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

FORM 10-Q

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

For the quarterly period ended: September 30, 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	**000-28508**	**98-1341933**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

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

+353-1-901-5201
(Registrant's telephone number, including area code)

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

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

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

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

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

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

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

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

Large accelerated filer	☐	Accelerated filer	☑
Non-accelerated	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☑

At November 4, 2021, 58,620,088 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 single manufacturer for the manufacturing of our lead product candidate and a single supplier for certain raw materials in our lead product candidate and any failure of such third party suppliers to either manufacture our product candidate in a timely manner or 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Product sales	$ —	$ —	$ —	$ 22,334
Operating expenses:				
Cost of products	—	—	—	5,742
Research and development expenses	4,380	5,569	14,994	15,156
Selling, general and administrative expenses	21,283	8,423	47,469	23,431
Intangible asset amortization	—	—	—	406
Changes in fair value of contingent consideration	—	(69)	—	3,327
Gain on sale of Hospital Products	—	—	—	(45,760)
Restructuring income	—	(226)	(53)	(43)
Total operating expense	25,663	13,697	62,410	2,259
Operating (loss) income	(25,663)	(13,697)	(62,410)	20,075
Investment and other income (expense), net	489	213	1,531	(906)
Interest expense	(1,929)	(3,259)	(5,788)	(9,686)
Gain from release of certain liabilities	—	—	166	—
Other expense - changes in fair value of contingent consideration payable	—	—	—	(435)
(Loss) income before income taxes	(27,103)	(16,743)	(66,501)	9,048
Income tax benefit	(5,101)	(5,040)	(11,473)	(9,258)
Net (loss) income	$ (22,002)	$ (11,703)	$ (55,028)	$ 18,306
Net (loss) income per share - basic	$ (0.38)	$ (0.20)	$ (0.94)	$ 0.36
Net (loss) income per share - diluted	(0.38)	(0.20)	(0.94)	0.35
Weighted average number of shares outstanding - basic	58,585	58,213	58,506	51,206
Weighted average number of shares outstanding - diluted	58,585	58,213	58,506	52,849

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net (loss) income	$ (22,002)	$ (11,703)	$ (55,028)	$ 18,306
Other comprehensive (loss) income, net of tax:				
Foreign currency translation (loss) income	(237)	534	(839)	539
Net other comprehensive (loss) income, net of income tax (benefit) provision of $(59), $1, $(220) and $131, respectively	(157)	66	(854)	349
Total other comprehensive (loss) income, net of tax	(394)	600	(1,693)	888
Total comprehensive (loss) income	$ (22,396)	$ (11,103)	$ (56,721)	$ 19,194

See accompanying notes to unaudited condensed consolidated financial statements.

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

	September 30, 2021	December 31, 2020
	(unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 58,169	$ 71,722
Marketable securities	122,924	149,680
Research and development tax credit receivable	2,493	3,326
Prepaid expenses and other current assets	22,234	38,726
Total current assets	205,820	263,454
Property and equipment, net	304	359
Operating lease right-of-use assets	2,070	2,604
Goodwill	16,836	16,836
Research and development tax credit receivable	961	3,445
Other non-current assets	38,098	24,939
Total assets	$ 264,089	$ 311,637
LIABILITIES AND SHAREHOLDERS' EQUITY		
Current liabilities:		
Current portion of operating lease liability	$ 504	$ 474
Accounts payable	6,874	2,934
Accrued expenses	8,738	6,501
Other current liabilities	1,471	5,200
Total current liabilities	17,587	15,109
Long-term debt	142,086	128,210
Long-term operating lease liability	1,460	1,840
Other non-current liabilities	3,999	4,212
Total liabilities	165,132	149,371
Shareholders' equity:		
Preferred shares, nominal value of $0.01 per share; 50,000 shares authorized; 488 issued and outstanding at September 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; 58,616 issued and outstanding at September 30, 2021 and 58,396 issued and outstanding at December 31, 2020	586	583
Additional paid-in capital	546,565	566,916
Accumulated deficit	(425,455)	(384,187)
Accumulated other comprehensive loss	(22,744)	(21,051)
Total shareholders' equity	98,957	162,266
Total liabilities and shareholders' equity	$ 264,089	$ 311,637

See accompanying notes to unaudited condensed consolidated financial statements.

