

**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, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 000-28508

AVADEL PHARMACEUTICALS PLC

(Exact name of registrant as specified in its charter)

Ireland

(State or Other Jurisdiction of Incorporation)

000-28508

(Commission File Number)

98-1341933

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

10 Earlsfort Terrace

Dublin 2, Ireland

D02 T380

(Address of Principal Executive Office and Zip Code)

+011-1-485-1200

(Registrant's telephone number, including area code)

N/A

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

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

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

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

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

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

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

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

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

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

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

At November 5, 2020, 58,272,734 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 and MicroPump. 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 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.avadelpharmaceuticals.com**](http://www.avadelpharmaceuticals.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 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, or 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 product candidate, FT218, and our ability to obtain regulatory approval of and successfully commercialize FT218, including any delays in submission or approval related to COVID-19;
- 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 ability of our product candidates, if approved, to gain market acceptance;
- Our ability to enter into strategic partnerships for the development, commercialization, manufacturing and distribution of our product candidates;
- Our dependence on a limited number of suppliers for the manufacturing of our products and certain raw materials in our products and any failure of such suppliers to deliver sufficient quantities of these raw materials, which could have a material adverse effect on our business;
- Our ability to finance our operations on acceptable terms, either through the raising of capital, the incurrence of convertible or other indebtedness or through strategic financing or commercialization partnerships;
- Our expectations about the potential market sizes and market participation potential for our approved or proposed products;
- The potential impact of COVID-19 on our business and future operating results;
- Our ability to 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 16, 2020 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
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF (LOSS) INCOME
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Product sales	\$ —	\$ 14,229	\$ 22,334	\$ 48,220
Operating expenses:				
Cost of products	—	2,823	5,742	9,711
Research and development expenses	5,569	7,539	15,156	25,160
Selling, general and administrative expenses	8,423	5,316	23,431	22,520
Intangible asset amortization	—	205	406	610
Changes in fair value of contingent consideration	(69)	627	3,327	2,384
Gain on sale of Hospital Products	—	—	(45,760)	—
Restructuring (income) costs	(226)	1,866	(43)	4,600
Total operating expense	13,697	18,376	2,259	64,985
Operating (loss) income	(13,697)	(4,147)	20,075	(16,765)
Investment and other income (expense), net	213	781	(906)	2,548
Interest expense	(3,259)	(3,125)	(9,686)	(9,293)
Loss on deconsolidation of subsidiary	—	—	—	(2,840)
Other expense - changes in fair value of contingent consideration payable	—	(139)	(435)	(496)
(Loss) income before income taxes	(16,743)	(6,630)	9,048	(26,846)
Income tax (benefit) provision	(5,040)	2,234	(9,258)	3,641
Net (loss) income	\$ (11,703)	\$ (8,864)	\$ 18,306	\$ (30,487)
Net (loss) income per share - basic	\$ (0.20)	\$ (0.24)	\$ 0.36	\$ (0.82)
Net (loss) income per share - diluted	(0.20)	(0.24)	0.35	(0.82)
Weighted average number of shares outstanding - basic	58,213	37,436	51,206	37,382
Weighted average number of shares outstanding - diluted	58,213	37,436	52,849	37,382

