

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

FORM 10-Q

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

For the quarterly period ended: June 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 000-28508

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland
(State or Other Jurisdiction of Incorporation)

000-28508
(Commission File Number)

98-1341933
(I.R.S. Employer Identification No.)

**10 Earlsfort Terrace
Dublin 2, Ireland
D02 T380**
(Address of Principal Executive Office and Zip Code)

+011-1-485-1200
(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 checked="" type="checkbox"/>
Non-accelerated	<input type="checkbox"/>	Smaller reporting company	<input 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 August 5, 2021, 58,596,238 ordinary shares, nominal value \$0.01 each, of the Company were outstanding.

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

From time to time, we may use our website, our 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, LinkedIn account or our Twitter posts are not incorporated into, and does not form a part of, this Quarterly Report.

Cautionary Disclosure Regarding Forward-Looking Statements

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

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

- Our reliance on a single lead product candidate, FT218, the timing of and our ability to obtain regulatory approval, if at all;
- Our ability to obtain desired regulatory exclusivity for FT218, including orphan drug exclusivity;
- Our ability to successfully commercialize FT218 in a timely manner or at all, if approved;
- The ability of FT218, if approved and launched commercially, to gain market acceptance;
- Our ability to enter into strategic partnerships for the commercialization, manufacturing and distribution of FT218, if approved;
- Our dependence on a limited number of suppliers for the manufacturing of our lead product candidate and certain raw materials in our lead product candidate 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 our lead product candidate, if approved and commercialized;
- Our expectations about pending and potential future patent infringement claims against us;
- Any further restructuring actions that may be required and our ability to obtain any required consents (including any consents required pursuant to the Indenture governing our exchange notes due 2023, or the 2023 Notes);
- Our ability to continue to service the 2023 Notes, including making the ongoing interest payments on the 2023 Notes, settling exchanges of the 2023 Notes in cash or completing any required repurchases of the 2023 Notes;
- The potential impact of COVID-19 on our business and future operating results;
- Our ability to hire and retain members of our management team and our employees; 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 9, 2021 and the risk factors and cautionary statements described in other documents that we file from time to time with the SEC. Given these uncertainties, readers should not place undue reliance on our forward-looking statements. These forward-looking statements speak only as of the date on which the statements were made and are not guarantees of future performance. Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to revise any forward-looking statements to reflect events or developments occurring after the date of this quarterly report, even if new information becomes available in the future.

PART I – FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Product sales	\$ —	\$ 10,091	\$ —	\$ —
Operating expenses:				
Cost of products	—	3,285	—	—
Research and development expenses	6,762	4,057	10,614	—
Selling, general and administrative expenses	15,174	7,095	26,186	—
Intangible asset amortization	—	203	—	—
Changes in fair value of contingent consideration	—	918	—	—
Gain on sale of Hospital Products	—	(45,760)	—	(—)
Restructuring costs (income)	—	24	(53)	—
Total operating expense (income)	21,936	(30,178)	36,747	(—)
Operating (loss) income	(21,936)	40,269	(36,747)	—
Investment and other income (expense), net	432	(741)	1,042	—
Interest expense	(1,930)	(3,237)	(3,859)	—
Gain from release of certain liabilities	88	—	166	—
Other expense - changes in fair value of contingent consideration payable	—	(125)	—	—
(Loss) income before income taxes	(23,346)	36,166	(39,398)	—
Income tax (benefit) expense	(3,765)	5,292	(6,372)	—
Net (loss) income	\$ (19,581)	\$ 30,874	\$ (33,026)	\$ —
Net (loss) income per share - basic	\$ (0.33)	\$ 0.57	\$ (0.56)	\$ —
Net (loss) income per share - diluted	(0.33)	0.49	(0.56)	—
Weighted average number of shares outstanding - basic	58,488	54,272	58,465	—
Weighted average number of shares outstanding - diluted	58,488	69,942	58,465	—

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
Net (loss) income	\$ (19,581)	\$ 30,874	\$ (33,026)	\$ 30,009
Other comprehensive (loss) income, net of tax:				
Foreign currency translation loss (income)	116	182	(602)	5
Net other comprehensive (loss) income, net of \$(78), \$(81), \$(133) and \$(130) tax, respectively	(160)	927	(697)	283
Total other comprehensive (loss) income, net of tax	(44)	1,109	(1,299)	288
Total comprehensive (loss) income	\$ (19,625)	\$ 31,983	\$ (34,325)	\$ 30,297

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
	<i>(unaudited)</i>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 67,142	\$ 71,722
Marketable securities	135,701	149,680
Research and development tax credit receivable	2,551	3,326
Prepaid expenses and other current assets	25,308	38,726
Total current assets	<u>230,702</u>	<u>263,454</u>
Property and equipment, net	321	359
Operating lease right-of-use assets	2,249	2,604
Goodwill	16,836	16,836
Research and development tax credit receivable	983	3,445
Other non-current assets	31,500	24,939
Total assets	<u>\$ 282,591</u>	<u>\$ 311,637</u>
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of operating lease liability	\$ 494	\$ 474
Accounts payable	5,116	2,934
Accrued expenses	7,524	6,501
Other current liabilities	3,146	5,200
Total current liabilities	<u>16,280</u>	<u>15,109</u>
Long-term debt	141,774	128,210
Long-term operating lease liability	1,589	1,840
Other non-current liabilities	4,068	4,212
Total liabilities	<u>163,711</u>	<u>149,371</u>
Shareholders' equity:		
Preferred shares, nominal value of \$0.01 per share; 50,000 shares authorized; 488 issued and outstanding at June 30, 2021 and 488 issued and outstanding at December 31, 2020, respectively	5	5
Ordinary shares, nominal value of \$0.01 per share; 500,000 shares authorized; 58,488 issued and outstanding at June 30, 2021 and 58,396 issued and outstanding at December 31, 2020	584	583
Additional paid-in capital	544,094	566,916
Accumulated deficit	(403,453)	(384,187)
Accumulated other comprehensive loss	(22,350)	(21,051)
Total shareholders' equity	<u>118,880</u>	<u>162,266</u>
Total liabilities and shareholders' equity	<u>\$ 282,591</u>	<u>\$ 311,637</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

Six Months Ended June 30, 2021

	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
Stock-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)
Stock-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>

AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(In thousands)

(Unaudited)

Six Months Ended June 30, 2020

	Ordinary shares		Preferred shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Treasury shares		Total shareholders' (deficit) equity
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2019	42,927	\$ 429	—	\$ —	\$ 434,391	\$ (391,215)	\$ (22,806)	5,407	\$ (49,998)	\$ (29,199)
Net loss	—	—	—	—	—	(865)	—	—	—	(865)
Other comprehensive loss	—	—	—	—	—	—	(821)	—	—	(821)
Exercise of stock options	146	2	—	—	1,387	—	—	—	—	1,389
February 2020 private placement	8,680	87	488	5	60,641	—	—	—	—	60,733
Vesting of restricted shares	19	—	—	—	—	—	—	—	—	—
Employee share purchase plan share issuance	40	—	—	—	88	—	—	—	—	88
Stock-based compensation expense	—	—	—	—	742	—	—	—	—	742
Balance, March 31, 2020	51,812	\$ 518	488	\$ 5	\$ 497,249	\$ (392,080)	\$ (23,627)	5,407	\$ (49,998)	\$ 32,067
Net income	—	—	—	—	—	30,874	—	—	—	30,874
Other comprehensive income	—	—	—	—	—	—	1,109	—	—	1,109
Exercise of stock options	95	1	—	—	392	—	—	—	—	393
February 2020 private placement	—	—	—	—	(94)	—	—	—	—	(94)
May 2020 public offering	11,630	116	—	—	116,858	—	—	—	—	116,974
Employee share purchase plan share issuance	—	—	—	—	33	—	—	—	—	33
Stock-based compensation expense	—	—	—	—	769	—	—	—	—	769
Balance, June 30, 2020	63,537	\$ 635	488	\$ 5	\$ 615,207	\$ (361,206)	\$ (22,518)	5,407	\$ (49,998)	\$ 182,125

AVADEL PHARMACEUTICALS PLC
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities:		
Net (loss) income	\$ (33,026)	\$ 30,009
Adjustments to reconcile net (loss) income to net cash provided by operating activities:		
Depreciation and amortization	417	975
Remeasurement of acquisition-related contingent consideration	—	3,396
Remeasurement of financing-related contingent consideration	—	435
Amortization of debt discount and debt issuance costs	625	3,193
Change in deferred tax and income tax deferred charge	(6,228)	161
Stock-based compensation expense	3,729	1,511
Gain from the disposition of the hospital products	—	(45,760)
Gain from the release of certain liabilities	(166)	—
Other adjustments	757	477
Net changes in assets and liabilities		
Accounts receivable	—	2,589
Inventories	—	(1,353)
Prepaid expenses and other current assets	(3,106)	(1,149)
Research and development tax credit receivable	3,078	2,036
Accounts payable & other current liabilities	176	(1,550)
Accrued expenses	1,199	(6,906)
Accrued income taxes	—	321
Earn-out payments for contingent consideration in excess of acquisition-date fair value	—	(3,736)
Royalty payments for contingent consideration payable in excess of original fair value	—	(608)
Other assets and liabilities	(1,021)	(3,458)
Net cash used in operating activities	(33,566)	(19,417)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	—
Proceeds from the disposition of the hospital products	16,500	14,500
Proceeds from sales of marketable securities	66,213	15,716
Purchases of marketable securities	(53,372)	(97,878)
Net cash provided by (used in) investing activities	29,315	(67,662)
Cash flows from financing activities:		
Proceeds from the February 2020 private placement	—	60,639
Proceeds from the May 2020 public offering	—	116,974
Proceeds from stock option exercises and employee stock purchase plan	149	1,903
Net cash provided by financing activities	149	179,516
Effect of foreign currency exchange rate changes on cash and cash equivalents	(478)	(37)
Net change in cash and cash equivalents	(4,580)	92,400
Cash and cash equivalents at January 1,	71,722	9,774
Cash and cash equivalents at June 30,	\$ 67,142	\$ 102,174
Supplemental disclosures of cash flow information:		
Interest paid	\$ 3,234	\$ 3,234
Income taxes paid (refund)	\$ 7	\$ (1,795)