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

Nine Months Ended September 30, 2021

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

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

Nine Months Ended September 30, 2020

	Ordinary shares		Preferred shares		Additional paid-in	Accumulated	Accumulated other comprehensive	Treasury shares		Total shareholders' (deficit)
	Shares	Amount	Shares	Amount	capital	deficit	loss	Shares	Amount	equity
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
Net loss	—	—	—	—	—	(11,703)	—	—	—	(11,703)
Other comprehensive income	—	—	—	—	—	—	600	—	—	600
Exercise of Stock Options	22	—	—	—	47	—	—	—	—	47
February 2020 private placement	—	—	—	—	(69)	—	—	—	—	(69)
May 2020 public offering	—	—	—	—	(50)	—	—	—	—	(50)
Vesting of restricted shares	82	1	—	—	(1)	—	—	—	—	—
Employee share purchase plan share issuance	9	—	—	—	56	—	—	—	—	56
Stock-based compensation expense	—	—	—	—	194	—	—	—	—	194
Retirement of treasury shares	(5,407)	(54)	—	—	(49,944)	—	—	(5,407)	49,998	—
Balance, September 30, 2020	58,243	$ 582	488	$ 5	$ 565,440	$ (372,909)	$ (21,918)	—	$ —	$ 171,200

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net (loss) income	$ (55,028)	$ 18,306
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	614	1,297
Remeasurement of acquisition-related contingent consideration	—	3,327
Remeasurement of financing-related contingent consideration	—	435
Amortization of debt discount and debt issuance costs	937	4,835
Change in deferred taxes	(11,322)	(4,582)
Stock-based compensation expense	6,088	1,705
Gain from the disposition of the hospital products	—	(45,760)
Gain from the release of certain liabilities	(166)	—
Other adjustments	1,056	306
Net changes in assets and liabilities		
Accounts receivable	—	8,281
Inventories	—	(1,352)
Prepaid expenses and other current assets	(54)	1,759
Research and development tax credit receivable	3,079	2,036
Accounts payable & other current liabilities	(201)	(4,051)
Accrued expenses	2,421	(6,625)
Earn-out payments for contingent consideration in excess of acquisition-date fair value	—	(5,323)
Royalty payments for contingent consideration payable in excess of original fair value	—	(866)
Other assets and liabilities	(2,228)	(3,337)
Net cash used in operating activities	(54,804)	(29,609)
Cash flows from investing activities:		
Purchases of property and equipment	(26)	(33)
Proceeds from the disposition of the hospital products	16,500	17,250
Proceeds from sales of marketable securities	83,726	30,075
Purchases of marketable securities	(58,591)	(124,254)
Net cash provided by (used in) investing activities	41,609	(76,962)
Cash flows from financing activities:		
Proceeds from the February 2020 private placement	—	60,570
Proceeds from the May 2020 public offering	—	116,924
Proceeds from stock option exercises and employee stock purchase plan	263	2,006
Net cash provided by financing activities	263	179,500
Effect of foreign currency exchange rate changes on cash and cash equivalents	(621)	406
Net change in cash and cash equivalents	(13,553)	73,335
Cash and cash equivalents at January 1,	71,722	9,774
Cash and cash equivalents at September 30,	$ 58,169	$ 83,109
Supplemental disclosures of cash flow information:		
Interest paid	$ 6,469	$ 6,469
Income taxes paid (refund)	$ 68	$ (1,788)

See accompanying notes to unaudited condensed consolidated financial statements

NOTE 1: Summary of Significant Accounting Policies

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

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. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date.

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

Basis of Presentation. The unaudited condensed consolidated balance sheet as of September 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.

Reclassifications

Certain reclassifications are made to prior year amounts whenever necessary to conform with the current year presentation. Certain adjustments have been made to the balances within *Note 11: Other Assets and Liabilities* for the year ended December 31, 2020 to condense line items of the same nature into a single line.

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 June 30, 2020 (the "Closing Date"), we announced the sale of our portfolio of sterile injectable drugs used in the hospital setting ("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 "Transaction").

Pursuant to the Asset 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. We collected the remaining six installment payments, totaling $16,500, during 2021. 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 income (loss) for the nine months ended September 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 Income (Loss)			
	Nine Months Ended September 30, 2020			
	As Reported	Pro Forma Adjustments	Notes	Pro Forma
Product sales	$ 22,334	$ (22,175)	(a)	$ 159
Total operating expense	2,259	(8,489)	(b)	(6,230)
Operating income (loss)	20,075	(13,686)		6,389
Income (loss) before income taxes	$ 9,048	$ (13,251)	(c)	$ (4,203)

Adjustments to the pro forma unaudited condensed combined statements of income (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 $809.
- Intangible asset amortization on acquired development technology for Vazculep of $406.
- Changes in fair value of related party contingent consideration of $3,327. 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.

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 deferred contract costs at September 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 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:

	As of September 30, 2021			As of December 31, 2020		
Fair Value Measurements:	**Level 1**	**Level 2**	**Level 3**	**Level 1**	**Level 2**	**Level 3**
Marketable securities (see *Note 6*)						
Mutual and money market funds	$ 88,568	$ —	$ —	$ 104,672	$ —	$ —
Corporate bonds	—	19,071	—	—	22,155	—
Government securities - U.S.	—	13,462	—	—	18,999	—
Other fixed-income securities	—	1,823	—	—	3,854	—
Total assets	$ 88,568	$ 34,356	$ —	$ 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 September 30, 2021 and December 31, 2020, respectively, there were no transfers in and out of Level 1, 2, or 3. During the three and nine months ended September 30, 2021 and 2020, respectively, we did not recognize any allowances for credit losses.

