,885	—	(707)	9,178
Government securities - U.S.	3,827	—	(369)	3,458
Other fixed-income securities	1,691	—	(48)	1,643
Total	\$ 48,325	\$ 220	\$ (2,785)	\$ 45,760

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

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

The Company recognized gross realized gains of \$64 and \$22 for the three months ended September 30, 2022 and 2021, respectively. These realized gains were offset by gross realized losses of \$61 and \$66 for the three months ended September 30, 2022 and 2021, respectively. We recognized gross realized gains of \$372 and \$74 for the nine months ended September 30, 2022 and 2021, respectively. These realized gains were offset by gross realized losses of \$1,092 and \$173 for the nine months ended September 30, 2022 and 2021, respectively.

The following table summarizes the estimated fair value of the Company's investments in marketable debt securities, accounted for as available-for-sale debt securities and classified by the contractual maturity date of the securities as of September 30, 2022:

Marketable Debt Securities:	Maturities				Total
	Less than 1 Year	1-5 Years	5-10 Years	Greater than 10 Years	
Corporate bonds	\$ 1,602	\$ 7,576	\$ —	\$ —	\$ 9,178
Government securities - U.S.	—	1,992	600	866	3,458
Other fixed-income securities	—	1,451	192	—	1,643
Total	\$ 1,602	\$ 11,019	\$ 792	\$ 866	\$ 14,279

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

The following table shows the gross unrealized losses and fair value of the Company's available-for-sale debt securities at September 30, 2022. The unrealized losses in the table below are driven by factors other than credit risk. The Company does not intend to sell the investments and it is not more likely than not that it will be required to sell the investments before recovery of their amortized cost bases.

	Less than 12 months		Greater than 12 months		Total	
	Fair value	Unrealized Losses	Fair value	Unrealized Losses	Fair value	Unrealized Losses
Marketable Debt Securities:						
Corporate bonds	\$ 6,264	\$ 440	\$ 2,914	\$ 267	\$ 9,178	\$ 707
Government securities - U.S.	1,042	63	2,416	306	3,458	369
Other fixed-income securities	1,065	17	578	31	1,643	48
Total	\$ 8,371	\$ 520	\$ 5,908	\$ 604	\$ 14,279	\$ 1,124

NOTE 4: Long-Term Debt

Long-term debt is summarized as follows:

	September 30, 2022	December 31, 2021
Principal amount of 4.50% exchangeable senior notes due February 2023	\$ 26,375	\$ 143,750
Principal amount of 4.50% exchangeable senior notes due October 2023	117,375	—
Less: unamortized debt discount and issuance costs, net	(7,517)	(1,353)
Net carrying amount of debt	136,233	142,397
Less: current maturities, net of \$76 unamortized debt discount and issuance costs	26,299	—
Long-term debt	\$ 109,934	\$ 142,397

For the three months ended September 30, 2022 and 2021, the total interest expense was \$3,564 and \$1,929, respectively, with coupon interest expense of \$1,646 and \$1,617 for each period, respectively, and the amortization of debt issuance costs and debt discount, totaling \$1,918 and \$312 for each period, respectively.

For the nine months ended September 30, 2022 and 2021, the total interest expense was \$9,087 and \$5,788, respectively, with coupon interest expense of \$4,852 and \$4,851 for each period, respectively, and the amortization of debt issuance costs and debt discount of \$4,147 and \$937 for each period, respectively. Current period interest expense also includes \$88 of additional interest expense owed to be in compliance with certain terms of the February 2023 Notes indenture and is not applicable to future periods.

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

On April 5, 2022, the Issuer completed the exchange of \$117,375 of its February 2023 Notes for a new series of its October 2023 Notes (the “Exchange Transaction”). The remaining \$26,375 aggregate principal amount of the February 2023 Notes were not exchanged and maintain a maturity date of February 1, 2023.

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

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

February 2023 Notes

Holders of the February 2023 Notes may convert their February 2023 Notes, at their option, prior to the close of business on the business day immediately preceding the maturity date.

October 2023 Notes

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

- Prior to the close of business on the business day immediately preceding May 1, 2023, a holder of the October 2023 Notes may surrender all or any portion of its October 2023 Notes for exchange at any time during the five business day period immediately after any five consecutive trading day period (the “Measurement Period”) in which the trading price per \$1 principal amount of October 2023 Notes, as determined following a request by a holder of the October 2023 Notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the ADSs and the exchange rate on each such trading day.
- If a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs prior to the close of business on the business day immediately preceding May 1, 2023, regardless of whether a holder of the October 2023 Notes has the right to require the Company to repurchase the October 2023 Notes, or if Avadel is a party to a merger event that occurs prior to the close of business on the business day immediately preceding May 1, 2023, all or any portion of a holder’s October 2023 Notes may be surrendered for exchange at any time from or after the date that is 95 scheduled trading days prior to the anticipated effective date of the transaction (or, if later, the earlier of (x) the business day after the Company gives notice of such transaction and (y) the actual effective date of such transaction) until 35 trading days after the actual effective date of such transaction or, if such transaction also constitutes a fundamental change, until the related fundamental change repurchase date.
- Prior to the close of business on the business day immediately preceding May 1, 2023, a holder of the October 2023 Notes may surrender all or any portion of its October 2023 Notes for exchange at any time during any calendar quarter commencing after the calendar quarter ending on March 31, 2022 (and only during such calendar quarter), if the last reported sale price of the ADSs for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price on each applicable trading day.
- If the Company calls the October 2023 Notes for redemption pursuant to Article 16 to the Indenture prior to the close of business on the business day immediately preceding May 1, 2023, then a holder of the October 2023 Notes may surrender all or any portion of its October 2023 Notes for exchange at any time prior to the close of business on the second business day prior to the redemption date, even if the October 2023 Notes are not otherwise exchangeable at such time. After that time, the right to exchange shall expire, unless the Company defaults in the payment of the redemption price, in which case a holder of the October 2023 Notes may exchange its October 2023 Notes until the redemption price has been paid or duly provided for.

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

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

NOTE 5: Income Taxes

The income tax provision was \$70 for the three months ended September 30, 2022 resulting in an effective tax rate of (0.3)%. The income tax benefit was \$5,101 for the three months ended September 30, 2021 resulting in an effective tax rate of 18.8%. The change in the effective income tax rate for the three months ended September 30, 2022, as compared to the prior period in 2021, is primarily due to the valuation allowances that were recorded against the net operating losses during the current period.

The income tax provision was \$25,940 for the nine months ended September 30, 2022 resulting in an effective tax rate of (30.9)%. The income tax benefit was \$11,473 for the nine months ended September 30, 2021 resulting in an effective tax rate of 17.3%. The change in the effective income tax rate for the nine months ended September 30, 2022, as compared to the prior period in 2021, is primarily due to the valuation allowances that were recorded against the deferred tax assets during the current 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 recorded a full valuation allowance on its deferred tax assets. The Company will be able to reverse the valuation allowance when it has shown its ability to generate taxable income on a consistent basis in future periods. The valuation allowance does not have an impact on the Company's ability to utilize any net operating losses or other tax attributes to offset cash taxes payable as these items are still eligible to be used.

During the nine months ended September 30, 2022, the Company collected all of the outstanding receivables due to the Company related to net operating loss carrybacks under the Coronavirus Aid, Relief, and Economic Security Act for losses incurred during 2019, which were carried back to 2015.

NOTE 6: Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	September 30, 2022	December 31, 2021
Prepaid and other expenses	\$ 3,745	\$ 3,179
Other	567	271
Guarantee from Armistice	277	279
Income tax receivable	81	29,097
Total	\$ 4,670	\$ 32,826

Other Non-Current Assets:	September 30, 2022	December 31, 2021
Right of use assets at contract manufacturing organizations	\$ 10,979	\$ 8,549
Guarantee from Armistice	564	771
Other	177	329
Deferred tax assets	—	24,128
Total	\$ 11,720	\$ 33,777

Accrued Expenses	September 30, 2022	December 31, 2021
Accrued professional fees	\$ 4,419	\$ 2,678
Accrued restructuring	1,515	41
Accrued compensation	1,293	3,167
Accrued outsource contract costs	738	1,048
Customer allowances	—	217
Total	\$ 7,965	\$ 7,151

Other Current Liabilities:	September 30, 2022	December 31, 2021
Income tax payable	\$ 3,265	\$ —
Guarantee to Deerfield	278	280
Accrued interest	199	4,920
Other	15	70
Total	\$ 3,757	\$ 5,270

Other Non-Current Liabilities:	September 30, 2022	December 31, 2021
Tax liabilities	\$ 5,161	\$ 3,143
Guarantee to Deerfield	566	774
Total	\$ 5,727	\$ 3,917

NOTE 7: Share Based Compensation

2022 Performance-Based Stock Options

In August 2022, the Board of Directors approved the grant of performance-based stock options to certain executive officers and employees. These performance-based stock options vest upon both the achievement of certain commercial milestones and specific service conditions. As of September 30, 2022, 2,165 performance-based stock options were outstanding, none of which had vested. The weighted-average grant date fair value of the performance-based stock options was \$3.71. The Company has not yet recognized any related share-based compensation expense as the commercial milestones have not been met; however, in the event that the performance conditions are met, \$8,032 will be recognized by the Company for the performance-based stock options outstanding as of September 30, 2022.

NOTE 8: Net Loss Per Share

Basic net loss per share is calculated by dividing net loss by the weighted average number of shares outstanding during each period. Diluted net loss per share is calculated by dividing net loss - diluted by the diluted number of shares outstanding during each period. Except where the result would be anti-dilutive to net loss, diluted net loss per share would be calculated assuming the impact of the conversion of the 2023 Notes, the conversion of the Company's preferred shares, the exercise of outstanding equity compensation awards, and ordinary shares expected to be issued under the Company's Employee Share Purchase Plan ("ESPP").

The Company has a choice to settle the conversion obligations under the 2023 Notes in cash, shares or any combination of the two. The Company utilizes the if-converted method to reflect the impact of the conversion of the 2023 Notes, unless the result is anti-dilutive. This method assumes the conversion of the 2023 Notes into shares of the Company's ordinary shares and reflects the elimination of the interest expense related to the 2023 Notes.