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. Our lead product candidate, FT218, is an investigational once-nightly, extended-release formulation of sodium oxybate for the treatment of excessive daytime sleepiness (“EDS”) and cataplexy in adults with narcolepsy. We are primarily focused on the development and potential United States (“U.S.”) Food and Drug Administration (“FDA”) approval of FT218. In December 2020, we submitted a New Drug Application (“NDA”) to the FDA for FT218 to treat excessive daytime sleepiness and cataplexy in adults with narcolepsy. The NDA for FT218 was accepted by the FDA in February 2021 and assigned a Prescription Drug User Fee Act (“PDUFA”) target action date of October 15, 2021.

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of June 30, 2021, we do not have any approved and commercialized products in our portfolio.

We are registered as an Irish public limited company. Our headquarters are in Dublin, Ireland and we have operations in St. Louis, Missouri, U.S.

FT218

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

On December 16, 2020, we announced the submission of our NDA to the FDA for FT218. On February 26, 2021, the FDA notified us of formal acceptance of the NDA with an assigned PDUFA target action date of October 15, 2021.

We conducted a Phase 3 clinical trial of FT218, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient, last visit was completed at the end of the first quarter of 2020 and positive top line data from the REST-ON trial was announced on April 27, 2020. Patients who received 9 g of once-nightly FT218, the highest dose administered in the trial, demonstrated a statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test, or MWT, clinical global impression-improvement, or CGI-I, and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated a statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-nightly FT218 to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of FT218 discontinued the trial due to adverse reactions.

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

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

New secondary endpoints from the REST-ON trial were presented at the American Academy of Neurology, beginning April 17, 2021. The first poster described FT218 improvements in disturbed nocturnal sleep (“DNS”), defined in REST-ON as the number of shifts from stages N1, N2, N3, and rapid eye movement (“REM”) sleep to wake and from stages N2, N3, and REM

sleep to stage N1. FT218 also decreased the number of nocturnal arousals as measured on polysomnography. Improvements in DNS were further supported by post-hoc analyses demonstrating increased time in deep sleep (N3, also known as slow wave sleep), and less time in N1. A second poster described the statistically significant improvements in the Epworth Sleepiness Scale, both the quality of sleep and the refreshing nature of sleep, and a decrease in sleep paralysis. These clinically relevant improvements were observed for all doses, beginning at Week 3, for the lowest 6 g dose, compared to placebo. FT218 did not demonstrate significant improvement for hypnagogic hallucinations compared to placebo.

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

Previously Approved FDA Products

On June 30, 2020 (the “Closing Date”), we announced the sale by Avadel Legacy Pharmaceuticals, LLC (the “Avadel Seller”) of the portfolio of sterile injectable drugs used in the hospital setting (the “Hospital Products”), which included our three commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to Exela Sterile Medicines LLC (“Exela Buyer”) pursuant to an asset purchase agreement (the “Purchase Agreement”) by and among the Avadel Seller, Avadel US Holdings, Inc., the Exela Buyer and Exela Holdings, Inc. This sale included the following FDA approved products:

- **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery.
- **Vazculep (phenylephrine hydrochloride injection)** - Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- **Akovaz (ephedrine sulfate injection)** - Akovaz was the first FDA approved formulation of ephedrine sulfate, an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- **Nouress (cysteine hydrochloride injection)** - Nouress is a sterile injectable product for use in the hospital setting to provide parenteral nutrition to neonates.

See Note 3: *Disposition of the Hospital Products*.

Basis of Presentation. The unaudited condensed consolidated balance sheet as of June 30, 2021, which is derived from the prior year 2020 audited consolidated financial statements, and the interim unaudited condensed consolidated financial statements presented herein, have been prepared in accordance with accounting principles generally accepted in the U.S. (U.S. GAAP), the requirements of Form 10-Q and Article 10 of Regulation S-X and, consequently, do not include all information or footnotes required by U.S. GAAP for complete financial statements or all the disclosures normally made in an Annual Report on Form 10-K. Accordingly, the unaudited condensed consolidated financial statements included herein should be read in conjunction with the audited consolidated financial statements and footnotes included in the Company’s 2020 Annual Report on Form 10-K filed with the SEC on March 9, 2021.

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.

Revenue. Prior to June 30, 2020, revenue was earned from the sales of pharmaceutical products.

Product Sales

Prior to June 30, 2020, we sold products primarily through wholesalers and considered these wholesalers to be our customers. Under ASC 606, revenue from product sales is recognized when the customer obtains control of our product, which occurs typically upon receipt by the customer. Our gross product sales were subject to a variety of price adjustments in arriving at

reported net product sales. These adjustments included estimates of product returns, chargebacks, payment discounts, rebates, and other sales allowances and were estimated based on analysis of historical data for the product or comparable products, future expectations for such products and other judgments and analysis.

For a complete discussion of the accounting for net product revenue, see *Note 4: Revenue Recognition*.

NOTE 2: Newly Issued Accounting Standards

Recently Adopted Accounting Guidance

In December 2019, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) 2019-12, *Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes*, as part of its overall simplification initiative to reduce costs and complexity of applying accounting standards while maintaining or improving the usefulness of the information provided to users of financial statements. The FASB’s amendments primarily impact ASC 740, *Income Taxes*, and may impact both interim and annual reporting periods. ASU 2019-12 is effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years and early adoption is permitted. We adopted the provisions of ASU 2019-12 on January 1, 2021. Adoption of ASU 2019-12 did not have any impact on our unaudited condensed consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging- Contracts in Entity’s Own Equity (Subtopic 815-40)*, to reduce the complexity associated with applying U.S. GAAP principles for certain financial instruments with characteristics of liabilities and equity. The amendments in this ASU reduce the number of accounting models for convertible instruments and expand the existing disclosure requirements over earnings per share as it relates to convertible instruments. Convertible debt will be accounted for as a single liability measured at its amortized cost, as long as no other features require bifurcation and recognition as derivatives. The update also requires the if-converted method to be used for convertible instruments and the effect of potential share settlement be included in the diluted earnings per share calculation when an instrument may be settled in cash or shares. This ASU is effective for our fiscal year beginning January 1, 2022 and interim periods therein. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The amendments may be adopted through either a modified retrospective method, or a fully retrospective method.

The Company elected to early adopt ASU 2020-06 as of January 1, 2021 using a modified retrospective method. The Company’s 4.50% exchangeable senior notes due 2023 (the “2023 Notes”) are a convertible instrument with a cash-conversion feature that is accounted for within the scope of Subtopic 470-20. The Company calculated the cumulative-effect adjustment as of January 1, 2021 by comparing (i) the historical amortization schedule for the 2023 Notes through December 31, 2020 and (ii) an updated amortization schedule wherein the conversion feature within the 2023 Notes would not be separated as an equity component and subsequently recognized as non-cash interest expense under ASC 835-30. The adoption resulted in a \$26,699 decrease in additional paid-in capital, a \$12,939 increase in long-term debt, and a \$13,760 increase to the opening balance of retained earnings.

NOTE 3: Disposition of the Hospital Products

On the Closing Date, we announced the sale of our Hospital Products to the Exela Buyer pursuant to the Purchase Agreement (the “Transaction”).

Pursuant to the Purchase Agreement, the Exela Buyer agreed to pay a total aggregate consideration amount of \$42,000, of which \$14,500 was paid on the Closing Date and an additional \$27,500 was paid in ten equal monthly installments following the Closing Date. During the year ended December 31, 2020, we collected four installment payments, totaling \$11,000 and during the six months ended June 30, 2021, we collected the remaining six installment payments, totaling \$16,500. In connection with the sale of the Hospital Products, the parties also agreed to cause the dismissal of the pending civil litigation related to Nouress in the District Court for the District of Delaware.

We were party to a Membership Interest Purchase Agreement, dated March 13, 2012, by and among us, Avadel Legacy, Breaking Stick Holdings, LLC, Deerfield Private Design International II, L.P. (“Deerfield International”), Deerfield Private Design Fund II, L.P. (“Deerfield Fund”) and Horizon Santé FLML, Sarl (“Horizon”) (the “Deerfield MIPA”) and a Royalty Agreement, dated February 4, 2013, by and among us, Avadel Legacy, the Deerfield Fund and Horizon (the “Deerfield Royalty Agreement”). In connection with the closing of the sale of the Hospital Products, the Deerfield MIPA (with respect to certain sections thereof) and the Royalty Agreement were assigned to the Exela Buyer. Pursuant to the Purchase Agreement, the Exela

Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Deerfield Royalty Agreement for obligations that arise after the Closing Date.