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

Debt

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 September 30, 2021 is $166,570.

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 September 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 September 30, 2021 and December 31, 2020, respectively:

	September 30, 2021			
Marketable Securities:	**Adjusted Cost**	**Unrealized Gains**	**Unrealized Losses**	**Fair Value**
Mutual and money market funds	$ 87,965	$ 1,083	$ (480)	$ 88,568
Corporate bonds	18,935	168	(32)	19,071
Government securities - U.S.	13,503	64	(105)	13,462
Other fixed-income securities	1,818	7	(2)	1,823
Total	$ 122,221	$ 1,322	$ (619)	$ 122,924

	December 31, 2020			
Marketable Securities:	**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 $22 and $136 for the three months ended September 30, 2021 and 2020, respectively. These realized gains were offset by realized losses of $66 and $8 for the three months ended September 30, 2021 and 2020, respectively. We recognized gross realized gains of $74 and $426 for the nine months ended September 30, 2021 and 2020, respectively. These realized gains were offset by realized losses of $173 and $886 for the nine months ended September 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 September 30, 2021:

	Maturities				
Marketable Debt Securities:	**Less than 1 Year**	**1-5 Years**	**5-10 Years**	**Greater than 10 Years**	**Total**
Corporate bonds	$ 4,733	$ 14,012	$ 326	$ —	$ 19,071
Government securities - U.S.	369	10,915	884	1,294	13,462
Other fixed-income securities	—	1,170	653	—	1,823
Total	$ 5,102	$ 26,097	$ 1,863	$ 1,294	$ 34,356

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 September 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 goodwill is $16,836 at September 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 $406 for the nine months ended September 30, 2020. Refer to *Note 3: Disposition of the Hospital Products*. There was no amortization expense recorded during the three and nine months ended September 30, 2021 and the three months ended September 30, 2020.

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 September 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 nine-month period ended September 30, 2020:

Contingent Consideration Payable Rollforward:	**Balance**
Balance, December 31, 2019	$ 17,327
Payments of contingent consideration	(6,189)
Fair value adjustments [(1)]	3,762
Disposition of the Hospital Products	(14,900)
Balance, September 30, 2020	$ —

[(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:

	September 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	(1,664)	(15,540)
Net carrying amount of liability component	142,086	128,210
Less: current maturities	—	—
Long-term debt	$ 142,086	$ 128,210
Equity component:		
Equity component of exchangeable notes, net of issuance costs	$ —	$ (26,699)

For the three months ended September 30, 2021 and 2020, the total interest expense was $1,929 and $3,259, respectively, with coupon interest expense of $1,617 for each period and the amortization of debt issuance costs and debt discount of $312 and $1,642, respectively.

For the nine months ended September 30, 2021 and 2020, the total interest expense was $5,788 and $9,686, respectively, with coupon interest expense of $4,851 for each period and the amortization of debt issuance costs and debt discount of $937 and $4,835, 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 and an indirect wholly-owned subsidiary of the Company (the "Issuer"), 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 $5,101 for the three months ended September 30, 2021 resulting in an effective tax rate of 18.8%. The income tax benefit was $5,040 for the three months ended September 30, 2020 resulting in an effective tax rate of 30.1%. The decrease in the effective tax rate for the three months ended September 30, 2021, when compared to the same period in 2020, is primarily attributable to a change in the mix of losses in our foreign entities.

The income tax benefit was $11,473 for the nine months ended September 30, 2021 resulting in an effective tax rate of 17.3%. The income tax benefit was $9,258 for the nine months ended September 30, 2020 resulting in an effective tax rate of (102.3)%. The net increase in the effective income tax rate for the nine months ended September 30, 2021 as compared to the prior period in 2020 is primarily due to the discrete tax benefits recognized during the nine months ended September 30, 2020 under the Coronavirus Aid, Relief and Economic Security Act, also known as the CARES Act, which did not occur during the nine months ended September 30, 2021.

NOTE 11: Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	**September 30, 2021**	**December 31, 2020**
Income tax receivable	$ 18,789	$ 18,615
Prepaid and other expenses	2,787	1,018
Other	382	798
Guarantee from Armistice	276	318
Short-term deposit	—	1,477
Receivable from Exela (see *Note 3*)	—	16,500
Total	$ 22,234	$ 38,726

Other Non-Current Assets:	September 30, 2021	December 31, 2020
Deferred tax assets	$ 29,798	$ 18,256
Right of use assets at contract manufacturing organizations	7,071	5,201
Guarantee from Armistice	841	1,050
Other	388	432
Total	$ 38,098	$ 24,939

Accrued Expenses	September 30, 2021	December 31, 2020
Accrued professional fees	$ 4,661	$ 2,781
Accrued compensation	2,403	1,697
Accrued outsource contract costs	909	473
Customer allowances	722	1,030
Accrued restructuring (see *Note 12*)	43	520
Total	$ 8,738	$ 6,501

Other Current Liabilities:	September 30, 2021	December 31, 2020
Accrued interest	$ 1,078	$ 2,695
Guarantee to Deerfield	277	319
Other	116	160
Due to Exela	—	2,026
Total	$ 1,471	$ 5,200

Other Non-Current Liabilities:	September 30, 2021	December 31, 2020
Tax liabilities and other	$ 3,155	$ 3,159
Guarantee to Deerfield	844	1,053
Total	$ 3,999	$ 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 nine months ended September 30, 2021 and 2020 were immaterial.