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

A reconciliation of basic and diluted net loss per share, together with the related shares outstanding, in thousands, is as follows:

Net Loss Per Share:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	\$ (20,146)	\$ (22,002)	\$ (110,014)	\$ (55,028)
Weighted average shares:				
Basic shares	60,201	58,585	59,359	58,506
Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes	—	—	—	—
Diluted shares	60,201	58,585	59,359	58,506
Net loss per share - basic	\$ (0.33)	\$ (0.38)	\$ (1.85)	\$ (0.94)
Net loss per share - diluted	\$ (0.33)	\$ (0.38)	\$ (1.85)	\$ (0.94)

Potential ordinary shares of 18,722 and 15,684 were excluded from the calculation of weighted average shares for the three months ended September 30, 2022 and 2021, respectively, and potential ordinary shares of 18,925 and 15,497 were excluded from the calculation of weighted average shares for the nine months ended September 30, 2022 and 2021 because either their effect was considered to be anti-dilutive or they were related to shares from PSUs for which the contingent vesting condition had not been achieved. For the three and nine months ended September 30, 2022 and 2021, the effects of dilutive securities were entirely excluded from the calculation of net loss per share as a net loss was reported in these periods.

NOTE 9: Comprehensive Loss

The following table shows the components of accumulated other comprehensive loss for the three and nine months ended September 30, 2022 and 2021, respectively, net of tax effects:

Accumulated Other Comprehensive Loss:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Foreign currency translation adjustment:				
Beginning balance	\$ (24,697)	\$ (23,229)	\$ (23,855)	\$ (22,627)
Net other comprehensive loss	(647)	(237)	(1,489)	(839)
Balance at September 30,	\$ (25,344)	\$ (23,466)	\$ (25,344)	\$ (23,466)
Unrealized (loss) gain on marketable debt securities, net				
Beginning balance	\$ (1,631)	\$ 879	\$ (85)	\$ 1,576
Net other comprehensive loss, net of income tax benefit of \$—, \$59, \$— and \$220, respectively	(934)	(157)	(2,480)	(854)
Balance at September 30,	\$ (2,565)	\$ 722	\$ (2,565)	\$ 722
Accumulated other comprehensive loss at September 30,	\$ (27,909)	\$ (22,744)	\$ (27,909)	\$ (22,744)

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 10: Commitments and Contingencies

Litigation

The Company is subject to potential liabilities generally incidental to the Company's business arising out of present and future lawsuits and claims related to product liability, personal injury, contract, commercial, intellectual property, tax, employment, compliance and other matters that arise in the ordinary course of business. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At September 30, 2022 and December 31, 2021, there were no contingent liabilities with respect to any litigation, arbitration or

administrative or other proceeding that are reasonably likely to have a material adverse effect on the Company's consolidated financial position, results of operations, cash flows or liquidity.

First Jazz Complaint

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

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

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

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

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

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

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

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

On June 23, 2022, Avadel CNS filed a Renewed Motion for Judgment on the Pleadings, with respect to its counterclaim against Jazz seeking to have U.S. Patent No. 8731963 (the "REMS Patent") de-listed from the Orange Book and seeking to have the motion resolved concurrent with the parties' *Markman* hearing on August 31, 2022. On July 7, 2022, Jazz filed a response it styled as Objections to Avadel CNS' Motion for Judgment on the Pleadings. On July 14, 2022, Avadel CNS replied to Jazz'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 de-listing of the REMS Patent. On October 28, 2022, the Court granted Avadel CNS' request and scheduled the hearing for November 15, 2022.

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 de-listing of the REMS Patent from the Orange Book, which is pending in response to 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) de-listing 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.

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

Administrative Procedure Act Complaint

On July 21, 2022, Avadel CNS filed an Administrative Procedure Act suit against the FDA, the U.S. Department of Health and Human Services, the Secretary of Health and Human Services and the Commissioner of Food and Drugs (the “Federal Defendants”) in the United States District Court for the District of Columbia (the “DC Court”) related to the NDA for LUMRYZ (sodium oxybate). This suit alleges that the FDA’s decision requiring Avadel CNS to file a patent certification concerning the REMS Patent was arbitrary, capricious and contrary to law and asks the DC Court to vacate the FDA’s decision and order the FDA to take final action on the LUMRYZ NDA. On July 28, 2022, the DC Court granted Jazz’s unopposed motion to intervene in the case to defend the FDA’s decision. The DC Court also entered an expedited briefing schedule governing Avadel CNS’s motion for preliminary injunction or, in the alternative, summary judgment, and the Federal Defendant’s and Jazz’s oppositions to that motion and anticipated cross-motions for summary judgment. On August 19, 2022, the Federal Defendants and Jazz filed their combined oppositions to Avadel CNS’s motion for preliminary injunction or, in the alternative, summary judgment, and cross-motions for summary judgment. On September 2, 2022, Avadel CNS filed its combined reply in support of its motion for preliminary injunction or, in the alternative, summary judgment, and opposition to the cross-motions for summary judgment. On September 14, 2022, the Federal Defendants and Jazz filed their replies in support of their cross-motions for summary judgment. On October 7, 2022, the DC Court heard oral arguments of Avadel CNS’s motion and the Federal Defendants and Jazz’s cross-motions. On November 3, 2022, the DC Court issued its opinion determining that Avadel CNS is not entitled to seek relief under the APA because of the availability of adequate alternative relief in the Court, specifically, in the form of its counterclaim to have the REMS Patent de-listed from the FDA’s Orange Book described above in the section regarding the First Jazz Complaint.

Material Commitments

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

Guarantees

The fair values of the Company’s guarantee to Deerfield Capital L.P. (“Deerfield”) and the guarantee received by the Company from Armistice Capital Master Fund, Ltd. largely offset and when combined are not material.

Deerfield Guarantee

In connection with the Company’s February 2018 divestiture of the Company’s pediatric assets, the Company guaranteed to Deerfield the quarterly royalty payment of 15% on net sales of the FSC products through February 6, 2026 (“FSC Product Royalties”), in an aggregate amount of up to approximately \$10,300. Given the Company’s explicit guarantee to Deerfield, the Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee liability was \$844 at September 30, 2022. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

Armistice Guarantee

In connection with the Company's February 2018 divestiture of the pediatric assets, Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, Inc., guaranteed to the Company the FSC Product Royalties. The Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee asset was \$841 at September 30, 2022. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

Off-Balance Sheet Arrangements

As of September 30, 2022, the Company did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

NOTE 11: Restructuring Costs

2022 Corporate Restructuring Plan

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

The Company's cost structure optimization efforts included a nearly 50% reduction in its workforce that was completed at the end of August 2022 (the "2022 Corporate Restructuring Plan"). Restructuring income of \$69 associated with this plan, comprised primarily of adjustments to the estimate of severance related costs, were recorded in the three months ended September 30, 2022. Restructuring charges of \$3,523 associated with this plan, comprised primarily of severance related costs, were recorded in the nine months ended September 30, 2022.

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

2022 Corporate Restructuring Plan Obligation:	2022
Balance of 2022 Corporate Restructuring Plan accrual at January 1,	\$ —
Charges for employee severance, benefits and other costs	3,592
Payments	(2,043)
Other adjustments	(69)
Balance of 2022 Corporate Restructuring Plan accrual at September 30,	<u>\$ 1,480</u>

The 2022 Corporate Restructuring Plan liabilities of \$1,480 are included in the unaudited condensed consolidated balance sheet in accrued expenses at September 30, 2022.

NOTE 12: Subsequent Events

On November 4, 2022, the Company repurchased \$8,875 of its February 2023 Notes for \$8,653 of cash consideration through an open market purchase.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Management's Discussion and Analysis

(In thousands, except per share data)

(Unaudited)

You should read the discussion and analysis of our financial condition and results of operations set forth in this Item 2 together with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this Quarterly Report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, and reference is made to the "Cautionary Note Regarding Forward-Looking Statements" set forth immediately following the Table of Contents of this Quarterly Report on Form 10-Q for further information on the forward looking statements herein. In addition, you should read the "Risk Factors" section in Part I, Item 1A of our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2022 and Part II, Item 1A in this Quarterly Report on Form 10-Q for a discussion of additional important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this Quarterly Report.

Overview

General Overview

Avadel Pharmaceuticals plc (Nasdaq: AVDL) ("Avadel," the "Company," "we," "our," or "us") is a biopharmaceutical company. Our lead product candidate, LUMRYZ, also known as FT218, is an investigational once-at-bedtime, extended-release formulation of sodium oxybate for the treatment of cataplexy or excessive daytime sleepiness ("EDS") in adults with narcolepsy. We are primarily focused on obtaining final United States ("U.S.") Food and Drug Administration ("FDA") approval of LUMRYZ.

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

LUMRYZ

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

On July 18, 2022, the FDA granted tentative approval to LUMRYZ for the treatment of cataplexy or EDS in adults suffering from narcolepsy. Tentative approval indicates that LUMRYZ has met all required quality, safety, and efficacy standards necessary for approval in the U.S.

A decision on final FDA approval of LUMRYZ is pending disposition of U.S. Patent No. 8731963 (the "REMS Patent"), which is listed in the FDA's Orange Book. The decision on final FDA approval could occur on or about the expiration of the REMS Patent on June 17, 2023 or sooner if the patent is earlier removed from the FDA's Orange Book, a court earlier determines that the REMS Patent is not infringed, invalid or otherwise unenforceable, or a court determines that the FDA erred in requiring certification. The FDA's tentative approval can be subject to change based on new information that may come to the FDA's attention between such time as the tentative approval and potential final approval. We cannot legally market LUMRYZ in the U.S. until final approval is granted by the FDA. In an effort to expedite the time between a potential final approval of LUMRYZ and product availability, we are advancing our preparations for the commercial launch of LUMRYZ, which, assuming final FDA approval in June 2023, is anticipated to occur in the third quarter of 2023.

With respect to clinical data generated for LUMRYZ, we conducted a Phase 3 clinical trial of LUMRYZ, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients who received at least one dose of LUMRYZ or placebo, and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient and last visit was completed at the end of the first quarter of 2020, and positive top line data from the REST-ON trial was announced on April 27, 2020. Patients who received 9 g of once-at-bedtime LUMRYZ, the highest dose administered in the trial, demonstrated statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test (“MWT”), clinical global impression-improvement (“CGI-I”), and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-at-bedtime LUMRYZ to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of LUMRYZ discontinued the trial due to adverse reactions.

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

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

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

Additional data supportive of the efficacy findings in REST-ON were presented at the 35th Annual Meeting of the Associated Professional Sleep Societies, a joint meeting of the American Academy of Sleep Medicine and the Sleep Research Society, also known as SLEEP 2021, beginning June 10, 2021. New data included post-hoc analyses demonstrating endpoints improvements, regardless of concomitant stimulant use, in both narcolepsy Type 1 (“NT1”) or Type 2 (“NT2”). Additionally, a post-hoc analysis showed that LUMRYZ was associated with decreased body mass index compared to placebo, which may be relevant as people with narcolepsy often have co-morbid obesity. In August 2021, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP.