We were also party to a Royalty Agreement, dated December 3, 2013, by and between us, Avadel Legacy and Broadfin Healthcare Master Fund, Ltd. (the "Broadfin Royalty Agreement"). In connection with the closing of the sale of the Hospital Products, the Broadfin Royalty Agreement was assigned to the Exela Buyer and the Exela Buyer assumed and shall pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy under the Broadfin Royalty Agreement for obligations that arise after the Closing Date.

The following table represents the major classes of assets and liabilities either transferred to the Exela Buyer or eliminated by us due to the sale of the Hospital Products in exchange for aggregate consideration of \$42,000, less transaction fees of \$2,928.

	June 30, 2020
Prepaid expenses and other current assets	\$ (134)
Inventories	(4,922)
Goodwill	(1,654)
Intangible assets, net	(407)
Other non-current assets	(1,095)
Total long-term contingent consideration payable	14,900
Net liabilities disposed of	6,688
Aggregate consideration	42,000
Less transaction fees	(2,928)
Net gain on the sale of the Hospital Products	\$ 45,760

We evaluated various qualitative and quantitative factors related to the disposition of the Hospital Products and determined that it did not meet the criteria for presentation as a discontinued operation.

The unaudited pro forma condensed combined statement of loss for the six months ended June 30, 2020 included below is being provided for information purposes only and are not necessarily indicative of the results of operations that would have resulted if the Transaction had actually occurred on the date indicated. The pro forma adjustments are based on available information and assumptions that the Company believes are attributable to the sale.

Unaudited Pro Forma Condensed Combined Statement of Loss					
Six Months Ended June 30, 2020					
	As Reported	Pro Forma Adjustments	Notes	Pro Forma	
Product sales	\$ 22,334	\$ (22,175)	(a)	\$	159
Total operating expense	(11,438)	(8,525)	(b)		(19,963)
Operating income (loss)	33,772	(13,650)			20,122
Loss before income taxes	\$ 25,791	\$ (13,215)	(c)	\$	12,576

Adjustments to the pro forma unaudited condensed combined statements of loss

(a) This adjustment reflects Product sales attributable to the Hospital Products.

(b) This adjustment reflects the following estimated expenses attributable to the Hospital Products:

- Cost of products of \$3,540.
- Research and development expenses of \$407.
- Selling, general and administrative expenses of \$776.
- Intangible asset amortization on acquired development technology for Vazculep of \$406.
- Changes in fair value of related party contingent consideration of \$3,396. The Company will no longer be responsible for these payments.

(c) This amount reflects the adjustments noted in (a) and (b) above, as well as estimated Changes in fair value of related party payable of \$435 attributable to the Hospital Products. The Company will no longer be responsible for these payments.

NOTE 4: Revenue Recognition

Prior to June 30, 2020, we generated revenue primarily from the sale of pharmaceutical products to customers. On June 30, 2020, we sold the Hospital Products. See *Note 3: Disposition of the Hospital Products*.

Product Sales

Prior to June 30, 2020, we sold products primarily through wholesalers and considered these wholesalers to be our customers. Revenue from product sales was recognized when the customer obtained control of our product and our performance obligations were met, which occurred typically upon receipt of delivery to the customer. As is customary in the pharmaceutical industry, our gross product sales were subject to a variety of price adjustments in arriving at reported net product sales. These adjustments included estimates for product returns, chargebacks, payment discounts, rebates, and other sales allowances and are estimated when the product is delivered based on analysis of historical data for the product or comparable products, as well as future expectations for such products.

Reserves to Reduce Gross Revenues to Net Revenues

Revenues from product sales were recorded at the net selling price, which included estimated reserves to reduce gross product sales to net product sales resulting from product returns, chargebacks, payment discounts, rebates, and other sales allowances that are offered within contracts between the Company and its customers and end users. These reserves were based on the amounts earned or to be claimed on the related sales and were classified as reductions of accounts receivable if the amount is payable to the customer, except in the case of the estimated reserve for future expired product returns, which are classified as a liability. The reserves are classified as a liability if the amount is payable to a party other than a customer. Where appropriate, these estimated reserves take into consideration relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. Overall, these reserves reflect the Company's best estimates to reduce gross selling price to net selling price to which it expects to be entitled based on the terms of its contracts. The actual selling price ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company adjusts these estimates, which would affect net product revenue and earnings in the period such variances become known.

Product Returns

Consistent with industry practice, the Company maintained a returns policy that generally offered customers a right of return for product that has been purchased from the Company. The Company estimated the amount of product returns and records this estimate as a reduction of revenue in the period the related product revenue was recognized. The Company estimated product return liabilities based on analysis of historical data for the product or comparable products, as well as future expectations for such products and other judgments and analysis.

Chargebacks, Discounts and Rebates

Chargebacks, discounts and rebates represent the estimated obligations resulting from contractual commitments to sell products to its customers or end users at prices lower than the list prices charged to our wholesale customers. Customers charge the Company for the difference between the gross selling price they pay for the product and the ultimate contractual price agreed to between the Company and these end users. These reserves are established in the same period that the related revenue is recognized, resulting in a reduction of product revenue and accounts receivable. Chargebacks, discounts and rebates are estimated at the time of sale to the customer.

Disaggregation of revenue

The Company's source of revenue was from the sale of pharmaceutical products, which are equally affected by the same economic factors as it relates to the nature, amount, timing, and uncertainty of revenue and cash flows. For further detail about the Company's revenues by product, see *Note 15: Revenue by Product*.

Contract Balances

The Company does not recognize revenue in advance of invoicing its customers and therefore has no related contract assets.

A receivable is recognized in the period the Company sells its products and when the Company's right to consideration is unconditional.

There were no material deferred contract costs at June 30, 2021 or December 31, 2020.

Transaction Price Allocated to the Remaining Performance Obligation

For product sales, the Company generally satisfied its performance obligations within the same period the product was delivered. Product sales recognized in the second quarter of 2020 from performance obligations satisfied (or partially satisfied) in previous periods were immaterial.

The Company has elected certain of the practical expedients from the disclosure requirement for remaining performance obligations for specific situations in which an entity need not estimate variable consideration to recognize revenue. Accordingly, the Company applies the practical expedient in ASC 606 to its stand-alone contracts and does not disclose information about variable consideration from remaining performance obligations for which the Company recognizes revenue.

NOTE 5: 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, we use 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, we 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 June 30, 2021			As of December 31, 2020		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Marketable securities (see Note 6)						
Mutual and money market funds	\$ 91,732	\$ —	\$ —	\$ 104,672	\$ —	\$ —
Corporate bonds	—	23,056	—	—	22,155	—
Government securities - U.S.	—	17,853	—	—	18,999	—
Other fixed-income securities	—	3,060	—	—	3,854	—
Total assets	\$ 91,732	\$ 43,969	\$ —	\$ 104,672	\$ 45,008	\$ —

A review of fair value hierarchy classifications is conducted on a quarterly basis. Changes in the observability of valuation inputs may result in a reclassification for certain financial assets or liabilities. During the periods ended June 30, 2021 and December 31, 2020, respectively, there were no transfers in and out of Level 1, 2, or 3. During the three and six months ended June 30, 2021 and 2020, respectively, we did not recognize any other-than-temporary impairment loss.

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

Debt

We estimate the fair value of our \$143,750 aggregate principal amount of the 2023 Notes based on interest rates that would be currently available to the Company for issuance of similar types of debt instruments with similar terms and remaining maturities or recent trading prices obtained from brokers (a Level 2 input). The estimated fair value of the 2023 Notes at June 30, 2021 is \$147,523.

See Note 9: Long-Term Debt for additional information regarding our debt obligations.

NOTE 6: 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 equity investments is recognized in our unaudited condensed consolidated statements of (loss) income and the change in the fair value of available-for-sale debt investments is recorded as other comprehensive loss in shareholders' equity, net of income tax effects. As of June 30, 2021, we considered any decreases in fair value on our marketable securities to be driven by factors other than credit risk, including market risk.

The following tables show the Company's available-for-sale securities' adjusted cost, gross unrealized gains, gross unrealized losses and fair value by significant investment category as of June 30, 2021 and December 31, 2020, respectively:

Marketable Securities:	June 30, 2021			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value
Mutual and money market funds	\$ 90,907	\$ 1,171	\$ (346)	\$ 91,732
Corporate bonds	22,853	224	(21)	23,056
Government securities - U.S.	17,873	78	(98)	17,853
Other fixed-income securities	3,055	13	(8)	3,060
Total	\$ 134,688	\$ 1,486	\$ (473)	\$ 135,701

Marketable Securities:	December 31, 2020			
	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value
Mutual and money market funds	\$ 103,404	\$ 1,288	\$ (20)	\$ 104,672
Corporate bonds	21,811	350	(6)	22,155
Government securities - U.S.	18,849	155	(5)	18,999
Other fixed-income securities	3,839	22	(7)	3,854
Total	\$ 147,903	\$ 1,815	\$ (38)	\$ 149,680

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

We recognized gross realized gains of \$41 and \$14 for the three months ended June 30, 2021 and 2020, respectively. These realized gains were offset by realized losses of \$39 and \$6 for the three months ended June 30, 2021 and 2020, respectively. We recognized gross realized gains of \$52 and \$290 for the six months ended June 30, 2021 and 2020, respectively. These realized gains were offset by realized losses of \$107 and \$878 for the six months ended June 30, 2021 and 2020, respectively.