The following table sets forth activities for the Company's cost reduction plan obligations as of September 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	(76)
Foreign currency impact	(7)
Balance of restructuring accrual at September 30,	$ 43

The 2019 French Restructuring liabilities of $43 are included in the unaudited condensed consolidated balance sheet in accrued expenses at September 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 was 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 three and nine months ended September 30, 2021 and 2020 were immaterial.

During 2021, the Company paid $272 for its cost reduction plan obligations and has no remaining obligation for the 2019 Corporate Restructuring plan as of September 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Net (Loss) Income Per Share:	**2021**	**2020**	**2021**	**2020**
Net (loss) income	$ (22,002)	$ (11,703)	$ (55,028)	$ 18,306
Weighted average shares:				
Basic shares	58,585	58,213	58,506	51,206
Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes	—	—	—	1,643
Diluted shares	58,585	58,213	58,506	52,849
Net (loss) income per share - basic	$ (0.38)	$ (0.20)	$ (0.94)	$ 0.36
Net (loss) income per share - diluted	$ (0.38)	$ (0.20)	$ (0.94)	$ 0.35

Potential ordinary shares of 15,684 and 15,969 were excluded from the calculation of weighted average shares for the three months ended September 30, 2021 and 2020, respectively, and potential ordinary shares of 15,497 and 15,789 were excluded from the calculation of weighted average shares for the nine months ended September 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 nine months ended September 30, 2021 and for the three months ended September 30, 2020, 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 nine months ended September 30, 2021 and 2020, respectively, net of tax effects:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Accumulated Other Comprehensive Loss:	**2021**	**2020**	**2021**	**2020**
Foreign currency translation adjustment:				
Beginning balance	$ (23,229)	$ (23,733)	$ (22,627)	$ (23,738)
Net other comprehensive (loss) income	(237)	534	(839)	539
Balance at September 30,	$ (23,466)	$ (23,199)	$ (23,466)	$ (23,199)
Unrealized gain on marketable debt securities, net				
Beginning balance	$ 879	$ 1,215	$ 1,576	$ 932
Net other comprehensive (loss) income, net of income tax (benefit) provision of $(59), $1 $(220) and $131, respectively	(157)	66	(854)	349
Balance at September 30,	$ 722	$ 1,281	$ 722	$ 1,281
Accumulated other comprehensive loss at September 30,	$ (22,744)	$ (21,918)	$ (22,744)	$ (21,918)

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 for the nine months ended September 30, 2020. The Company had no revenue during the three and nine months ended September 30, 2021 and the three months ended September 30, 2020:

	Nine Months Ended September 30,
Product Sales by Product:	**2020**
Bloxiverz	$ 2,201
Vazculep	10,429
Akovaz	9,545
Other	159
Total product sales	$ 22,334

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 September 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.

First Complaint

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

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

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

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

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

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

Second Complaint

On August 4, 2021, Jazz filed another formal complaint (the "Second Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Second Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS 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.

On October 22, 2021, the Court issued an oral order stating that this case should proceed on the same schedule as the case filed on May 12, 2021.

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 $1,121 at September 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 $1,117 at September 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 September 30, 2021, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

NOTE 17: Subsequent Events

On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date.

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. In February 2021, the NDA for FT218 was accepted by the FDA and was assigned a Prescription Drug User Fee Act ("PDUFA") target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date.

Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio. As of September 30, 2021, we do not have any approved or 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 and assigned PDUFA target action date of October 15, 2021. On October 15, 2021, we announced that the FDA informed us that the review of our NDA for FT218 was ongoing beyond its previously assigned target action date.

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 who received at least one dose of FT218 or placebo, 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. In August, the primary results from the REST-ON trial were published by Kushida et al. in the journal SLEEP. New data was presented at the American College of Chest Physicians annual meeting, beginning October 17, 2021, including additional post-hoc analyses from the REST-ON trial, demonstrating a greater proportion of patients receiving FT218 experienced reductions in weekly cataplexy attacks and improvement in mean sleep latency compared to placebo, as well as the results of a discrete choice experiment, indicating that the overall driver of patient preference between sodium oxybate treatments is a once-nightly, versus twice-nightly, formulation.