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

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

In addition, the results of a discrete choice experiment (“DCE”) were presented, which confirmed that once-at-bedtime dosing, when compared to twice-nightly dosing, was the most important attribute driving both patient and clinician preference for overall oxybate product choice, as well as patient quality of life and reduction of patient anxiety/stress; dosing frequency (twice-nightly versus once-at-bedtime) was also viewed as a more important attribute as compared to other attributes assessed, including sodium content. Accompanying the DCE was a background survey for both patients and clinicians, which showed that dosing frequency was noted as a significant stressor by both patients and clinicians. The World Sleep 2022 presentations also included the first presentation of an interim safety analysis from the ongoing RESTORE study, which showed that LUMRYZ has generally been well-tolerated, with some patients receiving therapy for more than 18 months. No new safety signals have been observed as of October 21, 2022.

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

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

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

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

MICROPUMP Drug-Delivery Technology

Our MICROPUMP drug-delivery technology allows for the controlled delivery of small molecule drugs taken orally, which has the potential to improve dosing compliance, reduce toxicity and improve patient compliance. We believe there could be product development opportunities for our MICROPUMP drug-delivery technology, representing either life cycle opportunities, whereby additional intellectual property can be added to a pharmaceutical product to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities.

Key Business Trends and Highlights

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

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

- **Competition and Technological Change:** Competition in the pharmaceutical and biotechnology industry continues to be intense and is expected to increase. We compete with other pharmaceutical and biotechnology companies. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our products, product candidates, or drug delivery platforms obsolete or noncompetitive.
- **Pricing Environment for Pharmaceuticals:** The pricing environment continues to be in the political spotlight in the U.S. As a result, the need to obtain and maintain appropriate pricing for pharmaceutical products may become more challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide.
- **Generics Playing a Larger Role in Healthcare:** Generic pharmaceutical products will continue to play a large role in the U.S. healthcare system. As such, we expect to see generic competition for our products in the future. If LUMRYZ receives final FDA approval, we anticipate LUMRYZ may face competition from manufacturers of generic twice-nightly sodium oxybate formulations, who have reached settlement agreements with the current marketer, which allows for entry of an authorized generic in 2023, or earlier under certain circumstances. For example, Hikma Pharmaceuticals plc is expected to launch an authorized generic version of sodium oxybate in 2023 or earlier, depending on certain circumstances. Beyond the potential of an authorized generic from Hikma Pharmaceuticals plc, there are other potential future competitive products and additional generic twice-nightly sodium oxybate formulations that could impact the marketplace.
- **Access to and Cost of Capital:** We have a recent history of generating losses from operations and expect to continue generating losses until we are able to launch LUMRYZ, if final FDA approval is obtained, and generate revenues sufficient to generate positive cash flow from operations. Similar to other businesses in our industry and at our stage of development, we will continue to rely on external sources of capital to fund our business. The process of raising capital and associated cost of such capital for a company of our financial profile can be difficult and potentially expensive. If the need were to arise to raise additional capital, access to that capital may be difficult, expensive and/or dilutive and, as a result, could create liquidity challenges for us.
- **Net Loss from Operations in 2022:** We do not have any commercialized products in our portfolio. We will incur substantial expenses to further the clinical development of and continue our preparations for the commercial launch of LUMRYZ, which, assuming final FDA approval in June 2023, is anticipated to occur in the third quarter of 2023.

Impact of COVID-19

Since early 2020, we have seen the profound impact that the coronavirus (“COVID-19”) pandemic is having on human health, the global economy and society at large. We have continued to actively monitor the COVID-19 pandemic, as well as new variants of the virus and recent increases in case numbers, and have taken measures to mitigate the potential impacts to our employees and business, such as continuing to offer a work from home policy. We believe the ongoing impact of COVID-19 and measures to prevent its spread could impact our business in a number of ways, including: i) possibly delaying our ongoing RESTORE study; ii) disruptions to our supply chain and third parties; iii) allowing our employees to work from home for an extended period of time; and iv) hindering sales efforts for LUMRYZ, if final FDA approval is obtained. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition. Despite vaccination efforts, future developments and impact on our operations remain uncertain and cannot be predicted with confidence, including the duration of the COVID-19 pandemic, new variants of the virus, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that governments, or we, may direct, which may result in extending continued business disruptions.

2022 Corporate Restructuring Plan

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

Our cost structure optimization efforts included a nearly 50% reduction in our workforce (the “2022 Corporate Restructuring Plan”). See *Note 11: Restructuring Costs* to our unaudited condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for more information.

At-the-Market Offering Program

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

As of September 30, 2022, we had issued and sold 1,768 ADSs, resulting in net proceeds to us of approximately \$10,532, pursuant to the 2020 Prospectus. We may offer and sell up to an additional \$39,142 of ADSs under the ATM Program that remain available for sale pursuant to the 2020 Prospectus and also up to \$100,000 of ADSs available for sale under the ATM Program pursuant to the 2022 Prospectus.

Financial Highlights

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

- Operating loss was \$16,960 and \$75,523 for the three and nine months ended September 30, 2022, respectively, compared to operating loss of \$25,663 and \$62,410 for the three and nine months ended September 30, 2021, respectively. Selling, general and administrative expenses increased during the nine months ended September 30, 2022 by \$10,066, driven by the increased legal and compensation spend of approximately \$7,400 and \$2,800, respectively, as well as approximately \$5,450 of debt issuance costs as part of the exchange of \$117,375 of our 4.50% exchangeable senior notes due February 2023 (the “February 2023 Notes”) for a new series of 4.50% exchangeable senior notes due October 2023 (the “October 2023 Notes”, together with the February 2023 Notes, the “2023 Notes”) (the “Exchange Transaction”), offset by lower commercial spend.
- Net loss was \$20,146 and \$110,014 for the three and nine months ended September 30, 2022, respectively, compared to net loss of \$22,002 and \$55,028 in the same periods last year, respectively.
- Diluted net loss per share was \$0.33 and \$1.85 for the three and nine months ended September 30, 2022, respectively, compared to diluted net loss per share of \$0.38 and \$0.94 in the same period last year, respectively.
- Cash and marketable securities decreased \$50,746 to \$106,475 at September 30, 2022, from \$157,221 at December 31, 2021. The decrease in cash during the nine months ended September 30, 2022 was driven primarily by net cash used in operating activities of \$54,938, which included \$9,660 of interest payments, approximately \$5,450 of fees paid to third parties that were expensed as part of the completed Exchange Transaction and approximately \$4,800 of insurance premiums. The decrease in cash was also due to the payment of approximately \$4,800 in fees to note holders of the October 2023 Notes that are amortized as interest expense over the remaining term of the October 2023 Notes. The uses of cash described above were offset by the receipt of approximately \$32,323 of tax refund claims associated with the carry-back of 2019 losses and net proceeds of \$10,532 from the sale and issuance of ADSs under the ATM Program.

Critical Accounting Estimates

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

Our significant accounting policies are described in Note 1 of the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2021 (the “2021 Form 10-K”). The SEC suggests companies provide additional disclosure on those accounting policies considered most critical. The SEC considers an accounting policy to be critical if it is important to our financial condition and results of operations and requires significant judgments and estimates on the part of management in its application. Our estimates are often based on complex judgments, probabilities and assumptions that management believes to be reasonable, but that are inherently uncertain and unpredictable. It is also possible that other professionals, applying reasonable judgment to the same facts and circumstances, could develop and support a range

of alternative estimated amounts. For a complete discussion of our critical accounting policies, see the “Critical Accounting Policies” section of the Management’s Discussion & Analysis in our 2021 Form 10-K.

Results of Operations

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

Comparative Statements of Loss	Three Months Ended September 30,		Change	
	2022	2021	\$	%
Operating expenses:				
Research and development expenses	\$ 2,933	\$ 4,380	\$ (1,447)	(33.0)%
Selling, general and administrative expenses	14,096	21,283	(7,187)	(33.8)%
Restructuring income	(69)	—	(69)	100.0%
Total operating expense	16,960	25,663	(8,703)	(33.9)%
Operating loss	(16,960)	(25,663)	8,703	33.9%
Investment and other income, net	448	489	(41)	(8.4)%
Interest expense	(3,564)	(1,929)	(1,635)	(84.8)%
Loss before income taxes	(20,076)	(27,103)	7,027	25.9%
Income tax provision (benefit)	70	(5,101)	5,171	101.4%
Net loss	\$ (20,146)	\$ (22,002)	\$ 1,856	8.4%
Net loss per share - diluted	\$ (0.33)	\$ (0.38)	\$ 0.05	13.2%

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

Comparative Statements of Loss	Nine Months Ended September 30,		Change	
	2022	2021	\$	%
Operating expenses:				
Research and development expenses	\$ 14,465	\$ 14,994	\$ (529)	(3.5)%
Selling, general and administrative expenses	57,535	47,469	10,066	21.2%
Restructuring expense (income)	3,523	(53)	3,576	6,747.2%
Total operating expense	75,523	62,410	13,113	21.0%
Operating loss	(75,523)	(62,410)	(13,113)	(21.0)%
Investment and other income, net	503	1,531	(1,028)	(67.1)%
Interest expense	(9,087)	(5,788)	(3,299)	(57.0)%
Gain from release of certain liabilities	33	166	(133)	(80.1)%
Loss before income taxes	(84,074)	(66,501)	(17,573)	(26.4)%
Income tax provision (benefit)	25,940	(11,473)	37,413	326.1%
Net loss	\$ (110,014)	\$ (55,028)	\$ (54,986)	(99.9)%
Net loss per share - diluted	\$ (1.85)	\$ (0.94)	\$ (0.91)	(96.8)%

Research and Development Expenses:	Three Months Ended September 30,		Change	
	2022	2021	\$	%
Research and development expenses	\$ 2,933	\$ 4,380	\$ (1,447)	(33.0)%

Research and development expenses decreased \$1,447 or 33.0% during the three months ended September 30, 2022 as compared to the same period in the prior year. This decrease was driven by lower research and development production costs during the current period of approximately \$1,100 and lower compensation related costs of approximately \$400 due to decreased headcount as a result of employees affected by the 2022 Corporate Restructuring Plan.

Research and Development Expenses:	Nine Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Research and development expenses	\$ 14,465	\$ 14,994	\$ (529)	(3.5)%

Research and development expenses decreased \$529 or 3.5% during the nine months ended September 30, 2022 as compared to the same period in the prior year. This decrease was driven by lower research and development production costs during the current period of approximately \$1,300 and share-based compensation costs of approximately \$400, partially offset by higher API purchases of \$1,200, the majority of which were purchased in the three months ended March 31, 2022.