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net (loss) income	\$ (11,703)	\$ (8,864)	\$ 18,306	\$ (30,487)
Other comprehensive (loss) income, net of tax:				
Foreign currency translation gain (loss)	534	(210)	539	(309)
Net other comprehensive income, net of \$(1), \$(5), \$(131) and \$(46) tax, respectively	66	86	349	753
Total other comprehensive income (loss), net of tax	600	(124)	888	444
Total comprehensive (loss) income	<u>\$ (11,103)</u>	<u>\$ (8,988)</u>	<u>\$ 19,194</u>	<u>\$ (30,043)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
	<i>(unaudited)</i>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 83,109	\$ 9,774
Marketable securities	148,467	54,384
Accounts receivable	—	8,281
Inventories	—	3,570
Research and development tax credit receivable	3,058	2,107
Prepaid expenses and other current assets	47,054	4,264
Total current assets	281,688	82,380
Property and equipment, net	373	544
Operating lease right-of-use assets	2,866	3,612
Goodwill	16,836	18,491
Intangible assets, net	—	813
Research and development tax credit receivable	3,608	6,322
Other non-current assets	22,264	39,274
Total assets	\$ 327,635	\$ 151,436
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Current portion of long-term contingent consideration payable	\$ —	\$ 5,554
Current portion of operating lease liability	520	645
Accounts payable	2,660	6,100
Accrued expenses	16,398	19,810
Other current liabilities	3,431	3,875
Total current liabilities	23,009	35,984
Long-term debt	126,520	121,686
Long-term contingent consideration payable, less current portion	—	11,773
Long-term operating lease liability	1,968	2,319
Other non-current liabilities	4,938	8,873
Total liabilities	156,435	180,635
Shareholders' equity (deficit):		
Preferred shares, nominal value of \$0.01 per share; 50,000 shares authorized; 488 issued and outstanding at September 30, 2020 and none issued and outstanding at December 31, 2019, respectively	5	—
Ordinary shares, nominal value of \$0.01 per share; 500,000 shares authorized; 58,243 issued and outstanding at September 30, 2020 and 42,927 issued and 37,520 outstanding at December 31, 2019	582	429
Treasury shares, at cost, 0 and 5,407 shares held at September 30, 2020 and December 31, 2019, respectively	—	(49,998)
Additional paid-in capital	565,440	434,391
Accumulated deficit	(372,909)	(391,215)
Accumulated other comprehensive loss	(21,918)	(22,806)
Total shareholders' equity (deficit)	171,200	(29,199)
Total liabilities and shareholders' equity (deficit)	\$ 327,635	\$ 151,436

See accompanying notes to unaudited condensed consolidated financial statements.

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

Nine Months Ended September 30, 2020

	Ordinary shares		Preferred shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Treasury shares		Total shareholders' equity (deficit)
	Shares	Amount	Shares	Amount				Shares	Amount	
Balance, December 31, 2019	42,927	\$ 429	—	\$ —	\$ 434,391	\$ (391,215)	\$ (22,806)	5,407	\$ (49,998)	\$ (29,199)
Net loss	—	—	—	—	—	(865)	—	—	—	(865)
Other comprehensive loss	—	—	—	—	—	—	(821)	—	—	(821)
Exercise of stock options	146	2	—	—	1,387	—	—	—	—	1,389
February 2020 private placement	8,680	87	488	5	60,641	—	—	—	—	60,733
Vesting of restricted shares	19	—	—	—	—	—	—	—	—	—
Employee share purchase plan share issuance	40	—	—	—	88	—	—	—	—	88
Stock-based compensation expense	—	—	—	—	742	—	—	—	—	742
Balance, March 31, 2020	<u>51,812</u>	<u>\$ 518</u>	<u>488</u>	<u>\$ 5</u>	<u>\$ 497,249</u>	<u>\$ (392,080)</u>	<u>\$ (23,627)</u>	<u>5,407</u>	<u>\$ (49,998)</u>	<u>\$ 32,067</u>
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	<u>63,537</u>	<u>\$ 635</u>	<u>488</u>	<u>\$ 5</u>	<u>\$ 615,207</u>	<u>\$ (361,206)</u>	<u>\$ (22,518)</u>	<u>5,407</u>	<u>\$ (49,998)</u>	<u>\$ 182,125</u>
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	<u>58,243</u>	<u>\$ 582</u>	<u>488</u>	<u>\$ 5</u>	<u>\$ 565,440</u>	<u>\$ (372,909)</u>	<u>\$ (21,918)</u>	<u>—</u>	<u>\$ —</u>	<u>\$ 171,200</u>