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standards 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 ("Closing Date"), 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. 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; iii) requiring our employees to work from home for an extended period of time; and iv) hindering sales efforts for FT218, if approved. 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 nine months ended September 30, 2021 are as follows:

- Revenue was $0 for the three and nine months ended September 30, 2021, compared to $0 and $22,334 in the same periods last year, respectively. The year over year decrease for the comparative nine month periods was the result of the sale of the Hospital Products on June 30, 2020.
- Operating loss was $25,663 and $62,410 for the three and nine months ended September 30, 2021, respectively, compared to operating loss of $13,697 for the three months ended September 30, 2020 and operating income of $20,075 and for the nine months ended September 30, 2020. Operating income for the nine months ended September 30, 2020 was driven by the sale of the Hospital Products on June 30, 2020.
- Net loss was $22,002 and $55,028 for the three and nine months ended September 30, 2021, respectively, compared to net loss of $11,703 and net income of $18,306 in the same period last year, respectively.
- Diluted net loss per share was $(0.38) and $(0.94) for the three and nine months ended September 30, 2021, respectively, compared to diluted net loss per share of $(0.20) and diluted net income per share of $0.35 in the same period last year, respectively.
- Cash and marketable securities decreased $40,309 to $181,093 at September 30, 2021, from $221,402 at December 31, 2020. The decrease in cash was driven primarily by cash used for operating expenses of approximately $50,000, approximately $6,470 of interest payments, and approximately $2,850 for the purchase of raw materials used for FT218 pre-NDA approval activities. Cash spend was offset by $14,500 of net cash received from Exela and approximately $4,500 related to research and development tax credits and other refunds.

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 September 30, 2021 and 2020, respectively:

	Three Months Ended September 30,		Change 2021 vs. 2020	
Comparative Statements of Loss	**2021**	**2020**	**$**	**%**
Operating expenses:				
Research and development expenses	4,380	5,569	(1,189)	(21.4)%
Selling, general and administrative expenses	21,283	8,423	12,860	152.7 %
Changes in fair value of contingent consideration	—	(69)	69	100.0 %
Restructuring income	—	(226)	226	100.0 %
Total operating expense	25,663	13,697	11,966	87.4 %
Operating loss	(25,663)	(13,697)	(11,966)	(87.4)%
Investment and other income (expense), net	489	213	276	129.6 %
Interest expense	(1,929)	(3,259)	1,330	40.8 %
Loss before income taxes	(27,103)	(16,743)	(10,360)	(61.9)%
Income tax benefit	(5,101)	(5,040)	(61)	(1.2)%
Net loss	$ (22,002)	$ (11,703)	$ (10,299)	(88.0)%
Net loss per share - diluted	$ (0.38)	$ (0.20)	$ (0.18)	(90.0)%

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

	Nine Months Ended September 30,		Change 2021 vs. 2020	
Comparative Statements of (Loss) Income	**2021**	**2020**	**$**	**%**
Product sales	$ —	$ 22,334	$ (22,334)	(100.0)%
Operating expenses:				
Cost of products	—	5,742	(5,742)	(100.0)%
Research and development expenses	14,994	15,156	(162)	(1.1)%
Selling, general and administrative expenses	47,469	23,431	24,038	102.6 %
Intangible asset amortization	—	406	(406)	(100.0)%
Changes in fair value of contingent consideration	—	3,327	(3,327)	(100.0)%
Gain on sale of Hospital Products	—	(45,760)	45,760	100.0 %
Restructuring income	(53)	(43)	(10)	(23.3)%
Total operating expense	62,410	2,259	60,151	2,662.7 %
Operating (loss) income	(62,410)	20,075	(82,485)	(410.9)%
Investment and other income (expense), net	1,531	(906)	2,437	269.0 %
Interest expense	(5,788)	(9,686)	3,898	40.2 %
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	(66,501)	9,048	(75,549)	(835.0)%
Income tax benefit	(11,473)	(9,258)	(2,215)	(23.9)%
Net (loss) income	$ (55,028)	$ 18,306	$ (73,334)	(400.6)%
Net (loss) income per share - diluted	$ (0.94)	$ 0.35	$ (1.29)	(368.6)%

On June 30, 2020, 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.

	Three Months Ended September 30,		Change 2021 vs. 2020	
Research and Development Expenses:	**2021**	**2020**	**$**	**%**
Research and development expenses	$ 4,380	$ 5,569	$ (1,189)	(21.4)%

Research and development expenses decreased $1,189 or 21.4% during the three months ended September 30, 2021 as compared to the same period in 2020. This decrease was driven by lower clinical studies expense as well as lower purchases of active pharmaceutical ingredients used in the research and development of FT218 during the current period when compared to the prior comparable period.

	Nine Months Ended September 30,		Change 2021 vs. 2020	
Research and Development Expenses:	**2021**	**2020**	**$**	**%**
Research and development expenses	$ 14,994	$ 15,156	$ (162)	(1.1)%

Research and development expenses decreased $162 or 1.1% during the nine months ended September 30, 2021 as compared to the same period in 2020. This decrease was driven by lower clinical studies expense due to the completion of the FT218 clinical study during the nine months ended September 30, 2020, offset by higher pre-NDA approval activities.