Selling, General and Administrative Expenses:	Three Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Selling, general and administrative expenses	\$ 14,096	\$ 21,283	\$ (7,187)	(33.8)%

Selling, general and administrative expenses decreased \$7,187 or 33.8% during the three months ended September 30, 2022 as compared to the same period in the prior year, driven by lower marketing and market access activities of approximately \$5,400, lower compensation costs of approximately \$1,400, lower medical affairs activities of approximately \$1,000, and lower consulting fees of \$600. These costs were partially offset by higher legal costs of approximately \$1,200.

Selling, General and Administrative Expenses:	Nine Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Selling, general and administrative expenses	\$ 57,535	\$ 47,469	\$ 10,066	21.2 %

Selling, general and administrative expenses increased \$10,066 or 21.2% during the nine months ended September 30, 2022 as compared to the same period in the prior year, driven by higher legal costs of approximately \$7,400, debt issuance costs of approximately \$5,450 related to the Exchange Transaction, higher compensation costs of \$2,800, and higher public relationship activities of \$1,100. The increase in selling, general and administrative expense was offset by lower marketing and market access activities of approximately \$3,500, lower medical affairs activities of \$1,700, and lower other consulting fees of \$1,600.

Restructuring Expense (Income)	Nine Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Restructuring expense (income)	\$ 3,523	\$ (53)	\$ 3,576	6,747.2 %

Restructuring expense (income) increased \$3,576 or 6,747.2% during the nine months ended September 30, 2022 as compared to the same period in the prior year, driven by the 2022 Corporate Restructuring Plan, which was announced in June 2022. See *Note 11: Restructuring Costs* to our unaudited condensed consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for further details for further details.

Investment and Other Income, net	Nine Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Investment and other income, net	\$ 503	\$ 1,531	\$ (1,028)	(67.1)%

Investment and other income, net decreased \$1,028 or 67.1% during the nine months ended September 30, 2022 as compared to the same period in the prior year. This decrease was driven by higher net realized losses on our marketable securities of approximately \$400 and less interest received on our marketable securities of approximately \$800 in comparison to the prior period.

Interest Expense	Three Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Interest expense	\$ 3,564	\$ 1,929	\$ 1,635	84.8 %

Interest expense increased \$1,635 or 84.8% during the three months ended September 30, 2022 as compared to the same period in the prior year. Interest expense increased by approximately \$900 due to non-cash amortization of the \$5,500 of debt discount related to the change in the fair value of the conversion feature of the October 2023 Notes. In addition, interest expense increased by \$700 due to non-cash amortization of the \$4,800 of debt issuance fees paid to note holders that participated in the Exchange Transaction in April 2022. These fees are amortized over the life of the October 2023 Notes. See *Note 4: Long-Term Debt* to our unaudited condensed consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for further details for further details.

Interest Expense	Nine Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Interest expense	\$ 9,087	\$ 5,788	\$ 3,299	57.0 %

Interest expense increased \$3,299 or 57.0% during the nine months ended September 30, 2022 as compared to the same period in the prior year. Interest expense increased by approximately \$1,800 due to non-cash amortization of the \$5,500 of debt discount related to the change in the fair value of the conversion feature of the October 2023 Notes. In addition, interest expense increased by \$1,400 due to amortization of the \$4,800 of debt issuance fees paid to note holders that participated in the Exchange Transaction in April 2022. These fees are amortized over the life of the October 2023 Notes. See *Note 4: Long-Term Debt* to our unaudited condensed consolidated financial statements included in Part 1, Item 1 of this Quarterly Report on Form 10-Q for further details for further details.

Income Tax Provision (Benefit):	Three Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Income tax provision (benefit)	\$ 70	\$ (5,101)	\$ 5,171	101.4 %
Percentage of loss before income taxes	(0.3)%	18.8 %		

The income tax provision was \$70 for the three months ended September 30, 2022 resulting in an effective tax rate of (0.3)%. The income tax benefit was \$5,101 for the three months ended September 30, 2021 resulting in an effective tax rate of 18.8%. The change in the effective tax rate for the three months ended September 30, 2022 is primarily due to the valuation allowances that were recorded against the net operating losses generated during the period.

Income Tax Provision (Benefit):	Nine Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
			\$	%
Income tax provision (benefit)	\$ 25,940	\$ (11,473)	\$ 37,413	326.1 %
Percentage of loss before income taxes	(30.9)%	17.3 %		

The income tax provision was \$25,940 for the nine months ended September 30, 2022 resulting in an effective tax rate of (30.9)%. The income tax benefit was \$11,473 for the nine months ended September 30, 2021 resulting in an effective tax rate of 17.3%. The change in the effective tax rate for the nine months ended September 30, 2022 is primarily driven by the valuation allowances recorded against our deferred tax assets during the period.

Liquidity and Capital Resources

Our cash flows from operating, investing and financing activities, as reflected in the unaudited condensed consolidated statements of cash flows, are summarized in the following table:

Net cash (used in) provided by:	Nine Months Ended September 30,		Change	
	2022	2021	2022 vs. 2021	
	\$	\$	\$	%
Operating activities	\$ (54,938)	\$ (54,804)	\$ (134)	(0.2)%
Investing activities	56,823	41,609	15,214	36.6 %
Financing activities	7,921	263	7,658	2,911.8 %

Operating Activities

Net cash used in operating activities was \$54,938 and \$54,804 for the nine months ended September 30, 2022 and 2021, respectively. Net cash used in operating activities for the nine months ended September 30, 2022 was driven by net loss of \$110,014, partially offset by favorable non-cash adjustments of \$37,562 and favorable changes in working capital of \$17,514. For the nine months ended September 30, 2021, net cash used in operating activities was driven by net loss of \$55,028, unfavorable change in non-cash adjustments of \$2,793, and favorable changes in working capital of \$3,017.

The September 30, 2022 net favorable change in working capital was driven by the receipt of \$32,323 of refund claims associated with the carryback of 2019 losses during the nine months ended September 30, 2022, of which \$3,265 is an overpayment that will be repaid to the Internal Revenue Service. This was offset by the timing of payments made related to our accounts payable and accrual balances.

Investing Activities

Net cash provided by investing activities was \$56,823 and \$41,609 for the nine months ended September 30, 2022 and 2021, respectively. Net cash provided by investing activities for the nine months ended September 30, 2022 was due to net proceeds received from the excess of sales over purchases of marketable securities of \$57,539. Net cash provided by investing activities for the nine months ended September 30, 2021 was driven by proceeds from the disposition of the hospital products of \$16,500, as well as net proceeds received from the excess of sales over purchases of marketable securities of \$25,135.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2022 was \$7,921, driven by the sale of ADSs through the ATM Program, resulting in net proceeds to us of approximately \$10,532, and by \$2,192 of proceeds from stock option exercises and employee share purchase plan (“ESPP”) issuances, offset by the payment of \$4,803 of debt issuance fees associated with the Exchange Transaction. Net cash provided by financing activities for the nine months ended September 30, 2021 of \$263 related to proceeds from stock option exercises and ESPP issuances.

Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our LUMRYZ clinical development, commercial launch plans and the FDA’s decision regarding final approval of LUMRYZ, our cost structure, and other factors set forth in “Risk Factors” within Part I, Item 1A of our Annual Report on Form 10-K filed with the SEC on March 16, 2022. To complete the LUMRYZ clinical development and commercial launch plans we will need to commit substantial resources, which could result in future losses or otherwise limit our opportunities or affect our ability to operate our business. Our assumptions concerning the outcome of certain business conditions may prove to be wrong or other factors may adversely affect our business, and as a result we could exhaust or significantly decrease our available cash and marketable securities balances which could, among other things, force us to raise additional funds and/or force us to reduce our expenses, either of which could have a material adverse effect on our business. Additionally, we are unable to estimate the near- or long-term impacts of COVID-19 and inflation, which may have a material adverse impact on our business.

In June 2022, we announced a plan to optimize our cost structure to reduce total quarterly cash operating expenses to between \$12,000 and \$14,000, excluding inventory purchases.

We have a recent history of generating losses and negative cash flows from operations, an accumulated shareholders' deficit as of the date of the unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q and approximately \$60,715 of cash and cash equivalents and \$45,760 of marketable securities available for use to fund our operations, debt service and capital requirements. Our ability to generate revenue is expected to start following the launch of LUMRYZ, which is dependent, in part, on final approval of LUMRYZ by the FDA. As of September 30, 2022, we have \$26,375 aggregate principal amount of the February 2023 Notes and \$117,375 aggregate principal amount of the October 2023 Notes. We do not currently have sufficient available liquidity to repay the outstanding balance of the October 2023 Notes. These conditions and events raise substantial doubt about our ability to continue as a going concern within one year after the date that the unaudited condensed consolidated financial statements are issued.

In response to these conditions and events, we are evaluating various financing strategies to obtain sufficient additional liquidity to meet its operating, debt service and capital requirements for the next twelve months following the date of this Quarterly Report. The potential sources of financing that we are evaluating include one or any combination of royalty financing, secured or unsecured debt, convertible debt and equity. In addition, our financing strategy could also include refinancing or negotiating new terms for the 2023 Notes. We also currently have authorized and available the use of our ATM Program, described in more detail below, which could provide us up to approximately \$135,000 (as of September 30, 2022), net of commissions, if fully utilized. While we have the ability to utilize the ATM Program, we intend to pursue the other financing strategies described above. Based on our ability to raise funds through the ATM Program, we have determined that it is probable that such proceeds would provide sufficient additional capital to meet our operating, debt service and capital requirements for the next twelve months following the date of this Quarterly Report. As a result, we have concluded that that management's plans are probable of being achieved to alleviate the substantial doubt about our ability to continue as a going concern.

The sources of financing described above that could be available to us and the timing and probability of obtaining sufficient capital depends, in part, on obtaining final FDA approval of LUMRYZ, resolving any legal and regulatory matters that could preclude us from launching LUMRYZ and future capital market conditions. If our current assumptions regarding timing of potential final approval, the timing of the launch of LUMRYZ or if there are any other changes or differences in our current assumptions that negatively impact our financing strategy, we may have to further reduce expenditures or significantly delay, scale back or discontinue the development or commercialization of LUMRYZ in order to extend our cash resources.