The following table summarizes the estimated fair value of our investments in marketable debt securities, accounted for as available-for-sale debt securities and classified by the contractual maturity date of the securities as of June 30, 2021:

Marketable Debt Securities:	Maturities				
	Less than 1 Year	1-5 Years	5-10 Years	Greater than 10 Years	Total
Corporate bonds	\$ 7,563	\$ 15,406	\$ 87	\$ —	\$ 23,056
Government securities - U.S.	4,399	10,889	881	1,684	17,853
Other fixed-income securities	1,003	1,352	705	—	3,060
Total	\$ 12,965	\$ 27,647	\$ 1,673	\$ 1,684	\$ 43,969

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

Total gross unrealized losses of our available-for-sale debt securities at June 30, 2021 were immaterial. The unrealized losses are driven by factors other than credit risk and have been in an unrealized loss position for less than one year. We do not intend to sell the investments and it is not more likely than not that we will be required to sell the investments before recovery of their amortized cost bases.

NOTE 7: Goodwill and Intangible Assets

The Company's unamortizable goodwill is \$16,836 at June 30, 2021 and December 31, 2020.

The Company recorded amortization expense related to an amortizable intangible asset that was assumed by the Exela Buyer as part of the disposition of the Hospital Products on June 30, 2020 of \$203 and \$406 for the three and six months ended June 30, 2020. Refer to *Note 3: Disposition of the Hospital Products*. There was no amortization expense recorded during the three and six months ended June 30, 2021.

NOTE 8: Contingent Consideration Payable

Prior to the sale of the Hospital Products on June 30, 2020, we computed the fair value of the contingent consideration using several significant assumptions and when those assumptions changed, due to underlying market conditions, the fair value of these liabilities changed as well. Each of the underlying assumptions used to determine the fair values of these contingent liabilities could, and often did, change based on adjustments in current market conditions, competition and other factors. Prior to the sale of the Hospital Products, these changes had a material impact on our unaudited condensed consolidated statements of (loss) income and balance sheets. As part of the sale of the Hospital Products on June 30, 2020, the Exela Buyer assumed and will pay, perform, satisfy and discharge the liabilities and obligations of Avadel Legacy and the Company under the Deerfield Royalty Agreement. As of June 30, 2021 and December 31, 2020, the balance of the contingent consideration payable is \$0.

The following table summarizes changes to the contingent consideration payable, a recurring Level 3 measurement, for the six-month period ended June 30, 2020:

Contingent Consideration Payable Rollforward:	Balance	
Balance, December 31, 2019	\$	17,327
Payments of contingent consideration		(4,344)
Fair value adjustments ⁽¹⁾		3,831
Disposition of the Hospital Products		(14,900)
Balance, June 30, 2020	\$	1,914

⁽¹⁾ Fair value adjustments are reported as changes in fair value of contingent consideration and other expense - changes in fair value of contingent consideration payable in the unaudited condensed consolidated statements of (loss) income.

NOTE 9: Long-Term Debt

Long-term debt is summarized as follows:

	June 30, 2021	December 31, 2020
Principal amount of 4.50% exchangeable senior notes due 2023	\$ 143,750	\$ 143,750
Less: unamortized debt discount and issuance costs, net	(1,976)	(15,540)
Net carrying amount of liability component	141,774	128,210
Less: current maturities	—	—
Long-term debt	\$ 141,774	\$ 128,210
Equity component:		
Equity component of exchangeable notes, net of issuance costs	\$ —	\$ (26,699)

For the three months ended June 30, 2021 and 2020, the total interest expense was \$1,930 and \$3,237, respectively, with coupon interest expense of \$1,617 for each period and the amortization of debt issuance costs and debt discount of \$313 and \$1,620, respectively.

For the six months ended June 30, 2021 and 2020, the total interest expense was \$3,859 and \$6,427, respectively, with coupon interest expense of \$3,234 for each period and the amortization of debt issuance costs and debt discount of \$625 and \$3,193, respectively.

As described in *Note 2: Newly Issued Accounting Standards*, the Company elected to early adopt ASU 2020-06 as of January 1, 2021 using a modified retrospective method. The adoption resulted in a \$12,939 increase in long-term debt and a \$26,699 decrease in the equity component of the 2023 Notes.

2023 Notes

On February 16, 2018, Avadel Finance Cayman Limited, a Cayman Islands exempted company (the “Issuer”) and an indirect wholly-owned subsidiary of the Company, issued \$125,000 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the “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 2023 Notes a 30-day option to purchase up to an additional \$18,750 aggregate principal amount of the 2023 Notes, which was fully exercised on February 16, 2018. Net proceeds received by the Company, after issuance costs and discounts of \$6,190, were approximately \$137,560. The 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.

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, which is equivalent to an initial exchange price of approximately \$10.79 per ADS. Such initial exchange price represents a premium of approximately 20% to the \$8.99 per ADS closing price on The Nasdaq Global Market on February 13, 2018. Upon the exchange of any 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. Holders of the 2023 Notes may convert their 2023 Notes, at their option, only under the following circumstances prior to the close of business on the business day immediately

preceding August 1, 2022, under the circumstances and during the periods set forth below and regardless of the conditions described below, on or after August 1, 2022 and prior to the close of business on the business day immediately preceding the maturity date:

- Prior to the close of business on the business day immediately preceding August 1, 2022, a holder of the 2023 Notes may surrender all or any portion of its 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 2023 Notes, as determined following a request by a holder of the 2023 Notes, for each trading day of the measurement period was less than 98% of the product of the last reported sale price of the ADSs and the exchange rate on each such trading day.
- If a transaction or event that constitutes a fundamental change or a make-whole fundamental change occurs prior to the close of business on the business day immediately preceding August 1, 2022, regardless of whether a holder of the 2023 Notes has the right to require the Company to repurchase the 2023 Notes, or if Avadel is a party to a merger event that occurs prior to the close of business on the business day immediately preceding August 1, 2022, all or any portion of a the holder's 2023 Notes may be surrendered for exchange at any time from or after the date that is 95 scheduled trading days prior to the anticipated effective date of the transaction (or, if later, the earlier of (x) the business day after the Company gives notice of such transaction and (y) the actual effective date of such transaction) until 35 trading days after the actual effective date of such transaction or, if such transaction also constitutes a fundamental change, until the related fundamental change repurchase date.
- Prior to the close of business on the business day immediately preceding August 1, 2022, a holder of the 2023 Notes may surrender all or any portion of its 2023 Notes for exchange at any time during any calendar quarter commencing after the calendar quarter ending on June 30, 2018 (and only during such calendar quarter), if the last reported sale price of the ADSs for at least 20 trading days (whether or not consecutive) during the period of 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the exchange price on each applicable trading day.
- If the Company calls the 2023 Notes for redemption pursuant to Article 16 to the Indenture prior to the close of business on the business day immediately preceding August 1, 2022, then a holder of the 2023 Notes may surrender all or any portion of its 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 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 2023 Notes may exchange its 2023 Notes until the redemption price has been paid or duly provided for.

We 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. We determined that this exception applies due, in part, to our ability to settle the 2023 Notes in cash, ADSs or a combination of cash and ADSs, at our option. We have therefore applied the guidance provided by ASC 470-20, *Debt with Conversion and Other Options*, as amended by ASU 2020-06.

NOTE 10: Income Taxes

The income tax benefit was \$3,765 for the three months ended June 30, 2021 resulting in an effective tax rate of 16.1%. The income tax expense was \$5,292 for the three months ended June 30, 2020 resulting in an effective tax rate of 14.6%.

The income tax benefit was \$6,372 for the six months ended June 30, 2021 resulting in an effective tax rate of 16.2%. The income tax benefit was \$4,218 for the six months ended June 30, 2020 resulting in an effective tax rate of (16.4)%. The net increase in the effective income tax rate for the six months ended June 30, 2021 as compared to the prior period in 2020 is primarily due to the discrete tax benefits recognized during the six months ended June 30, 2020 under the Coronavirus Aid, Relief and Economic Security Act, also known as the CARES Act, which did not occur during the six months ended June 30, 2021.

During the six months ended June 30, 2021 and 2020, the Company received \$3,078 and \$2,036, respectively, of cash primarily related to refundable French Research & Development Tax Credits generated in prior years.

NOTE 11: Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	June 30, 2021	December 31, 2020
Value-added tax recoverable	\$ 306	\$ 341
Prepaid and other expenses	3,983	1,018
Short-term deposit	1,418	1,477
Guarantee from Armistice	274	318
Income tax receivable	18,835	18,615
Receivable from Exela (see Note 3)	—	16,500
Other	492	457
Total	\$ 25,308	\$ 38,726
Other Non-Current Assets:	June 30, 2021	December 31, 2020
Deferred tax assets	\$ 24,484	\$ 18,256
Guarantee from Armistice	910	1,050
Right of use assets at contract manufacturing organizations	5,749	5,201
Other	357	432
Total	\$ 31,500	\$ 24,939
Accrued Expenses	June 30, 2021	December 31, 2020
Accrued compensation	\$ 1,504	\$ 1,697
Accrued restructuring (see Note 12)	177	520
Customer allowances	821	1,030
Accrued outsource contract costs	837	473
Other	4,185	2,781
Total	\$ 7,524	\$ 6,501
Other Current Liabilities:	June 30, 2021	December 31, 2020
Accrued interest	\$ 2,695	\$ 2,695
Due to Exela	—	2,026
Guarantee to Deerfield	275	319
Other	176	160
Total	\$ 3,146	\$ 5,200
Other Non-Current Liabilities:	June 30, 2021	December 31, 2020
Unrecognized tax benefits	\$ 3,143	\$ 3,143
Guarantee to Deerfield	913	1,053
Other	12	16
Total	\$ 4,068	\$ 4,212

NOTE 12: Restructuring Costs*2019 French Restructuring*

During the second quarter of 2019, the Company initiated a plan to substantially reduce all of its workforce at its Vénissieux, France site (“2019 French Restructuring”). This reduction was part of an effort to align the Company’s cost structure with our ongoing and future planned projects. The reduction in workforce was completed during 2020. Restructuring (income) charges associated with this plan recognized during the three and six months ended June 30, 2021 and 2020 were immaterial.