Selling, General and Administrative Expenses:	Three Months Ended September 30, 2021	2020	Change 2021 vs. 2020 $	%
Selling, general and administrative expenses	$ 21,283	$ 8,423	$ 12,860	152.7 %

Selling, general and administrative ("SG&A") expenses increased $12,860 or 152.7% during the three months ended September 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 $4,400, an increase in other launch planning and preparation activities totaling $1,400 and an increase in patient education costs of approximately $400. Compensation costs increased by approximately $3,600 due to an increase in headcount, primarily in commercial and medical affairs. Legal, other professional fees and insurance costs increased by approximately $2,700.

Selling, General and Administrative Expenses:	Nine Months Ended September 30, 2021	2020	Change 2021 vs. 2020 $	%
Selling, general and administrative expenses	$ 47,469	$ 23,431	$ 24,038	102.6 %

SG&A expenses increased $24,038 or 102.6% during the nine months ended September 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 activities of approximately $8,300, and an increase in other launch planning and preparation activities totaling approximately $3,600. Compensation costs increased by approximately $6,800 due to an increase in headcount, primarily in commercial and medical affairs. Legal, other professional fees and insurance costs increased by approximately $4,800.

Investment and Other Income (Expense), net	Three Months Ended September 30, 2021	2020	Change 2021 vs. 2020 $	%
Investment and other income (expense), net	$ 489	$ 213	$ 276	129.6 %

Investment and other income (expense), net increased for the three months ended September 30, 2021 when compared to the same period in the prior year driven by higher foreign currency gains.

Investment and Other Income (Expense), net	Nine Months Ended September 30, 2021	2020	Change 2021 vs. 2020 $	%
Investment and other income (expense), net	$ 1,531	$ (906)	$ 2,437	269.0 %

Investment and other income (expense), net increased for the nine months ended September 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 foreign currency gains of approximately $700, higher interest income of approximately $600 and lower realized losses on our marketable securities of approximately $400.

Interest Expense	Three Months Ended September 30, 2021	2020	Change 2021 vs. 2020 $	%
Interest expense	$ 1,929	$ 3,259	$ (1,330)	(40.8)%

Interest expense of $1,929 and $3,259 for the three months ended September 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 $312 and $250 for the three months ended September 30, 2021 and 2020, respectively. Prior period interest expense also included amortization of a debt discount of $1,392, which is no longer recognized 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	Nine Months Ended September 30, 2021	2020	Change 2021 vs. 2020 $	%
Interest expense	$ 5,788	$ 9,686	$ (3,898)	(40.2)%

Interest expense of $5,788 and $9,686 for the nine months ended September 30, 2021 and 2020, respectively, is related to interest on the 2023 Notes. Included in these amounts are coupon interest expense of $4,851 for each period and the amortization of debt issuance costs of $937 and $744 for the nine months ended September 30, 2021 and 2020, respectively. Prior period interest expense also included amortization of a debt discount of $4,091, which is no longer recognized 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:	Three Months Ended September 30, 2021	2020	Change 2021 vs. 2020 $	%
Income tax benefit	$ (5,101)	$ (5,040)	$ (61)	(1.2)%
Percentage of (loss) income before income taxes	18.8 %	30.1 %		

The income tax benefit was $5,101 for the three months ended September 30, 2021 resulting in an effective tax rate of 18.8%. The income tax benefit was $5,040 for the three months ended September 30, 2020 resulting in an effective tax rate of 30.1%. The decrease in the effective tax rate for the three months ended September 30, 2021, when compared to the same period in 2020, is primarily attributable to a change in the mix of losses in our foreign entities.

Income Tax Benefit:	Nine Months Ended September 30, 2021	2020	Change 2021 vs. 2020 $	%
Income tax benefit	$ (11,473)	$ (9,258)	$ (2,215)	(23.9)%
Percentage of (loss) income before income taxes	17.3 %	(102.3)%		

The income tax benefit was $11,473 for the nine months ended September 30, 2021 resulting in an effective tax rate of 17.3%. The income tax benefit was $9,258 for the nine months ended September 30, 2020 resulting in an effective tax rate of (102.3)%. The net increase in the effective income tax rate for the nine months ended September 30, 2021 as compared to the prior period in 2020 is primarily due to the discrete tax benefits recognized during the nine months ended September 30, 2020 under the Coronavirus Aid, Relief and Economic Security Act, also known as the CARES Act, which did not occur during the nine months ended September 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:

	Nine Months Ended September 30,		Change 2021 vs. 2020	
Net cash (used in) provided by:	**2021**	**2020**	**$**	**%**
Operating activities	$ (54,804)	$ (29,609)	$ (25,195)	(85.1)%
Investing activities	41,609	(76,962)	118,571	154.1 %
Financing activities	263	179,500	(179,237)	(99.9)%

Operating Activities

Net cash used in operating activities was $54,804 and $29,609 for the nine months ended September 30, 2021 and 2020, respectively. Net cash used in operating activities for the nine months ended September 30, 2021 was driven by net loss of $55,028 and non-cash adjustments of $2,793, offset by favorable changes in working capital of $3,017. For the nine months ended September 30, 2020, net cash used in operating activities was driven by net income of $18,306 and favorable non-cash adjustments of $7,323, offset by the $45,760 gain recorded for the sale of the Hospital Products and a $9,478 unfavorable change in working capital. The year over year change in working capital is driven by the sale of the Hospital Products on June 30, 2020, as well as increased accrued expenses in 2021 as a result of the Company's commercial preparations and launch readiness activities for potential approval of FT218.