At-the-Market Offering Program

As of September 30, 2022, we had issued and sold 1,768 ADSs, resulting in net proceeds to us of approximately \$10,532, pursuant to the 2020 Prospectus. We may offer and sell up to an additional \$39,142 of ADSs under the ATM Program that remain available for sale pursuant to the 2020 Prospectus and also up to \$100,000 of ADSs available for sale under the ATM Program pursuant to the 2022 Prospectus.

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, 2022 and December 31, 2021, there were no contingent liabilities with respect to any litigation, arbitration or administrative or other proceeding that are reasonably likely to have a material adverse effect on our consolidated financial position, results of operations, cash flows or liquidity. For information regarding legal proceedings we are involved in, see *Note 10: 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' (deficit) equity. The reported results of this non-U.S. subsidiary will be influenced by their translation into U.S. dollars by currency movements against the U.S. dollar. Our primary currency translation exposure is related to one subsidiary that has functional currencies denominated in euro. A 10% strengthening/weakening in the rates used to translate the results of our non-U.S. subsidiaries that have functional currencies denominated in euro as of September 30, 2022 would have had an immaterial impact on net loss for the three and nine months ended September 30, 2022.

Transactional exposure arises where transactions occur in currencies other than the functional currency. Transactions in foreign currencies are recorded at the exchange rate prevailing at the date of the transaction. The resulting monetary assets and liabilities are translated into the appropriate functional currency at exchange rates prevailing at the balance sheet date and the resulting gains and losses are reported in investment and other income, net in the condensed consolidated statements of loss. As of September 30, 2022, our primary exposure is to transaction risk related to euro net monetary assets and liabilities held by subsidiaries with a U.S. dollar functional currency. Realized and unrealized foreign exchange gains and losses resulting from transactional exposure were immaterial for the three and nine months ended September 30, 2022.

Inflation Risk

Inflation generally affects us by increasing our costs of labor and supplies and the costs of our third parties we rely on for the development, manufacture and supply of our product candidates. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the three and nine months ended September 30, 2022. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future (especially if inflation rates continue to rise) due to an impact on the costs to conduct clinical trials, the costs to prepare for the potential commercialization of 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, 2022, the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended ("Exchange Act"), means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to the Company's management, including its Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on their evaluation, as of the end of the period covered by this Quarterly Report on Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective as of September 30, 2022.

Material Weakness

Remediation of Previously Reported Material Weakness

As previously described in the Company's Annual Report on Form 10-K for the year ended December 31, 2021, management had identified a material weakness in the Company's internal controls over financial reporting specifically related to its February 2023 Notes indenture. The Company is committed to maintaining a strong internal control environment and implemented measures in the first quarter of 2022 to remediate the control deficiency contributing to the material weakness. Specifically, management implemented a remediation plan that included:

- Adoption of additional control procedures surrounding timely and periodic evaluation of all terms of the Company's debt agreements and the associated calculation of interest expense in accordance with the terms of any such debt agreement.
- A review of all Company contractual and debt agreements for potential terms or tentative conditions that could impact the calculation of interest expense similar to those terms underlying the control deficiency alongside the Exchange Transaction on April 5, 2022, noting none.

Management believes these additional internal controls and procedures will ensure the completeness and accuracy of the calculation and timely payment of interest expense, classification of debt and compliance with terms of the Company's debt agreements.

Management evaluated the design and operational effectiveness of the remediation activities and concluded that there is sufficient evidence that the previously reported material weakness pertaining to the February 2023 Notes indenture had been remediated as of June 30, 2022.

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, 2022 that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

The information contained in *Note 10: 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.

Except as set forth below, there have been no material changes in our risk factors from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the SEC on March 16, 2022.

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

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

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

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

An NDA must include extensive preclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. An NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. For example, we submitted an NDA to the FDA for LUMRYZ, also known as FT218, for the treatment of cataplexy or EDS in adults with narcolepsy to the FDA in December 2020 through the Section 505(b)(2) regulatory pathway. In February 2021, the FDA assigned LUMRYZ a PDUFA target action date of October 15, 2021. In October 2021, the FDA notified us that its review was still ongoing and action would not be taken by the PDUFA date. On May 24, 2022, we were notified by the FDA that the LUMRYZ NDA patent statement pertaining to the REMS Patent was deemed inappropriate. As such, the FDA requested the Company add a certification to the REMS Patent to its NDA. On June 29, 2022, we announced that we had submitted a Paragraph IV patent certification pertaining to the REMS Patent to LUMRYZ's NDA. On July 15, 2022, Jazz filed a patent infringement suit in the U.S. District of Delaware asserting that LUMRYZ will infringe at least one claim of that patent. The filing of that lawsuit triggers a regulatory stay on FDA approval of LUMRYZ. On July 18, 2022, we received tentative approval from the FDA for LUMRYZ for the treatment of cataplexy or EDS in adults suffering from narcolepsy. As such, we anticipate a decision regarding the final approval of LUMRYZ from the FDA on or about the expiration of the REMS Patent on June 17, 2023 or sooner if the patent is earlier removed from the FDA's Orange Book or a court earlier determines the patent is not infringed, invalid or otherwise unenforceable. Our receipt of tentative approval does not mean we will receive final FDA approval for the LUMRYZ NDA in a timely manner or at all. In addition, a drug product that is granted tentative approval, like LUMRYZ, may be subject to additional review before final approval. The FDA's tentative approval of LUMRYZ was based on information available to the FDA at the time of the tentative approval letter (i.e., information in the application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug product) and is therefore subject to change on the basis of new information that may come to the FDA's attention. We cannot legally market LUMRYZ in the U.S. until we obtain final approval from the FDA. Any delay or setback in obtaining final approval or the commercialization of our lead product candidate will adversely affect our business.

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

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

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

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

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

Risks Related to Our Financial Position and Capital Requirements

Uncertainties relating to our ability to procure additional debt, equity or other financing prior to the maturity of our outstanding exchangeable senior notes raises substantial doubt about our ability to continue as a going concern.

As of September 30, 2022, we had an accumulated shareholders' deficit of approximately \$12.4 million and approximately \$60.7 million of cash and cash equivalents and \$45.8 million of marketable securities available for use to fund our operations and capital requirements. Within twelve months of the date of this Quarterly Report, our interest and principal payments of \$143.8 million aggregate principal amount of our outstanding exchangeable senior notes will fall due. Consequently, absent further actions by the Company, these matters raise substantial doubt about our ability to continue as a going concern within one year after the date that the financial statements in this Quarterly Report on Form 10-Q are issued.

We have a recent history of generating losses and negative cash flows from operations. Our ability to generate revenue is expected to start following the launch of LUMRYZ, which is dependent, in part, on final approval of LUMRYZ by the FDA. Our unaudited financial statements have been prepared under the assumption that we will continue as a going concern for the next twelve months. Our ability to continue as a going concern is dependent upon our ability to obtain additional debt, equity or other financing or otherwise address the upcoming maturities of our outstanding exchangeable senior notes. If we are not able to resolve the going concern prior to the issuance of our financial statements for the fiscal year ending December 31, 2022, the reaction of investors to the inclusion of a going concern statement by our auditors, and our potential inability to continue as a going concern in future years could materially adversely affect our share price and our ability to raise new capital or enter into strategic alliances. Furthermore, we also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our intellectual property or product candidates or otherwise agree to terms unfavorable to us.

Risks Related to Regulation

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

Any name we intend to use for our product candidates will require approval from the FDA or other regulatory authorities in jurisdictions where we may seek approval regardless of whether we have secured a trademark registration from the USPTO or similar protection in other jurisdictions. The FDA and other regulatory authorities each typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. The FDA or other regulatory authorities in jurisdictions where we may seek approval may object to any product name we submit if it believes the name inappropriately implies medical claims. If the FDA or other regulatory authorities in jurisdictions where we may seek approval objects to any of our proposed product names, we may be required to adopt an alternative name for our product candidates. There is no guarantee that we will be able to use the same proprietary name for our product candidates in each jurisdiction where we market our products, if approved. If we adopt an alternative name, we would lose the benefit of any existing trademark applications for such product candidate and may be required to expend significant additional resources in an effort to identify a suitable product name that would qualify under applicable trademark laws, not infringe the existing rights of third

parties and be acceptable to the FDA or other regulatory authorities. The FDA has tentatively accepted our proprietary name for our lead product candidate, LUMRYZ. Final acceptance of a proposed proprietary name occurs as part of the final approval of the drug product. We may be unable to build a successful brand identity for a new proprietary name or trademark in a timely manner or at all, which would limit our ability to commercialize our product candidates.

Risks Related to our Reliance on Third Parties

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

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

Risks Related to Our Business and Industry

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

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

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

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

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

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all.

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

General Risk Factors

Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints.

Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on the Company's product candidate development, commercialization preparations for LUMYRZ (if approved) and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third-party suppliers and manufacturers to manufacture clinical trial materials for our product candidates and the potential commercial launch of LUMRYZ.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

<u>Exhibit No.</u>	<u>Description</u>
10.1‡*	First Amendment to Employment Agreement, dated as of September 28, 2022, between Avadel Management Corporation and Gregory J. Divis
10.2‡*	First Amendment to Employment Agreement, dated as of September 28, 2022, between Avadel Management Corporation and Thomas S. McHugh
10.3‡*	First Amendment to Employment Agreement, dated as of September 28, 2022, between Avadel Management Corporation and Richard Kim
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.

‡ Management contract or compensatory plan or arrangement.

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 9, 2022

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

Date: November 9, 2022

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

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to Employment Agreement (this "Amendment") is made effective as of September 28, 2022 (the "Amendment Effective Date"), by and between Avadel Management Corporation, a Delaware corporation (the "Company"), and Gregory J. Divis (the "Executive").

WITNESSETH

WHEREAS, the Company and the Executive are parties to an Amended Employment Agreement dated as of June 3, 2019 (the "Employment Agreement");

WHEREAS, the Company and the Executive wish to amend certain provisions of the Employment Agreement;

WHEREAS, the Executive is entering into this Amendment for good and valuable consideration set forth herein as well as in consideration and as a condition of his continued employment with the Company; and

WHEREAS, capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Employment Agreement.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Section 3.2(i) of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

(i) severance pay in an amount equal to 1.5 times the Executive's then-current annual base salary, which shall be paid in substantially equal installments in accordance with the Company's normal payroll practices; provided that, solely to the extent such severance pay is exempt from Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and does not constitute "non-qualified deferred compensation" within the meaning of Section 409A of the Code, the Company may, in its sole discretion, elect to pay such amount in a lump sum within 60 days following the date of termination; and

2. The last sentence of Section 3.2 of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

The Severance Indemnity (to the extent payable in installments) shall be paid in substantially equal installments in accordance with the Company's payroll practice over 18 months commencing within 60 days after the date of termination; *provided, however*, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall begin to be paid in the second calendar year by the last day of such 60-day period; *provided, further*, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the date of termination.