The following table sets forth activities for the Company's cost reduction plan obligations for the six months ended June 30, 2021:

2019 French Restructuring Obligation:	2021
Balance of restructuring accrual at January 1,	\$ 248
Income for employee severance, benefits and other costs	(122)
Payments	(13)
Foreign currency impact	(6)
Balance of restructuring accrual at June 30,	<u>\$ 107</u>

The 2019 French Restructuring liabilities of \$107 are included in the unaudited condensed consolidated balance sheet in accrued expenses at June 30, 2021.

2019 Corporate Restructuring

During the first quarter of 2019, the Company announced a plan to reduce its Corporate workforce by more than 50% ("2019 Corporate Restructuring"). The reduction in workforce is primarily a result of the exit of Noctiva during the first quarter of 2019, as well as an effort to better align the Company's remaining cost structure at our U.S. and Ireland locations with our ongoing and future planned projects. The reduction in workforce was completed during 2020. The restructuring charges associated with this plan recognized during the six months ended June 30, 2021 and 2020 were immaterial.

The following table sets forth activities for the Company's cost reduction plan obligations for the six months ended June 30, 2021:

2019 Corporate Restructuring Obligation:	2021
Balance of restructuring accrual at January 1,	\$ 272
Charges for employee severance, benefits and other costs	—
Payments	(202)
Balance of restructuring accrual at June 30,	<u>\$ 70</u>

The 2019 Corporate Restructuring liabilities of \$70 are included in the unaudited condensed consolidated balance sheet in accrued expenses at June 30, 2021.

NOTE 13: Net (Loss) Income Per Share

Basic net (loss) income per share is calculated by dividing net (loss) income by the weighted average number of shares outstanding during each period. Diluted net (loss) income per share is calculated by dividing net (loss) income - diluted by the diluted number of shares outstanding during each period. Except where the result would be anti-dilutive to net (loss) income, diluted net (loss) income per share would be calculated assuming the impact of the conversion of the 2023 Notes, the conversion of our preferred shares, the exercise of outstanding equity compensation awards, and ordinary shares expected to be issued under our employee stock purchase plan ("ESPP").

We have a choice to settle the conversion obligation under the 2023 Notes in cash, shares or any combination of the two. We utilize 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 our 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 our ESPP has been calculated using the treasury stock method. The dilutive effect of the performance share units ("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) income per share, together with the related shares outstanding in thousands is as follows:

Net (Loss) Income Per Share:	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net (loss) income	\$ (19,581)	\$ 30,874	\$ (33,026)	\$ 30,009
Add: interest from 2023 Notes, net of tax	—	3,237	—	6,427
Net (loss) income - diluted	\$ (19,581)	\$ 34,111	\$ (33,026)	\$ 36,436
Weighted average shares:				
Basic shares	58,488	54,272	58,465	47,665
Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes	—	15,670	—	15,418
Diluted shares	58,488	69,942	58,465	63,083
Net (loss) income per share - basic	\$ (0.33)	\$ 0.57	\$ (0.56)	\$ 0.63
Net (loss) income per share - diluted	\$ (0.33)	\$ 0.49	\$ (0.56)	\$ 0.58

Potential ordinary shares of 15,586 and 2,472 were excluded from the calculation of weighted average shares for the three months ended June 30, 2021 and 2020, respectively, and potential ordinary shares of 15,426 and 2,537 were excluded from the calculation of weighted average shares for the six months ended June 30, 2021 and 2020, respectively, because either their effect was considered to be anti-dilutive or they were related to shares from PSUs for which the contingent vesting condition had not been achieved. For the three and six months ended June 30, 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 14: Comprehensive Loss

The following table shows the components of accumulated other comprehensive loss for the three and six months ended June 30, 2021 and 2020, respectively, net of tax effects:

Accumulated Other Comprehensive Loss:	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Foreign currency translation adjustment:				
Beginning balance	\$ (23,345)	\$ (23,915)	\$ (22,627)	\$ (23,738)
Net other comprehensive income (loss)	116	182	(602)	5
Balance at June 30,	\$ (23,229)	\$ (23,733)	\$ (23,229)	\$ (23,733)
Unrealized gain on marketable debt securities, net				
Beginning balance	\$ 1,039	\$ 288	\$ 1,576	\$ 932
Net other comprehensive (loss) income, net of \$(78), \$(81) \$(133) and \$(130) tax, respectively	(160)	927	(697)	283
Balance at June 30,	\$ 879	\$ 1,215	\$ 879	\$ 1,215
Accumulated other comprehensive loss at June 30,	\$ (22,350)	\$ (22,518)	\$ (22,350)	\$ (22,518)

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 15: Revenue by Product

The Company has determined that it operates in one segment, the development and commercialization of pharmaceutical products, including controlled-release therapeutic products based on our proprietary polymer based technology. The Company's Chief Operating Decision Maker is the Chief Executive Officer (the "CEO"). The CEO reviews profit and loss information on a consolidated basis to assess performance and make overall operating decisions as well as resource allocations. All products were included in one segment because the Company's products have similar economic and other characteristics, including the nature of the products and production processes, type of customers, distribution methods and regulatory environment.

On June 30, 2020, we sold the Hospital Products. See *Note 3: Disposition of the Hospital Products*. The following table presents a summary of total product sales by these products:

Product Sales by Product:	Three Months Ended June 30,		Six Months Ended June 30,	
	2020		2020	
Bloxiverz	\$	800	\$	2,201
Vazculep		4,915		10,429
Akovaz		4,196		9,545
Other		180		159
Total product sales	\$	10,091	\$	22,334

On June 30, 2020, we sold the Hospital Products. See *Note 3: Disposition of the Hospital Products*.

NOTE 16: Commitments and Contingencies

Litigation

The Company is 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. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At June 30, 2021 and December 31, 2020, 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 unaudited condensed consolidated financial position, results of operations, cash flows or liquidity.

On May 12, 2021, Jazz Pharmaceuticals, Inc. ("Jazz") filed a formal complaint (the "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 Complaint, Jazz alleges the sodium oxybate product ("Proposed Product") described in the New Drug Application ("NDA") owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 8731963, 10758488, 10813885, 10959956 and/or 10966931 (collectively, the "patents-in-suit"). The 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 Complaint. The Avadel Answer generally denies the allegations set forth in the 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, ii) a declaratory judgment of invalidity of each patent-in-suit, and iii) a declaratory judgement requiring delisting of US Patent No. 8731963 from FDA's Orange Book.

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 preliminary injunction hearing date of November 23, 2021 (only relevant in the event that Jazz files a motion for a preliminary injunction by October 22, 2021), ii) a claim construction hearing date of August 2, 2022, and iii) a trial date of October 30, 2023.

On August 4, 2021, Jazz filed another formal complaint (the "Second Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Second Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 11077079. The Second Complaint further includes

typical relief requests such as preliminary and permanent injunctive relief, monetary damages and attorneys' fees, costs and expenses.

Material Commitments

Other than commitments disclosed in *Note 17: Contingent Liabilities and Commitments* to the Company's consolidated financial statements included in the 2020 Annual Report on Form 10-K, there were no other material commitments outside of the normal course of business.

Guarantees

Deerfield Guarantee

The fair values of our guarantee to Deerfield and the guarantee received by us from Armistice largely offset and when combined are not material.

In connection with our February 2018 divestiture of our pediatric assets, we 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 our explicit guarantee to Deerfield, the Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee liability was \$1,188 at June 30, 2021. This liability is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

Armistice Guarantee

In connection with our February 2018 divestiture of the pediatric assets, Armistice Capital Master Fund, Ltd., the majority shareholder of Cerecor, guaranteed to us the FSC Product Royalties. The Company recorded the guarantee in accordance with ASC 460. The balance of this guarantee asset was \$1,184 at June 30, 2021. This asset is being amortized proportionately based on undiscounted cash outflows through the remainder of the contract with Deerfield.

Off-Balance Sheet Arrangements

As of June 30, 2021, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

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 9, 2021 and Part II, Item 1A in this Quarterly Report on Form 10-Q for a discussion of additional important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis and elsewhere in this Quarterly Report.

Overview

General Overview

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

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of June 30, 2021, we do not have any approved and commercialized products in our portfolio.

FT218

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

On December 16, 2020, we announced the submission of our NDA to the FDA for FT218. On February 26, 2021, the FDA notified us of formal acceptance of the NDA with an assigned PDUFA target action date of October 15, 2021.