Investing Activities

Net cash provided by investing activities was $41,609 for the nine months ended September 30, 2021 and net cash used in investing activities was $76,962 for the nine months ended September 30, 2020. Net cash provided by investing activities for the nine months ended September 30, 2021 was driven by proceeds from the disposition of the Hospital Products of $16,500, as well as net proceeds received from the excess of sales over purchases of marketable securities of $25,135. Net cash used in investing activities for the nine months ended September 30, 2020 was driven by net purchases of marketable securities of $94,179, partially offset by the proceeds from the disposition of the Hospital Products of $17,250.

Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2021 was $263 related to proceeds from stock option exercises and employee stock purchase plan ("ESPP") issuances. Net cash provided by financing activities for the nine months ended September 30, 2020 of $179,500 is driven by the February 2020 private placement and May 2020 public offering that resulted in net proceeds of $60,570 and $116,924, respectively, as well as stock option exercises and ESPP issuances of $2,006.

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 September 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 September 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.

First Complaint

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

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

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

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

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

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

Second Complaint

On August 4, 2021, Jazz filed another formal complaint (the "Second Complaint") initiating a lawsuit in the Court against the Avadel Parties. In the Second Complaint, Jazz alleges the Proposed Product described in the NDA owned by Avadel CNS 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.

On October 22, 2021, the Court issued an oral order stating that this case should proceed on the same schedule as the case filed on May 12, 2021.

Material Commitments and Contractual Obligations

Disclosures regarding material commitments and contractual obligations are included in Part II, Item 7 of the Company's 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 is incorporated by reference herein.

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 September 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 September 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 September 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 Quarterly 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. The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

Our product candidate and future product candidates will generally be subject to regulatory approval. If we or our pharmaceutical and biotechnology company partners do not obtain such approvals, or if such approvals are delayed, our ability to generate future revenues may be adversely affected.

Our lead product candidate, FT218, as well as product candidates we may wish to market in the future, may not gain regulatory approval and reach the commercial market for a variety of reasons. We submitted a 505(b)(2) NDA, for FT218 in December 2020. In February 2021, the FDA assigned the NDA a PDUFA target action date of October 15, 2021 and in October 2021, the FDA notified us that its review of the FT218 NDA was still ongoing.

In the U.S., federal, state and local government agencies, primarily the FDA, regulate all pharmaceutical products, including existing products and those under development. Neither we nor our pharmaceutical and biotechnology partners can control whether we obtain regulatory approval for any of these products or, if obtained, the timing thereof. There may be significant delays in expected product releases while attempting to obtain regulatory approval for products incorporating our technologies. If we or our partners are not successful in timely obtaining such approvals, our revenues and profitability may decline.

Applicants for FDA approval often must submit to the FDA extensive clinical and pre-clinical data, as well as information about product manufacturing processes and facilities and other supporting information. Varying interpretations of the data obtained from pre-clinical and clinical testing could delay, limit or prevent regulatory approval of a drug product. The FDA also may require us, or our partners to conduct additional pre-clinical studies or clinical trials.

Similarly, although we have submitted a 505(b)(2) NDA for our sodium oxybate candidate and anticipate submitting applications for approval for our development products that rely on existing data to demonstrate safety and effectiveness, the FDA may determine that additional studies particular to our product candidate and future product candidates are necessary. If the FDA requires such additional studies, it would impact development plans for those products.

Changes in law or FDA's policies during the development period or regulatory review of each submitted new product application, also may delay an approval, result in a narrower approved use or result in rejection of an application. For instance, under the Food and Drug Administration Amendments Act ("FDAAA"), we or our partners may be required to develop Risk Evaluation and Mitigation Strategies ("REMS") to ensure the safe use of our lead product candidate. If the FDA disagrees with such REMS proposals, it may be more difficult and costly to obtain regulatory approval for our lead product candidate. Similarly, FDAAA provisions may make it more likely that the FDA will refer a marketing application for a new product to an advisory committee for review, evaluation and recommendation as to whether the application should be approved. This review may add to the time for approval, and, although the FDA is not bound by the recommendation of an advisory committee, objections or concerns expressed by an advisory committee may cause the FDA to delay or deny approval.

The FDA has substantial discretion in the approval process and may disagree with our or our partners' interpretations of data and information submitted in an application, which also could cause delays of an approval or rejection of an application. Even if the FDA approves a product, the approval may limit the uses or indications for which the product may be marketed, restrict distribution of the product or require further studies.