3. Section 4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

4.RESTRICTIVE COVENANTS

4.a Confidentiality.

(i) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of Companies to the extent necessary to perform his obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(ii) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) "Restricted Information" means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) "Confidential Information" means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive's employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date his employment with the Company began.

(iii) "Trade Secret" means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(iii) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive's attorney and use the Trade Secret in the court proceeding, if the Executive (i) files any document containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.b Invention Assignment.

(iv) The Executive will make full and prompt disclosure to the Company of all inventions, discoveries, designs, developments, methods, modifications, improvements, processes, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, and audio or visual works and other works of authorship (collectively "Developments"), whether or not patentable or copyrightable, that are created, made, conceived or reduced to practice by the Executive (alone or jointly with others) or under the Executive's direction during the period of the Executive's employment. The Executive acknowledges that all work performed by him is on a "work for hire" basis, and the Executive hereby does assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns all his right, title and interest in all Developments that (a) relate to the business of the Company or any customer of or supplier to the Company or any of the products or services being researched, developed, manufactured or sold by the Avadel Group of Companies or which may be used with such products or services; or (b) result from tasks assigned to him by the Avadel Group of Companies; or (c) result from the use of premises or personal property (whether tangible or intangible) owned, leased or contracted for by the Avadel Group of Companies ("Company-Related Developments"), and all related patents, patent applications, trademarks and trademark applications, copyrights and copyright applications, and other intellectual property rights in all countries and territories worldwide and under any international conventions ("Intellectual Property Rights"). For the avoidance of doubt, this Section 4.2 applies to the Executive's entire service relationship with the Company.

(v) To preclude any possible uncertainty, the Executive has set forth on Exhibit A attached hereto a complete list of Developments that the Executive has, alone or jointly with others, conceived, developed or reduced to practice prior to the commencement of his employment with the Company that he considers to be his property or the property of third parties and that he wishes to have excluded from the scope of this Agreement ("Prior Inventions"). If disclosure of any such Prior Invention would cause the Executive to violate any prior confidentiality agreement, the Executive understands that he is not to list such Prior Inventions in Exhibit A but is only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. The Executive has also listed on Exhibit A all patents and patent applications in which he is named as an inventor, other than those which have been assigned to the Company ("Other Patent").

Rights”). If no such disclosure is attached, the Executive represents that there are no Prior Inventions or Other Patent Rights. If, in the course of the Executive’s employment with the Company, he incorporates a Prior Invention into a Company product, process or machine or other work done for the Avadel Group of Companies, the Executive hereby grants to the Company a nonexclusive, royalty-free, paid-up, irrevocable, worldwide license (with the full right to sublicense) to make, have made, modify, use, sell, offer for sale and import such Prior Invention. Notwithstanding the foregoing, the Executive will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company’s prior written consent.

(vi) This Agreement does not obligate the Executive to assign to the Company any Development which, in the sole judgment of the Company, reasonably exercised, is developed entirely on the Executive’s own time and does not relate to the business efforts or research and development efforts in which, during the period of his employment, the Avadel Group of Companies actually is engaged or reasonably would be engaged, and does not result from the use of premises or equipment owned or leased by the Avadel Group of Companies. However, the Executive will also promptly disclose to the Company any such Developments for the purpose of determining whether they qualify for such exclusion. The Executive understands that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section 4.2 will be interpreted not to apply to any invention that a court rules and/or the Company agrees falls within such classes. The Executive also hereby waives all claims to any moral rights or other special rights which the Executive may have or accrue in any Company-Related Developments.

4.a Non-Competition. In order to protect Confidential Information and goodwill, during the Executive’s employment with the Company and for a period of one (1) year after the termination of the Executive’s employment with the Company for any reason (the “Restricted Period”), the Executive shall not, directly or indirectly, whether as owner, partner, shareholder, director, manager, consultant, agent, employee, co-venturer or otherwise, anywhere in the United States or in any other country in which the Avadel Group of Companies does business, engage or otherwise participate in any business that develops, manufactures or markets any products, or performs any services, that are competitive with the products or services of the Avadel Group of Companies, or products or services that the Avadel Group of Companies or its affiliates, has under development or that are the subject of active planning at any time during the Executive’s employment.

4.b Non-Solicitation of Employees and Contractors. During the Restricted Period, the Executive shall not, directly or indirectly, solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee’s, consultant’s or other contractor’s service with any member of the Avadel Group of Companies. “Material Contact” means contact in person, by telephone, or by paper or electronic correspondence in furtherance of the business of any member of the Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel

Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.c Non-Solicitation of Customers and Suppliers. During the Restricted Period, the Executive shall not, directly or indirectly, solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any member of the Avadel Group of Companies. This Section 4.5 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.d Relief. The Executive agrees that it would be difficult to measure any damages caused to the Company that might result from any breach by the Executive of any portion of Sections 4.1 through 4.5, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of Section 4.1 through 4.5, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company and without the posting of a bond.

4.e Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any

amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

4. All other provisions of the Employment Agreement shall remain in full force and effect according to their respective terms, and nothing contained herein shall be deemed a waiver of any right or abrogation of any obligation otherwise existing under the Employment Agreement except to the extent specifically provided for herein.

5. Notwithstanding the place where this Amendment may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, without giving effect to the principles of choice or conflicts of laws thereof.

6. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Amendment may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Amendment.

[Signature page follows]

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

THE COMPANY

AVADEL MANAGEMENT CORPORATION

/s/ Angela Woods
By: Angela Woods
Its: Vice President

THE EXECUTIVE

Gregory J. Divis /s/ Gregory J. Divis

EXHIBIT A

To: Avadel Management Corporation

From: EMPLOYEE

Date: _____

SUBJECT: Prior Inventions

The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

No inventions or improvements

See below:

Additional sheets attached

The following is a list of all patents and patent applications in which I have been named as an inventor:

None

See below:

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to Employment Agreement (this "Amendment") is made effective as of September 28, 2022 (the "Amendment Effective Date"), by and between Avadel Management Corporation, a Delaware corporation (the "Company"), and Thomas S. McHugh (the "Executive").

WITNESSETH

WHEREAS, the Company and the Executive are parties to an Employment Agreement dated as of May 15, 2020 (the "Employment Agreement");

WHEREAS, the Company and the Executive wish to amend certain provisions of the Employment Agreement;

WHEREAS, the Executive is entering into this Amendment for good and valuable consideration set forth herein as well as in consideration and as a condition of his continued employment with the Company; and

WHEREAS, capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Employment Agreement.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Section 2.2 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

Bonus. The Executive shall be eligible for a potential annual bonus with a target payout of no less than forty five percent (45%) of the Executive's base salary based upon the Executive's achievement of certain business and individual performance objectives as well as the performance of Avadel plc against its objectives as determined by the Company. The Company may review the Executive's bonus target from time to time, and, in the Company's sole discretion, make any increases that the Company deems warranted. Subject to the requirement that the Executive shall be employed by a member of the Avadel Group of Companies on the date that the bonus is deemed earned by the Compensation Committee of the Company's Board of Directors, any bonus payments due hereunder shall be paid to the Executive no later than March 15 of the calendar year following the applicable year to which the annual bonus relates, subject to ordinary and lawful deductions.

2. Section 3.2(i) of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

(i) severance pay in an amount equal to 1.0 times the Executive's then-current annual base salary, which shall be paid in substantially equal installments in accordance with the Company's normal payroll practices; provided that, solely to the extent such severance pay is exempt from Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and does not constitute "non-qualified deferred compensation" within the meaning of Section 409A of the Code, the Company may, in its sole discretion, elect to pay such amount in a lump sum within 60 days following the date of termination; and

3. The last sentence of Section 3.2 of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

The amounts payable under this Section 3.2 (to the extent payable in installments) shall be paid in substantially equal installments in accordance with the Company's payroll practice over 12 months commencing within 60 days after the date of termination; *provided, however*, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall begin to be paid in the second calendar year by the last day of such 60-day period; *provided, further*, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the date of termination.

4. Section 3.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

3.3 Change of Control.

(a) If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company without Cause or by non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period (as hereinafter defined), then, in addition to the Executive being eligible for the Severance Pay and Benefits, subject to the terms of Section 3.2 above, and notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement:

(i) all of Executive's stock options and other stock-based awards (the "Equity Awards") shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of (i) the date of termination or (ii) the effective date of the Separation and Release Agreement (the "Accelerated Vesting Date"); provided that any termination or forfeiture of the unvested portion of such Equity Awards that would otherwise occur on the date of termination in the absence of this Agreement will be delayed until the effective date of the Separation and Release Agreement and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation and Release Agreement becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Equity Awards shall occur during the period between the date of termination and the Accelerated Vesting Date; and

(ii) the Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term as of the original date of the grant (the "Extended Exercise Period").

(b) The Executive's receipt of the foregoing (i) and (ii) is conditioned upon his execution and delivery to the Company of the Separation and Release Agreement within the time period set forth in the Separation and Release Agreement and in no event more than sixty (60) days following the date of termination of the Executive's employment.

5. Section 4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

4. RESTRICTIVE COVENANTS

4.a Confidentiality.

(i) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of Companies to the extent necessary to perform his obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(ii) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) "Restricted Information" means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) "Confidential Information" means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive's employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date his employment with the Company began.

(iii) “Trade Secret” means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(iii) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive’s attorney and use the Trade Secret in the court proceeding, if the Executive (i) files any document containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.b Invention Assignment.

(iv) The Executive will make full and prompt disclosure to the Company of all inventions, discoveries, designs, developments, methods, modifications, improvements, processes, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, and audio or visual works and other works of authorship (collectively “Developments”), whether or not patentable or copyrightable, that are created, made, conceived or reduced to practice by the Executive (alone or jointly with others) or under the Executive’s direction during the period of the Executive’s employment. The Executive acknowledges that all work performed by him is on a “work for hire” basis, and the Executive hereby does assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns all his right, title and interest in all Developments that (a) relate to the business of the Company or any customer of or supplier to the Company or any of the products or services being researched, developed, manufactured or sold by the Avadel Group of Companies or which may be used with such products or services; or (b) result from tasks assigned to him by the Avadel Group of Companies; or (c) result from the use of premises or personal property (whether tangible or intangible) owned, leased or contracted for by the Avadel Group of Companies (“Company-Related Developments”), and all related patents, patent applications, trademarks and trademark applications, copyrights and copyright applications, and other intellectual property rights in all countries and territories worldwide and under any international conventions (“Intellectual Property Rights”). For the avoidance of doubt, this Section 4.2 applies to the Executive’s entire service relationship with the Company.