We conducted a Phase 3 clinical trial of FT218, the REST-ON trial, which was a randomized, double-blind, placebo-controlled study that enrolled 212 patients and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient, last visit was completed at the end of the first quarter of 2020 and positive top line data from the REST-ON trial was announced on April 27, 2020. Patients who received 9 g of once-nightly FT218, the highest dose administered in the trial, demonstrated a statistically significant and clinically meaningful improvement compared to placebo across the three co-primary endpoints of the trial: maintenance of wakefulness test, or MWT, clinical global impression-improvement, or CGI-I, and mean weekly cataplexy attacks. The lower doses assessed, 6 g and 7.5 g also demonstrated a statistically significant and clinically meaningful improvement on all three co-primary endpoints compared to placebo. We observed the 9 g dose of once-nightly FT218 to be generally well tolerated. Adverse reactions commonly associated with sodium oxybate were observed in a small number of patients (nausea 1.3%, vomiting 5.2%, decreased appetite 2.6%, dizziness 5.2%, somnolence 3.9%, tremor 1.3% and enuresis 9%), and 3.9% of the patients who received 9 g of FT218 discontinued the trial due to adverse reactions.

In January 2018, the FDA granted FT218 Orphan Drug Designation, which makes the drug eligible for certain development and

commercial incentives, including potential U.S. market exclusivity for up to seven years. Additionally, several FT218-related U.S. patents have been issued, and there are additional patent applications currently in development and/or pending at the U.S. Patent and Trademark Office (“USPTO”), as well as foreign patent offices.

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

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

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

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standard of care for EDS and cataplexy in patients with narcolepsy, which are twice-nightly oxybate formulations. If approved, we believe FT218 has the potential to take a significant share of the oxybate market. The current market size for the twice-nightly administration of oxybate products is an estimated \$1.8 billion annually.

Micropump Drug-Delivery Technology

Our Micropump drug-delivery technology allows for the controlled delivery of small molecule drugs taken orally, which has the potential to improve dosing compliance, reduce toxicity and improve patient compliance. Beyond FT218, we believe there could be other product development opportunities for our Micropump drug-delivery technology, representing either life cycle opportunities, whereby additional intellectual property can be added to a pharmaceutical product to extend the commercial viability of a currently marketed product, or innovative formulation opportunities for new chemical entities.

Previously Approved FDA Products

On June 30, 2020, we announced the sale of our portfolio of sterile injectable drugs used in the hospital setting (the “Hospital Products”), including our three commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to Exela Sterile Medicines LLC (“Exela Buyer”). This sale included the following FDA approved products:

- **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery.
- **Vazculep (phenylephrine hydrochloride injection)** - Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- **Akovaz (ephedrine sulfate injection)** - Akovaz was the first FDA approved formulation of ephedrine sulfate, an alpha- and beta- adrenergic agonist and a norepinephrine-releasing agent that is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- **Nouress (cysteine hydrochloride injection)** - Nouress is a sterile injectable product for use in the hospital setting to provide parenteral nutrition to neonates.

Corporate Information

We are an Irish public limited company. Our registered address is at 10 Earlsfort Terrace, Dublin 2, Ireland and our phone number is +353-1-920-1000. We file annual, quarterly and current reports, proxy statements and other documents with the SEC under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). Our website is www.avadel.com, where we make available free of charge our reports (and any amendments thereto) on Forms 10-K, 10-Q and 8-K as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. These filings are also available to the public at www.sec.gov.

We currently have five direct wholly-owned subsidiaries: (a) Avadel US Holdings, Inc., (b) Flamel Ireland Limited is an Irish limited company, which conducts business under the name Avadel Ireland, (c) Avadel Investment Company Limited, (d) Avadel Finance Ireland Designated Activity Company and (e) Avadel France Holding SAS. Avadel US Holdings, Inc., a Delaware corporation, is the holding entity of (i) Avadel Specialty Pharmaceuticals, LLC, (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, and (iv) Avadel CNS Pharmaceuticals LLC. Avadel Finance Ireland Designated Activity Company is the holding entity of Avadel Finance Cayman Limited. Avadel France Holding SAS is the holding entity of Avadel Research SAS. A complete list of our subsidiaries can be found in Exhibit 21.1 of our Annual Report on Form 10-K filed with the SEC on March 9, 2021.

Key Business Trends and Highlights

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

- **Healthcare and Regulatory Reform:** Various health care reform laws in the U.S. may impact our ability to successfully commercialize our products and technologies. The success of our commercialization efforts may depend on the extent to which the government health administration authorities, the health insurance funds in the E.U. Member States, private health insurers and other third-party payers in the U.S. will reimburse consumers for the cost of healthcare products and services.
- **Competition and Technological Change:** Competition in the pharmaceutical and biotechnology industry continues to be intense and is expected to increase. We compete with academic laboratories, research institutions, universities, joint ventures, and other pharmaceutical and biotechnology companies, including other companies developing niche branded or generic specialty pharmaceutical products or drug delivery platforms. Furthermore, major technological changes can happen quickly in the pharmaceutical and biotechnology industries. Such rapid technological change, or the development by our competitors of technologically improved or differentiated products, could render our products, product candidates, or drug delivery platforms obsolete or noncompetitive.
- **Pricing Environment for Pharmaceuticals:** The pricing environment continues to be in the political spotlight in the U.S. As a result, the need to obtain and maintain appropriate pricing for pharmaceutical products may become more challenging due to, among other things, the attention being paid to healthcare cost containment and other austerity measures in the U.S. and worldwide.
- **Generics Playing a Larger Role in Healthcare:** Generic pharmaceutical products will continue to play a large role in the U.S. healthcare system. As such, we expect to see generic competition for our products in the future.
- **Access to and Cost of Capital:** The process of raising capital and associated cost of such capital for a company of our financial profile can be difficult and potentially expensive. If the need were to arise to raise additional capital, access to that capital may be difficult, expensive and/or dilutive and, as a result, could create liquidity challenges for the Company.
- **Net Loss from Operations in 2021:** We sold our Hospital Products at June 30, 2020 and no longer generate revenue from sales of these products. We will incur substantial expenses to further the clinical development of and continue our preparations for the commercial launch of FT218, if approved.

Impact of COVID-19

Since early 2020, we have seen the profound impact that the ongoing 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 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 impact of COVID-19 and measures to prevent its spread could impact our business in a number of ways,

including: i) possibly delaying any remaining development activities for FT218, the FDA review timeline of FT218, and/or our ongoing RESTORE open-label extension/switch study, ii) disruptions to our supply chain and third parties; and iii) requiring our employees to work from home for an extended period of time. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition. Despite progress in vaccination efforts, future developments and impact on our operations remain uncertain and cannot be predicted with confidence, including the duration of the COVID-19 pandemic, new strains of the virus, new information which may emerge concerning the severity of the COVID-19 pandemic, and any additional preventative and protective actions that governments, or we, may direct, which may result in extending continued business disruptions.

Financial Highlights

Highlights of our consolidated results for the three and six months ended June 30, 2021 are as follows:

- Revenue was \$0 for the three and six months ended June 30, 2021, compared to \$10,091 and \$22,334 in the same periods last year, respectively. The year over year decrease was the result of the sale of the Hospital Products on June 30, 2020.
- Operating loss was \$21,936 and \$36,747 for the three and six months ended June 30, 2021, respectively, compared to operating income of \$40,269 and \$33,772 and for the same periods last year, respectively. The operating income for the three and six months ended June 30, 2020 was driven by sale of the Hospital Products on June 30, 2020.
- Net loss was \$19,581 and \$33,026 for the three and six months ended June 30, 2021, respectively, compared to net income of \$30,874 and \$30,009 in the same period last year, respectively.
- Diluted net loss per share was \$(0.33) and \$(0.56) for the three and six months ended June 30, 2021, respectively, compared to diluted net income per share of \$0.49 and \$0.58 in the same period last year, respectively.
- Cash and marketable securities decreased \$18,559 to \$202,843 at June 30, 2021, from \$221,402 at December 31, 2020. This decrease was driven by \$33,566 of cash used in operations during the six months ended June 30, 2021, partially offset by \$16,500 of installment proceeds received from the disposition of the Hospital Products.

Critical Accounting Estimates

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

Our significant accounting policies are described in Note 1 of the audited consolidated financial statements included in our Annual Report Form 10-K for the year ended December 31, 2020 (the "2020 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 2020 Form 10-K.

Results of Operations

The following is a summary of our financial results (in thousands, except per share amounts) for the three months ended June 30, 2021 and 2020, respectively:

Comparative Statements of (Loss) Income	Three Months Ended June 30,		Three Months Ended Increase / (Decrease)	
	2021	2020	2021 vs. 2020	
	\$	\$	\$	%
Product sales	\$ —	\$ 10,091	\$ (10,091)	(100.0)%
Operating expenses:				
Cost of products	—	3,285	(3,285)	(100.0)%
Research and development expenses	6,762	4,057	2,705	66.7 %
Selling, general and administrative expenses	15,174	7,095	8,079	113.9 %
Intangible asset amortization	—	203	(203)	(100.0)%
Changes in fair value of contingent consideration	—	918	(918)	(100.0)%
Gain on sale of Hospital Products	—	(45,760)	45,760	100.0 %
Restructuring costs	—	24	(24)	(100.0)%
Total operating expense (income)	21,936	(30,178)	52,114	172.7 %
Operating (loss) income	(21,936)	40,269	(62,205)	(154.5)%
Investment and other income (expense), net	432	(741)	1,173	158.3 %
Interest expense	(1,930)	(3,237)	1,307	40.4 %
Gain from release of certain liabilities	88	—	88	100.0 %
Other expense - changes in fair value of contingent consideration payable	—	(125)	125	100.0 %
(Loss) income before income taxes	(23,346)	36,166	(59,512)	(164.6)%
Income tax (benefit) expense	(3,765)	5,292	(9,057)	(171.1)%
Net (loss) income	\$ (19,581)	\$ 30,874	\$ (50,455)	(163.4)%
Net (loss) income per share - diluted	\$ (0.33)	\$ 0.49	\$ (0.82)	(167.3)%