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

Nine Months Ended September 30, 2019

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive (loss) income	Treasury shares		Total shareholders' (deficit) equity
	Shares	Amount				Shares	Amount	
Balance, December 31, 2018	42,720	\$ 427	\$ 433,756	\$ (357,989)	\$ (23,416)	5,407	\$ (49,998)	\$ 2,780
Net loss	—	—	—	(13,018)	—	—	—	(13,018)
Other comprehensive income	—	—	—	—	213	—	—	213
Vesting of restricted shares	1	—	—	—	—	—	—	—
Employee share purchase plan share issuance	42	—	92	—	—	—	—	92
Stock-based compensation expense	—	—	351	—	—	—	—	351
Balance, March 31, 2019	42,763	\$ 427	\$ 434,199	\$ (371,007)	\$ (23,203)	5,407	\$ (49,998)	\$ (9,582)
Net loss	—	—	—	(8,605)	—	—	—	(8,605)
Other comprehensive income	—	—	—	—	355	—	—	355
Stock-based compensation expense	—	—	55	—	—	—	—	55
Balance, June 30, 2019	42,763	\$ 427	\$ 434,254	\$ (379,612)	\$ (22,848)	5,407	\$ (49,998)	\$ (17,777)
Net loss	—	—	—	(8,864)	—	—	—	(8,864)
Other comprehensive loss	—	—	—	—	(124)	—	—	(124)
Stock-based compensation expense	—	—	(229)	—	—	—	—	(229)
Vesting of restricted shares	82	1	(1)	—	—	—	—	—
Employee share purchase plan share issuance	12	—	31	—	—	—	—	31
Balance, September 30, 2019	<u>42,857</u>	<u>\$ 428</u>	<u>\$ 434,055</u>	<u>\$ (388,476)</u>	<u>\$ (22,972)</u>	<u>5,407</u>	<u>\$ (49,998)</u>	<u>\$ (26,963)</u>

AVADEL PHARMACEUTICALS PLC
UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2020	2019
Cash flows from operating activities:		
Net income (loss)	\$ 18,306	\$ (30,487)
Adjustments to reconcile net income (loss) to net cash provided by operating activities:		
Depreciation and amortization	1,297	1,690
Loss on disposal of property and equipment	—	478
Remeasurement of acquisition-related contingent consideration	3,327	2,384
Remeasurement of financing-related contingent consideration	435	496
Amortization of debt discount and debt issuance costs	4,835	4,424
Change in deferred tax and income tax deferred charge	(4,582)	1,333
Stock-based compensation expense	1,705	177
Gain on the disposition of the hospital products	(45,760)	—
Loss on deconsolidation of subsidiary	—	1,750
Other adjustments	306	(667)
Net changes in assets and liabilities		
Accounts receivable	8,281	2,026
Inventories	(1,352)	2,465
Prepaid expenses and other current assets	1,759	(1,859)
Research and development tax credit receivable	2,036	(749)
Accounts payable & other current liabilities	(4,051)	259
Accrued expenses	(6,625)	(2,379)
Earn-out payments for contingent consideration in excess of acquisition-date fair value	(5,323)	(8,640)
Royalty payments for contingent consideration payable in excess of original fair value	(866)	(1,374)
Other assets and liabilities	(3,337)	(1,399)
Net cash used in operating activities	(29,609)	(30,072)
Cash flows from investing activities:		
Purchases of property and equipment	(33)	(29)
Proceeds from the disposal of property and equipment	—	154
Proceeds from the disposition of the hospital products	17,250	—
Proceeds from sales of marketable securities	30,075	57,242
Purchases of marketable securities	(124,254)	(23,814)
Net cash (used in) provided by investing activities	(76,962)	33,553
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 ESPP	2,006	123
Other financing activities, net	—	(109)
Net cash provided by financing activities	179,500	14
Effect of foreign currency exchange rate changes on cash and cash equivalents	406	47
Net change in cash and cash equivalents	73,335	3,542
Cash and cash equivalents at January 1,	9,774	9,325
Cash and cash equivalents at September 30,	\$ 83,109	\$ 12,867
Supplemental disclosures of cash flow information:		
Interest paid	\$ 6,469	\$ 6,469
Income taxes (refund) paid, net	\$ (1,788)	\$ 140

See accompanying notes to unaudited condensed consolidated financial statements.

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

NOTE 1: Summary of Significant Accounting Policies

Nature of Operations. Avadel Pharmaceuticals plc (Nasdaq: AVDL) (“Avadel,” the “Company,” “we,” “our,” or “us”) is an emerging biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness (“EDS”) and cataplexy in narcolepsy patients. FT218 uses our Micropump controlled release drug-delivery technology.

We are primarily focused on the development and potential United States (“U.S.”) Food and Drug Administration (“FDA”) approval of FT218. Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio.