(v) To preclude any possible uncertainty, the Executive has set forth on Exhibit A attached hereto a complete list of Developments that the Executive has, alone or jointly with others, conceived, developed or reduced to practice prior to the commencement of his employment with the Company that he considers to be his property or the property of third parties and that he wishes to have excluded from the scope of this Agreement (“Prior Inventions”). If disclosure of any such Prior Invention would cause the Executive to violate any prior confidentiality agreement, the Executive understands that he is not to list such Prior Inventions in Exhibit A but is only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such

inventions has not been made for that reason. The Executive has also listed on Exhibit A all patents and patent applications in which he is named as an inventor, other than those which have been assigned to the Company (“Other Patent Rights”). If no such disclosure is attached, the Executive represents that there are no Prior Inventions or Other Patent Rights. If, in the course of the Executive’s employment with the Company, he incorporates a Prior Invention into a Company product, process or machine or other work done for the Avadel Group of Companies, the Executive hereby grants to the Company a nonexclusive, royalty-free, paid-up, irrevocable, worldwide license (with the full right to sublicense) to make, have made, modify, use, sell, offer for sale and import such Prior Invention. Notwithstanding the foregoing, the Executive will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company’s prior written consent.

(vi) This Agreement does not obligate the Executive to assign to the Company any Development which, in the sole judgment of the Company, reasonably exercised, is developed entirely on the Executive’s own time and does not relate to the business efforts or research and development efforts in which, during the period of his employment, the Avadel Group of Companies actually is engaged or reasonably would be engaged, and does not result from the use of premises or equipment owned or leased by the Avadel Group of Companies. However, the Executive will also promptly disclose to the Company any such Developments for the purpose of determining whether they qualify for such exclusion. The Executive understands that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section 4.2 will be interpreted not to apply to any invention that a court rules and/or the Company agrees falls within such classes. The Executive also hereby waives all claims to any moral rights or other special rights which the Executive may have or accrue in any Company-Related Developments.

4.a Non-Competition. In order to protect Confidential Information and goodwill, during the Executive’s employment with the Company and for a period of one (1) year after the termination of the Executive’s employment with the Company for any reason (the “Restricted Period”), the Executive shall not, directly or indirectly, whether as owner, partner, shareholder, director, manager, consultant, agent, employee, co-venturer or otherwise, anywhere in the United States or in any other country in which the Avadel Group of Companies does business, engage or otherwise participate in any business that develops, manufactures or markets any products, or performs any services, that are competitive with the products or services of the Avadel Group of Companies, or products or services that the Avadel Group of Companies or its affiliates, has under development or that are the subject of active planning at any time during the Executive’s employment.

4.b Non-Solicitation of Employees and Contractors. During the Restricted Period, the Executive shall not, directly or indirectly, solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee’s, consultant’s or other contractor’s service with any member of the Avadel Group of Companies. “Material Contact” means contact in person, by telephone, or by paper or

electronic correspondence in furtherance of the business of any member of the Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.c Non-Solicitation of Customers and Suppliers. During the Restricted Period, the Executive shall not, directly or indirectly, solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any member of the Avadel Group of Companies. This Section 4.5 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.d Relief. The Executive agrees that it would be difficult to measure any damages caused to the Company that might result from any breach by the Executive of any portion of Sections 4.1 through 4.5, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of Section 4.1 through 4.5, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company and without the posting of a bond.

4.e Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach

any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

6. All other provisions of the Employment Agreement shall remain in full force and effect according to their respective terms, and nothing contained herein shall be deemed a waiver of any right or abrogation of any obligation otherwise existing under the Employment Agreement except to the extent specifically provided for herein.

7. Notwithstanding the place where this Amendment may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be construed in accordance with and governed by the laws of the State of Missouri, without giving effect to the principles of choice or conflicts of laws thereof.

8. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Amendment may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Amendment.

[Signature page follows]

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

THE COMPANY

AVADEL MANAGEMENT CORPORATION

/s/ Angela Woods
By: Angela Woods
Its: Vice President

THE EXECUTIVE

Thomas S. McHugh

/s/ Thomas S. McHugh

EXHIBIT A

To: Avadel Management Corporation

From: EMPLOYEE

Date: _____

SUBJECT: Prior Inventions

The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

No inventions or improvements

See below:

Additional sheets attached

The following is a list of all patents and patent applications in which I have been named as an inventor:

None

See below:

FIRST AMENDMENT TO EMPLOYMENT AGREEMENT

This First Amendment to Employment Agreement (this "Amendment") is made effective as of September 28, 2022 (the "Amendment Effective Date"), by and between Avadel Management Corporation, a Delaware corporation (the "Company"), and Richard Kim (the "Executive").

WITNESSETH

WHEREAS, the Company and the Executive are parties to an Employment Agreement dated as of March 18, 2021 (the "Employment Agreement");

WHEREAS, the Company and the Executive wish to amend certain provisions of the Employment Agreement;

WHEREAS, the Executive is entering into this Amendment for good and valuable consideration set forth herein as well as in consideration and as a condition of his continued employment with the Company; and

WHEREAS, capitalized terms used herein and not otherwise defined shall have the meanings ascribed to them in the Employment Agreement.

NOW, THEREFORE, in consideration of the mutual agreements and covenants set forth herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto, intending to be legally bound, hereby agree as follows:

1. Section 3.2(i) of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

(i) severance pay in an amount equal to 1.0 times the Executive's then-current annual base salary (the "Severance Amount"), which shall be paid in substantially equal installments in accordance with the Company's normal payroll practices; provided that, solely to the extent such severance pay is exempt from Section 409A of the Internal Revenue Code of 1986, as amended (the "Code") and does not constitute "non-qualified deferred compensation" within the meaning of Section 409A of the Code, the Company may, in its sole discretion, elect to pay such amount in a lump sum within 60 days following the date of termination; and

2. The last sentence of Section 3.2 of the Employment Agreement is hereby deleted in its entirety and replaced with the following:

The amounts payable under this Section 3.2 (to the extent payable in installments) shall be paid in substantially equal installments in accordance with the Company's payroll practice over 12 months commencing within 60 days after the date of termination; *provided, however*, that if the 60-day period begins in one calendar year and ends in a second calendar year, the Severance Amount, to the extent it qualifies as "non-qualified deferred compensation" within the meaning of Section 409A of the Code, shall begin to be paid in the second calendar year by the last day of such 60-day period; *provided, further*, that the initial payment shall include a catch-up payment to cover amounts retroactive to the day immediately following the date of termination.

3. Section 3.3 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

3.3 Change of Control.

(a) If the Executive terminates this Agreement and his employment with the Company for Good Reason or if the Executive's employment with the Company is terminated by the Company without Cause or by non-renewal of this Agreement by the Company, and such termination occurs during a Change of Control Period (as hereinafter defined), then, in addition to the Executive being eligible for the Severance Pay and Benefits, subject to the terms of Section 3.2 above, and notwithstanding any other provision in any applicable equity compensation plan and/or individual stock option plan or agreement:

(i) all of Executive's stock options and other stock-based awards (the "Equity Awards") shall immediately accelerate and become fully exercisable or nonforfeitable as of the later of (i) the date of termination or (ii) the effective date of the Separation and Release Agreement (the "Accelerated Vesting Date"); provided that any termination or forfeiture of the unvested portion of such Equity Awards that would otherwise occur on the date of termination in the absence of this Agreement will be delayed until the effective date of the Separation and Release Agreement and will only occur if the vesting pursuant to this subsection does not occur due to the absence of the Separation and Release Agreement becoming fully effective within the time period set forth therein. Notwithstanding the foregoing, no additional vesting of the Equity Awards shall occur during the period between the date of termination and the Accelerated Vesting Date; and

(ii) the Executive's outstanding and vested stock options as of the Executive's termination of employment date will remain exercisable until the eighteen (18) month anniversary of the termination of employment date; provided, however, that the post-termination exercise period for any individual stock option right will not extend beyond its original maximum term as of the original date of the grant (the "Extended Exercise Period").

(b) The Executive's receipt of the foregoing (i) and (ii) is conditioned upon his execution and delivery to the Company of the Separation and Release Agreement within the time period set forth in the Separation and Release Agreement and in no event more than sixty (60) days following the date of termination of the Executive's employment.

4. Section 4 of the Employment Agreement is hereby amended and restated in its entirety to read as follows:

4. RESTRICTIVE COVENANTS

4.a Confidentiality.

(i) Restriction. To the fullest extent permitted under applicable law, at all times during the Executive's employment by the Company and for a period of five (5) years after termination of the Executive's employment with the Company, the Executive (i) shall hold in strictest confidence all Restricted Information (as hereinafter defined), (ii) shall not directly or indirectly use, copy, disclose or otherwise distribute any Restricted Information, except for the benefit of a member of the Avadel Group of Companies to the extent necessary to perform his obligations to Avadel plc and the Company under this Agreement, and (iii) shall not disclose any Restricted Information to any person, firm, corporation or other entity without written authorization of the Chief Executive Officer or Board of

Directors of Avadel plc. Any breach of any provision of this Section 4.1(a) shall be considered a material breach of this Agreement.

(ii) Definitions. As used in this Section 4, the following terms shall have the meanings set forth below:

(i) “Restricted Information” means any Confidential Information (as hereinafter defined) and any Trade Secrets (as hereinafter defined).

(ii) “Confidential Information” means any information of or about any member of the Avadel Group of Companies, and any of the employees, customers and/or suppliers of any member of the Avadel Group of Companies, which is not generally known outside of the Avadel Group of Companies, which the Executive obtains (whether before, on or after the date of this Agreement) in connection with the Executive’s employment with the Company, and which may be useful to any competitor of the Avadel Group of Companies or the disclosure of which would be damaging to any member of the Avadel Group of Companies. Confidential Information includes, but is not limited to, any and all of the following information about any member of the Avadel Group of Companies: (A) information about products, product candidates, and research and development plans, activities and results (including information about planned and in-process clinical trials); (B) information about business and employment policies, marketing methods and the targets of those methods, finances, business plans, promotional materials and price lists; (C) the manner or terms upon which products or services are obtained from suppliers or on which products or services are provided to customers; (D) without duplication of item (A) above, the nature, origin, composition, performance and development of any products or services; (E) information about finances, financial condition, results of operations and prospects; and (F) information about employees, consultants or customers or suppliers. For the avoidance of doubt, Confidential Information shall not include information that (1) is or has been made generally available to the public through the disclosure thereof in a manner that was authorized by the Company and did not violate any common law or contractual right of the applicable party; (2) is or becomes generally available to the public other than as a result of a disclosure by the Executive in violation of the provisions hereof; or (3) was already in the possession of the Executive without an obligation of confidentiality prior to the date his employment with the Company began.