The following is a summary of our financial results (in thousands, except per share amounts) for the six months ended June 30, 2021 and 2020, respectively:

Comparative Statements of (Loss) Income	Six Months Ended June 30,		Six Months Ended Increase / (Decrease)	
	2021	2020	2021 vs. 2020	
			\$	%
Product sales	\$ —	\$ 22,334	\$ (22,334)	(100.0)%
Operating expenses:				
Cost of products	—	5,742	(5,742)	(100.0)%
Research and development expenses	10,614	9,587	1,027	10.7 %
Selling, general and administrative expenses	26,186	15,008	11,178	74.5 %
Intangible asset amortization	—	406	(406)	(100.0)%
Changes in fair value of contingent consideration	—	3,396	(3,396)	(100.0)%
Gain on sale of Hospital Products	—	(45,760)	45,760	100.0 %
Restructuring (income) costs	(53)	183	(236)	(129.0)%
Total operating expense (income)	36,747	(11,438)	48,185	421.3 %
Operating (loss) income	(36,747)	33,772	(70,519)	(208.8)%
Investment and other income (expense), net	1,042	(1,119)	2,161	193.1 %
Interest expense	(3,859)	(6,427)	2,568	40.0 %
Gain from release of certain liabilities	166	—	166	100.0 %
Other expense - changes in fair value of contingent consideration payable	—	(435)	435	100.0 %
(Loss) income before income taxes	(39,398)	25,791	(65,189)	(252.8)%
Income tax benefit	(6,372)	(4,218)	(2,154)	(51.1)%
Net (loss) income	\$ (33,026)	\$ 30,009	\$ (63,035)	(210.1)%
Net (loss) income per share - diluted	\$ (0.56)	\$ 0.58	\$ (1.14)	(196.6)%

On June 30, 2020 (“Closing Date”), we announced the sale of the Hospital Products, including our three commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, to the Exela Buyer. As a result of the sale, the Company no longer recorded revenue, cost of products, intangible amortization and changes to the fair value of the contingent consideration related to these products subsequent to the Closing Date.

Research and Development Expenses:	Three Months Ended June 30,		Three Months Ended Increase / (Decrease)	
	2021	2020	2021 vs. 2020	
			\$	%
Research and development expenses	\$ 6,762	\$ 4,057	\$ 2,705	66.7 %

Research and development expenses increased \$2,705 or 66.7% during the three months ended June 30, 2021 as compared to the same period in 2020. This increase was driven by increased pre-NDA approval activities, primarily the purchase of raw materials in preparation for product launch, if FT218 is approved.

Research and Development Expenses:	Six Months Ended June 30,		Six Months Ended Increase / (Decrease)	
	2021	2020	2021 vs. 2020	
			\$	%
Research and development expenses	\$ 10,614	\$ 9,587	\$ 1,027	10.7 %

Research and development expenses increased \$1,027 or 10.7% during the six months ended June 30, 2021 as compared to the same period in 2020. This increase was driven by higher pre-NDA approval activities, primarily the purchase of raw materials in preparation for product launch, if FT218 is approved, during the current period, partially offset by lower clinical studies expense due to the completion of the FT218 clinical study during the six months ended June 30, 2020.

Selling, General and Administrative Expenses:	Three Months Ended June 30,		Three Months Ended	
	2021	2020	Increase / (Decrease)	
			2021 vs. 2020	
	\$	\$	\$	%
Selling, general and administrative expenses	\$ 15,174	\$ 7,095	\$ 8,079	113.9 %

Selling, general and administrative (“SG&A”) expenses increased \$8,079 or 113.9% during the three months ended June 30, 2021 as compared to the same prior year period, driven by the Company’s continued commercial preparations and launch readiness activities for potential approval of FT218. These activities included an increase in marketing and market research costs of approximately \$3,000 and an increase in other launch planning and preparation activities totaling \$1,400. Compensation costs increased by approximately \$2,100 due to an increase in headcount, primarily in commercial and medical affairs, and legal and insurance costs increased by approximately \$1,400.

Selling, General and Administrative Expenses:	Six Months Ended June 30,		Six Months Ended	
	2021	2020	Increase / (Decrease)	
			2021 vs. 2020	
	\$	\$	\$	%
Selling, general and administrative expenses	\$ 26,186	\$ 15,008	\$ 11,178	74.5 %

SG&A expenses increased \$11,178 or 74.5% during the six months ended June 30, 2021 as compared to the same prior year period, driven by the Company’s continued commercial preparations and launch readiness activities for potential approval of FT18. These activities included an increase in marketing and market research activities of approximately \$3,800, and an increase in other launch planning and preparation activities totaling approximately \$2,300. Compensation costs increased by approximately \$3,200 due to an increase in headcount, primarily in commercial and medical affairs. Legal and insurance costs increased by approximately \$2,500, which was offset by a decrease in other professional fees of approximately \$400.

Investment and Other Income (Expense), net	Three Months Ended June 30,		Three Months Ended	
	2021	2020	Increase / (Decrease)	
			2021 vs. 2020	
	\$	\$	\$	%
Investment and other income (expense), net	\$ 432	\$ (741)	\$ 1,173	158.3 %

Investment and other income (expense), net increased for the three months ended June 30, 2021 when compared to the same period in the prior year driven by an \$800 legal settlement related to a bankruptcy claim recognized in the prior period and higher interest income of approximately \$400 in the current period.

Investment and Other Income (Expense), net	Six Months Ended June 30,		Six Months Ended	
	2021	2020	Increase / (Decrease)	
			2021 vs. 2020	
	\$	\$	\$	%
Investment and other income (expense), net	\$ 1,042	\$ (1,119)	\$ 2,161	193.1 %

Investment and other income (expense), net increased for the six months ended June 30, 2021 when compared to the same period in the prior year driven by an \$800 legal settlement related to a bankruptcy claim recognized in the prior period, higher interest income of approximately \$500, lower realized losses on our marketable securities of approximately \$500 and higher foreign currency gains of approximately \$400.

Interest Expense	Three Months Ended June 30,		Three Months Ended Increase / (Decrease)	
	2021	2020	2021 vs. 2020	
			\$	%
Interest expense	\$ 1,930	\$ 3,237	\$ (1,307)	(40.4)%

Interest expense of \$1,930 and \$3,237 for the three months ended June 30, 2021 and 2020, respectively, is related to interest on the 2023 Notes. Included in these amounts are coupon interest expense of \$1,617 for each period and the amortization of debt issuance costs of \$313 and \$250 for the three months ended June 30, 2021 and 2020, respectively. Prior period interest expense also included amortization of a debt discount of \$1,370, which was eliminated upon our adoption of ASU 2020-06. See *Note 9: 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	Six Months Ended June 30,		Six Months Ended Increase / (Decrease)	
	2021	2020	2021 vs. 2020	
			\$	%
Interest expense	\$ 3,859	\$ 6,427	\$ (2,568)	(40.0)%

Interest expense of \$3,859 and \$6,427 for the six months ended June 30, 2021 and 2020, respectively, is related to interest on the 2023 Notes. Included in these amounts are coupon interest expense of \$3,234 for each period and the amortization of debt issuance costs of \$625 and \$495 for the six months ended June 30, 2021 and 2020, respectively. Prior period interest expense also included amortization of a debt discount of \$2,698, which was eliminated upon our adoption of ASU 2020-06. See *Note 9: 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 (Benefit) Provision:	Three Months Ended June 30,		Three Months Ended Increase / (Decrease)	
	2021	2020	2021 vs. 2020	
			\$	%
Income tax (benefit) provision	\$ (3,765)	\$ 5,292	\$ (9,057)	(171.1)%
Percentage of (loss) income before income taxes	16.1 %	14.6 %		

The income tax benefit was \$3,765 for the three months ended June 30, 2021 resulting in an effective tax rate of 16.1%. The income tax provision was \$5,292 for the three months ended June 30, 2020 resulting in an effective tax rate of 14.6%. The income tax expense recorded in 2020 was the result of taxes recorded on the gain from the sale of the Hospital Products.

Income Tax (Benefit) Provision:	Six Months Ended June 30,		Six Months Ended Increase / (Decrease)	
	2021	2020	2021 vs. 2020	
			\$	%
Income tax (benefit) provision	\$ (6,372)	\$ (4,218)	\$ (2,154)	(51.1)%
Percentage of (loss) income before income taxes	16.2 %	(16.4)%		

The income tax benefit was \$6,372 for the six months ended June 30, 2021 resulting in an effective tax rate of 16.2%. The income tax benefit was \$4,218 for the six months ended June 30, 2020 resulting in an effective tax rate of (16.4)%. The net increase in the effective income tax rate for the six months ended June 30, 2021 as compared to the prior period in 2020 is primarily due to the discrete tax benefits recognized during the six months ended June 30, 2020 under the Coronavirus Aid, Relief and Economic Security Act, also known as the CARES Act, which did not occur during the six months ended June 30, 2021.