The FDA may also withdraw product approvals for failure to comply with regulatory requirements or if problems follow initial marketing. In the same way, medicinal products for supply on the EU market are subject to marketing authorization by either the European Commission, following an opinion by the European Medicines Agency ("EMA"), or by the competent authorities of EU Member States. Applicants for marketing authorization must submit extensive technical and clinical data essentially in the form of the ICH Common Technical Document. The data is subject to extensive review by the competent authorities, and after such review the data may be considered inappropriate or insufficient. If applications for marketing authorization by pharmaceutical and biotechnology company partners are delayed or rejected, if the therapeutic indications for which the product is approved are limited, or if conditional marketing authorization imposing post-marketing clinical trials or surveillance is imposed, our revenues, operating results and liquidity may decline and earnings may be negatively impacted.

Our product candidate and future product candidates may not reach the commercial market for a number of reasons.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Successful R&D of pharmaceutical products is difficult, expensive and time consuming. Many product candidates fail to reach the market. Our success will depend on the development and the successful commercialization of new drugs and products that utilize our drug delivery technologies.

Even if our product candidates and current drug delivery technologies appear promising during development, there may not be successful commercial applications developed for them for a number of reasons, including:

- the FDA, the EMA, the competent authority of an EU Member State or an Institutional Review Board ("IRB"), or an Ethics Committee (EU equivalent to IRB), or our partners may delay or halt applicable clinical trials;

- we or our partners may face slower than expected rate of patient recruitment and enrollment in clinical trials, or may devote insufficient funding to the clinical trials;

- our drug delivery technologies and drug products may be found to be ineffective or to cause harmful side effects, or may fail during any stage of pre-clinical testing or clinical trials;

- we or our partners may find that certain products cannot be manufactured on a commercial scale and, therefore, may not be economical or feasible to produce;

- we or our partners may face delays in completing our clinical trials due to circumstances outside of our control, including natural disasters, labor or civil unrest, global health concerns or pandemics or acts of war or terrorism;

- the FDA may determine that we have identified the wrong listed drug or drugs or that approval of our 505(b)(2) application for our sodium oxybate candidate or future product candidates is blocked by patent or non-patent exclusivity of the listed drug or drugs or of other previously approved drugs with the same conditions of approval as any of our product candidates (as applicable); or

- our product candidate and future product candidates could fail to obtain regulatory approval or, if approved, could fail to achieve market acceptance, could fail to be included within the pricing and reimbursement schemes of the U.S. or EU Member States, or could be precluded from commercialization by proprietary rights of third parties.

Disruptions at the FDA, the U.S. Drug Enforcement Administration and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals and conducting mission critical U.S. and non-U.S. inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to maintain its current pace and approval timelines could be extended due to the ongoing COVID-19 pandemic. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. We cannot guarantee

that the FDA will be able to complete any required inspections or take other necessary actions in respect to our product candidate or future product candidates.

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 reasonably 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.

We currently depend on a single third party manufacturer and a single third party supplier of raw materials related to the development of our product candidate and any interruption of operations of either such provider could significantly delay or have a material adverse effect on our business.

Currently, we use a single supplier of raw materials and a single manufacturer of clinical materials. If FT218 is approved, we anticipate using the same third party manufacturer for commercial supply of FT218. If the supplies or manufacture of these products or materials were interrupted for any reason, including but not limited to, quality issues, natural disasters, labor or civil unrest, global health concerns or pandemics or acts of war or terrorism, the manufacturing and supply of FT218 could be delayed. If the supplies of these materials were interrupted for any reason, our manufacturing of our lead product candidate could be delayed. These delays could be extensive and expensive, especially in situations where a substitution was not readily available or required variations of existing regulatory approvals and certifications or additional regulatory approval. For example, an alternative supplier may be required to pass an inspection by the FDA, EMA or the competent authorities of EU Member States for compliance with current cGMP, requirements before supplying us with product or before we may incorporate that supplier's ingredients into the manufacturing of our product candidate by our contract, development, and manufacturing organizations ("CDMOs"). Additionally, as a result of any such delays in either the supply or manufacturing, we may be unable to meet our projected needs for clinical supplies to support our activities through commercial manufacturing, if approved, and we may not be able to market or distribute FT218, if approved, on our expected timeline, or at all. Failure to obtain adequate supplies in a timely manner could have a material adverse effect on our business, financial condition and results of operations. While we plan to engage with additional suppliers and manufacturers for the supply of commercial batches for FT218, if approved, there can be no guarantee we will establish appropriate arrangements on acceptable terms, if at all.

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: November 8, 2021

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

Date: November 8, 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)*

Exhibit 31.1

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

I, Gregory J. Divis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2021

/s/ Gregory J. Divis
Gregory J. Divis
Chief Executive Officer

Exhibit 31.2

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

I, Thomas S. McHugh, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2021

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the "Company") for the period ended September 30, 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: November 8, 2021

/s/ Gregory J. Divis
Gregory J. Divis
Chief Executive Officer

Exhibit 32.2

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the "Company") for the period ended September 30, 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: November 8, 2021

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