(iii) “Trade Secret” means any Confidential Information to the extent such information constitutes a trade secret under applicable law.

(iii) Certain Permitted Disclosures. Notwithstanding the foregoing, the Executive will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a Trade Secret that (i) is made (A) in confidence to a Federal, State or local government official, either directly or indirectly, or to an attorney, and (B) solely for purposes of reporting or investigating a suspected violation of law, or (ii) is made in a complaint or other document filed in a lawsuit or other proceeding filed in a lawsuit or other proceeding, if such filing is made under seal. If the Executive files a lawsuit for retaliation by the Company for reporting a suspected violation of law, the Executive may disclose the Trade Secret to the Executive’s attorney and use the Trade Secret in the court proceeding, if the Executive (i) files any document

containing the Trade Secret under seal and (ii) does not disclose the Trade Secret, except pursuant to court order.

4.b Invention Assignment.

(iv) The Executive will make full and prompt disclosure to the Company of all inventions, discoveries, designs, developments, methods, modifications, improvements, processes, algorithms, databases, computer programs, formulae, techniques, trade secrets, graphics or images, and audio or visual works and other works of authorship (collectively "Developments"), whether or not patentable or copyrightable, that are created, made, conceived or reduced to practice by the Executive (alone or jointly with others) or under the Executive's direction during the period of the Executive's employment. The Executive acknowledges that all work performed by him is on a "work for hire" basis, and the Executive hereby does assign and transfer and, to the extent any such assignment cannot be made at present, will assign and transfer, to the Company and its successors and assigns all his right, title and interest in all Developments that (a) relate to the business of the Company or any customer of or supplier to the Company or any of the products or services being researched, developed, manufactured or sold by the Avadel Group of Companies or which may be used with such products or services; or (b) result from tasks assigned to him by the Avadel Group of Companies; or (c) result from the use of premises or personal property (whether tangible or intangible) owned, leased or contracted for by the Avadel Group of Companies ("Company-Related Developments"), and all related patents, patent applications, trademarks and trademark applications, copyrights and copyright applications, and other intellectual property rights in all countries and territories worldwide and under any international conventions ("Intellectual Property Rights"). For the avoidance of doubt, this Section 4.2 applies to the Executive's entire service relationship with the Company.

(v) To preclude any possible uncertainty, the Executive has set forth on Exhibit A attached hereto a complete list of Developments that the Executive has, alone or jointly with others, conceived, developed or reduced to practice prior to the commencement of his employment with the Company that he considers to be his property or the property of third parties and that he wishes to have excluded from the scope of this Agreement ("Prior Inventions"). If disclosure of any such Prior Invention would cause the Executive to violate any prior confidentiality agreement, the Executive understands that he is not to list such Prior Inventions in Exhibit A but is only to disclose a cursory name for each such invention, a listing of the party(ies) to whom it belongs and the fact that full disclosure as to such inventions has not been made for that reason. The Executive has also listed on Exhibit A all patents and patent applications in which he is named as an inventor, other than those which have been assigned to the Company ("Other Patent Rights"). If no such disclosure is attached, the Executive represents that there are no Prior Inventions or Other Patent Rights. If, in the course of the Executive's employment with the Company, he incorporates a Prior Invention into a Company product, process or machine or other work done for the Avadel Group of Companies, the Executive hereby grants to the Company a nonexclusive, royalty-free, paid-up, irrevocable, worldwide license (with the full right to sublicense) to make, have made, modify, use, sell, offer for sale and import such Prior Invention. Notwithstanding the foregoing, the Executive will not incorporate, or permit to be incorporated, Prior Inventions in any Company-Related Development without the Company's prior written consent.

(vi) This Agreement does not obligate the Executive to assign to the Company any Development which, in the sole judgment of the Company, reasonably exercised, is developed entirely on the Executive's own time and does not relate to the business efforts or research and development efforts in which, during the period of his employment, the Avadel Group of Companies actually is engaged or reasonably would be engaged, and does not result from the use of premises or equipment owned or leased by the Avadel Group of Companies. However, the Executive will also promptly disclose to the Company any such Developments for the purpose of determining whether they qualify for such exclusion. The Executive understands that to the extent this Agreement is required to be construed in accordance with the laws of any state which precludes a requirement in an employee agreement to assign certain classes of inventions made by an employee, this Section 4.2 will be interpreted not to apply to any invention that a court rules and/or the Company agrees falls within such classes. The Executive also hereby waives all claims to any moral rights or other special rights which the Executive may have or accrue in any Company-Related Developments.

4.a Non-Competition. In order to protect Confidential Information and goodwill, during the Executive's employment with the Company and for a period of one (1) year after the termination of the Executive's employment with the Company for any reason (the "Restricted Period"), the Executive shall not, directly or indirectly, whether as owner, partner, shareholder, director, manager, consultant, agent, employee, co-venturer or otherwise, anywhere in the United States or in any other country in which the Avadel Group of Companies does business, engage or otherwise participate in any business that develops, manufactures or markets any products, or performs any services, that are competitive with the products or services of the Avadel Group of Companies, or products or services that the Avadel Group of Companies or its affiliates, has under development or that are the subject of active planning at any time during the Executive's employment.

4.b Non-Solicitation of Employees and Contractors. During the Restricted Period, the Executive shall not, directly or indirectly, solicit or attempt to solicit any employee, consultant or other contractor of or service provider to any member of the Avadel Group of Companies with whom the Executive had Material Contact to perform services for the Executive or for any other business or entity, whether as an executive, consultant, partner or participant in any such business or entity, or to terminate or lessen any such employee's, consultant's or other contractor's service with any member of the Avadel Group of Companies. "Material Contact" means contact in person, by telephone, or by paper or electronic correspondence in furtherance of the business of any member of the Avadel Group of Companies. This Section 4.4 shall cease to be applicable to any activity of the Executive from and after such time as all members of the Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.c Non-Solicitation of Customers and Suppliers. During the Restricted Period, the Executive shall not, directly or indirectly, solicit any actual or prospective customers or suppliers of any member of the Avadel Group of Companies with whom the Executive had Material Contact, for the purpose of selling any products or services which compete with the business of any member of the Avadel Group of Companies. This Section 4.5 shall cease to be applicable to any activity of the Executive from and after such time as all members of the

Avadel Group of Companies have ceased all business activities or have made a decision to cease all business activities.

4.d Relief. The Executive agrees that it would be difficult to measure any damages caused to the Company that might result from any breach by the Executive of any portion of Sections 4.1 through 4.5, and that in any event money damages would be an inadequate remedy for any such breach. Accordingly, the Executive agrees that if the Executive breaches, or proposes to breach, any portion of Section 4.1 through 4.5, the Company shall be entitled, in addition to all other remedies that it may have, to an injunction or other appropriate equitable relief to restrain any such breach without showing or proving any actual damage to the Company and without the posting of a bond.

4.e Protected Rights. Notwithstanding any other provision of this Agreement, the Company and the Executive hereby acknowledge and agree that:

(i) Nothing in this Agreement shall prohibit the Executive from reporting possible violations of Federal, State or other law or regulations to, or filing a charge or other complaint with, any governmental agency or entity, including but not limited to the Department of Justice, the Equal Employment Opportunity Commission, the National Labor Relations Board, the Occupational Safety and Health Administration, the Securities and Exchange Commission, Congress, and any Inspector General, or making any other disclosures that are protected under any whistleblower provisions of Federal, State or other law or regulation or assisting in any such investigation or proceeding.

(ii) Nothing herein limits the Executive's ability to communicate with any such governmental agency or entity or otherwise participate in any such investigation or proceeding that may be conducted by any such governmental agency or entity, including providing documents or other information, without notice to the Company.

(iii) The Executive does not need the prior authorization of the Company to make any such reports or disclosures, and the Executive is not required to notify the Company that the Executive made any such reports or disclosures or is assisting in any such investigation.

(iv) The Executive (A) does not waive any rights to any individual monetary recovery or other awards in connection with reporting any such information to any such governmental agency or entity, (B) does not breach any confidentiality or other provision hereunder in connection with any such reporting or disclosures, and (C) will not be prohibited from receiving any amounts hereunder as the result of making any such reports or disclosures or assisting with any such investigation or proceeding.

5. All other provisions of the Employment Agreement shall remain in full force and effect according to their respective terms, and nothing contained herein shall be deemed a waiver of any right or abrogation of any obligation otherwise existing under the Employment Agreement except to the extent specifically provided for herein.

6. Notwithstanding the place where this Amendment may be executed by any of the parties hereto, the parties expressly agree that all of the terms and provisions hereof shall be

construed in accordance with and governed by the laws of the State of Missouri, without giving effect to the principles of choice or conflicts of laws thereof.

7. This Amendment may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Signatures on this Amendment may be conveyed by facsimile or other electronic transmission and shall be binding upon the parties so transmitting their signatures. Counterparts with original signatures shall be provided to the other parties following the applicable facsimile or other electronic transmission; provided, that failure to provide the original counterpart shall have no effect on the validity or the binding nature of this Amendment.

[Signature page follows]

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

THE COMPANY

AVADEL MANAGEMENT CORPORATION

/s/ Angela Woods
By: Angela Woods
Its: Vice President

THE EXECUTIVE

Richard Kim /s/ Richard Kim

EXHIBIT A

To: Avadel Management Corporation

From: EMPLOYEE

Date: _____

SUBJECT: Prior Inventions

The following is a complete list of all inventions or improvements relevant to the subject matter of my employment by the Company that have been made or conceived or first reduced to practice by me alone or jointly with others prior to my engagement by the Company:

No inventions or improvements

See below:

Additional sheets attached

The following is a list of all patents and patent applications in which I have been named as an inventor:

None

See below:

**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 9, 2022

/s/ Gregory J. Divis

Gregory J. Divis

Chief Executive Officer

**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 9, 2022

/s/ Thomas S. McHugh

Thomas S. McHugh

Senior Vice President and Chief Financial Officer

**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, 2022 (the “Report”), the undersigned hereby certifies in his capacity as Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2022

/s/ Gregory J. Divis

Gregory J. Divis

Chief Executive Officer

**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, 2022 (the “Report”), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and
2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 9, 2022

/s/ Thomas S. McHugh

Thomas S. McHugh

Senior Vice President and Chief Financial Officer