Liquidity and Capital Resources

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

Net cash (used in) provided by:	Six Months Ended June 30,		Six Months Ended Increase / (Decrease)	
			2021 vs. 2020	
	2021	2020	\$	%
Operating activities	\$ (33,566)	\$ (19,417)	\$ (14,149)	(72.9)%
Investing activities	29,315	(67,662)	96,977	143.3 %
Financing activities	149	179,516	(179,367)	(99.9)%

Operating Activities

Net cash used in operating activities was \$33,566 and \$19,417 for the six months ended June 30, 2021 and 2020, respectively. Net cash used in operating activities for the six months ended June 30, 2021 was driven by net loss for the period and higher prepaid expenses due to the payment of annual insurance premiums, partially offset by cash received during the period related to research and development tax credits. Net cash used in operating activities for the six months ended June 30, 2020 was due to lower accounts payable, accrued expenses and other liabilities, and cash paid related to the earn-out and royalty payments for contingent consideration.

Investing Activities

Net cash provided by investing activities was \$29,315 for the six months ended June 30, 2021 and cash used in investing activities was \$67,662 for the six months ended June 30, 2020. Net cash provided by investing activities for the six months ended June 30, 2021 was driven by proceeds from the disposition of the Hospital Products of \$16,500, as well as higher net proceeds received from the excess of sales over purchases of marketable securities of \$12,841. Net cash used in investing activities for the six months ended June 30, 2020 was driven by higher net purchases of marketable securities of \$82,162, partially offset by the proceeds from the disposition of the Hospital Products of \$14,500.

Financing Activities

Net cash provided by financing activities for the six months ended June 30, 2021 was \$149 related to proceeds from stock option exercises and employee stock purchase plan ("ESPP") issuances. Net cash provided by financing activities for the six months ended June 30, 2020 of \$179,516 is driven by the February 2020 private placement and May 2020 public offering that resulted in net proceeds of \$60,639 and \$116,974, respectively, as well as stock option exercises and ESPP issuances of \$1,903.

Liquidity and Risk Management

The adequacy of our cash resources depends on the outcome of certain business conditions including the cost of our FT218 clinical development plan, our cost structure, and other factors set forth in "Risk Factors" within Part I, Item 1A of the 2020 Form 10-K. To complete the FT218 clinical development and commercialization plan 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 impact of COVID-19, which may have a material adverse impact on our business.

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

Cash, cash equivalent and marketable security balances as of June 30, 2021 and unused financing sources are expected to provide us with the flexibility to meet our liquidity needs in 2021, including its operating requirements related to the development of FT218.

Other Matters

Litigation

The Company is 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. The Company accrues for potential liabilities when it is probable that future costs (including legal fees and expenses) will be incurred and such costs can be reasonably estimated. At June 30, 2021 and December 31, 2020, 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 unaudited condensed consolidated financial position, results of operations, cash flows or liquidity.

On May 12, 2021, Jazz Pharmaceuticals, Inc. ("Jazz") filed a formal complaint (the "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 Complaint, Jazz alleges the sodium oxybate product ("Proposed Product") described in the New Drug Application ("NDA") owned by Avadel CNS Pharmaceuticals, LLC will infringe at least one claim of US Patent No. 8731963, 10758488, 10813885, 10959956 and/or 10966931 (collectively, the "patents-in-suit"). The 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 Complaint. The Avadel Answer generally denies the allegations set forth in the 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, ii) a declaratory judgment of invalidity of each patent-in-suit, and iii) a declaratory judgment requiring delisting of US Patent No. 8731963 from FDA's Orange Book.

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 preliminary injunction hearing date of November 23, 2021 (only relevant in the event that Jazz files a motion for a preliminary injunction by October 22, 2021), ii) a claim construction hearing date of August 2, 2022, and iii) a trial date of October 30, 2023.

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

Material Commitments and Contractual Obligations

Disclosures regarding material commitments and contractual obligations are included in Part II, Item 7 of the Company's 2020 Annual Report on Form 10-K and updated in *Note 16: Commitments and Contingencies* to the Company's 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

The Company is subject to interest rate risk as a result of its portfolio of marketable securities. The primary objectives of our investment policy are as follows: safety and preservation of principal and diversification of risk; liquidity of investments

sufficient to meet cash flow requirements; and competitive yield. Although our investments are subject to market risk, our investment policy specifies credit quality standards for our investments and limits the amount of credit exposure from any single issue, issuer or certain types of investment. Our investment policy allows us to maintain a portfolio of cash equivalents and marketable securities in a variety of instruments, including U.S. federal government and federal agency securities, European Government bonds, corporate bonds or commercial paper issued by U.S. or European corporations, money market instruments, certain qualifying money market mutual funds, certain repurchase agreements, tax-exempt obligations of states, agencies, and municipalities in the U.S and Europe, and equities. A hypothetical 50 basis point change in interest rates would not result in a material decrease or increase in the fair value of our securities due to the general short-term nature of our investment portfolio.

ITEM 4. CONTROLS AND PROCEDURES.

Management of the Company, with the participation of its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of the Company's disclosure controls and procedures as of June 30, 2021, 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 Form 10-Q, the Company's Chief Executive Officer and Chief Financial Officer have concluded that the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended) were effective as of June 30, 2021.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by paragraph (d) of Exchange Act Rule 13a-15 or 15d-15 that occurred during the three months ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

The information contained in *Note 16: Commitments and Contingencies* to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this Report 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, 2020 filed with the SEC on March 9, 2021.

Our product candidate and future product candidates, if approved by the FDA, may not obtain desired regulatory exclusivities, including orphan drug exclusivity.

Under the Orphan Drug Act, as amended, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 where there is no reasonable expectation that the cost of developing the drug for the rare disease or condition will be recovered from sales of the drug in the United States. Generally, if a drug with orphan drug designation subsequently receives the first marketing approval for the disease or condition for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the FDA from approving another marketing application for the same drug for the same disease or condition for seven years, except in limited circumstances, such as if the FDA concludes that a subsequent same drug is clinically superior through greater safety, greater effectiveness, or a major contribution to patient care. A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan designation.

Although our lead product candidate, FT218, obtained orphan drug designation for the treatment of narcolepsy from the FDA in January 2018, there is no guarantee that we will obtain approval or orphan drug exclusivity for FT218. Orphan drug designation does not give a product candidate any advantage in, or shorten the timeline for, the FDA regulatory review and approval process. In addition, because FT218 would not be the first sodium oxybate product to be approved for the treatment of

narcolepsy, we must demonstrate that FT218 is clinically superior to any previously approved same drug in order to obtain orphan drug exclusivity for FT218, and we may be required to demonstrate clinical superiority for the approval and exclusivity of other product candidates in the future. Even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition. Moreover, any orphan drug exclusive marketing rights may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantity of the drug to meet the needs of patients with the particular rare disease or condition.

Third parties may claim that our product candidate or future product candidates infringe their rights, and we may incur significant costs resolving these claims. Additionally, legal proceedings related to such claims could materially delay or otherwise adversely affect commercialization plans related to our product candidate, if approved.

Third parties may claim infringement of their patents and other intellectual property rights by the manufacture, use, import, offer for sale or sale of our drug delivery technologies or our other products. For example, in connection with us seeking regulatory approval for a product candidate, a third party may allege that our product candidate infringes its patents or other intellectual property rights and file suit to delay/prevent regulatory approval and/or commercialization of such product.

In May 2021, Jazz Pharmaceuticals filed a complaint against us and certain of our subsidiaries in the United States District Court for the District of Delaware alleging infringement of certain of its patents.

In response to any claim of infringement, we may choose or be forced to seek licenses, defend infringement actions or challenge the validity or enforceability of those patent rights in court or administrative proceedings. If we cannot obtain required licenses on commercially reasonable terms, or at all, are found liable for infringement or are not able to have such patent rights declared invalid or unenforceable, our business could be materially harmed. We may be subject to claims (and even held liable) for significant monetary damages (including enhanced damages and/or attorneys' fees), encounter significant delays in bringing products to market or be precluded from the manufacture, use, import, offer for sale or sale of products or methods of drug delivery covered by the patents of others. Even if a license is available, it may not be available on commercially reasonable terms or may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. We may not have identified, or be able to identify in the future, U.S. or non-U.S. patents that pose a risk of potential infringement claims.

In addition to the possibility of intellectual property infringement claims, a third party could submit a citizen petition to the FDA requesting relief that, if granted, could materially adversely affect the NDA and/or underlying product candidate. For example, such a third-party petition could, if granted, materially adversely affect the likelihood and/or timing of NDA approval, content of final product labeling, and/or resulting regulatory exclusivity (if any) for such product.

Parties making claims against us may be able to sustain the costs of patent litigation more effectively than we can because they have substantially greater resources. In addition, any claims, with or without merit, that our product candidate, future product candidates or drug delivery technologies infringe proprietary rights of third parties could be time-consuming, result in costly litigation or divert the efforts of our technical and management personnel, any of which could disrupt our relationships with our partners and could significantly harm our financial positions and operating results.

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

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit No.	Description
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) and Rule 15d-14(a) promulgated under the Exchange Act
32.1**	Certification of the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.*) (filed herewith)

* Filed herewith.

** Furnished herewith.

+ Indicates 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: August 9, 2021

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

Date: August 9, 2021

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

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

I, Gregory J. Divis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 9, 2021

/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: August 9, 2021

/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 June 30, 2021 (the "Report"), the undersigned hereby certifies in his capacity as Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

Date: August 9, 2021

/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 June 30, 2021 (the "Report"), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

Date: August 9, 2021

/s/ Thomas S. McHugh

Thomas S. McHugh

Senior Vice President and Chief Financial Officer