We were incorporated in Ireland on December 1, 2015 as a private limited company, and re-registered as an Irish public limited company on November 21, 2016. Our headquarters are in Dublin, Ireland and we have operations in St. Louis, Missouri, U.S.

FT218 (Micropump sodium oxybate)

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 patients 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 Europe and the U.S. as a twice-nightly formulation indicated for the treatment of EDS and cataplexy in patients with narcolepsy. In December 2019, we completed patient enrollment of our Phase 3 REST-ON clinical trial of FT218 to assess the safety and efficacy of a once-nightly formulation of FT218 for the treatment of EDS and cataplexy in patients suffering from narcolepsy and on April 27, 2020, we announced topline results from our Phase 3 REST-ON clinical trial of FT218. On July 13, 2020, we announced the dosing of the first patient of our open-label extension/switch study of FT218 as a potential treatment for EDS and cataplexy in patients with narcolepsy.

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, which is approved by the FDA to Exela Sterile Medicines LLC (“Exela Buyer”) (the “Transaction”) pursuant to an asset purchase agreement between Avadel U.S. Holdings Inc., Avadel Legacy Pharmaceuticals, LLC, Exela Holdings, Inc. and the Exela Buyer (“Purchase Agreement”). Pursuant to the Purchase Agreement, Exela Buyer paid us \$14,500 on the Closing Date and will pay an additional \$27,500 in ten equal monthly installments which began in September 2020 for total aggregate consideration of \$42,000. The following four FDA approved products were included in the sale of the hospital products:

- **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz was approved by the FDA in May 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz was the first FDA-approved version of neostigmine methylsulfate. Today, neostigmine is one of the two most frequently used products for the reversal of the effects of other agents used for neuromuscular blocks.
- **Vazculep (phenylephrine hydrochloride injection)** - Vazculep was approved by the FDA in June 2014 and was launched in October 2014. Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.
- **Akovaz (ephedrine sulfate injection)** - Akovaz, was approved by the FDA in April 2016 and was launched in August 2016. 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 was approved by the FDA in December 2019. Nouress is a sterile injectable product for use in the hospital setting, and two issued U.S. patents currently cover that product. Several additional patent applications for Nouress are pending with the U.S. Patent and Trademark Office (“USPTO”).

Basis of Presentation. The unaudited condensed consolidated balance sheet as of September 30, 2020, which is derived from the prior year 2019 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 2019 Annual Report on Form 10-K filed with the SEC on March 16, 2020.

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.

On February 6, 2019, our indirect wholly-owned subsidiary, Avadel Specialty Pharmaceuticals, LLC ("Specialty Pharma"), filed a voluntary petition for reorganization under Chapter 11 of the U.S. Code (the "Bankruptcy Code") in the U.S. District Bankruptcy Court for the District of Delaware (the "Bankruptcy Court"), Case No. 19-10248. Specialty Pharma is operating and managing its business as "debtors-in-possession" under the jurisdiction of the Bankruptcy Court and in accordance with the applicable provisions of the Bankruptcy Code and order of the Bankruptcy Court. As a result of Specialty Pharma's voluntary bankruptcy filing on February 6, 2019, we no longer controlled the operations of Specialty Pharma; therefore, we deconsolidated Specialty Pharma effective with the bankruptcy filing and the Company recorded its investment in Specialty Pharma under the cost method. See *Note 3: Subsidiary Bankruptcy and Deconsolidation*. Our results of operations for the period January 1, 2019 through February 6, 2019 include the results of Specialty Pharma prior to its February 6, 2019 voluntary petition for reorganization under Chapter 11 of the U.S. Bankruptcy Code.

Reclassifications

Certain reclassifications are made to prior year amounts whenever necessary to conform with the current year presentation. In *Note 9: Goodwill and Intangible Assets*, we presented the December 31, 2019 amortizable intangible assets - Acquired developed technology - Vazculep amount as total accumulated depreciation in this Form 10-Q as compared to showing year-to-date amortization in the Company's 2019 Annual Report on Form 10-K filed with the SEC on March 16, 2020.

Revenue. Prior to June 30, 2020, we generated revenue primarily from the sale of pharmaceutical products to customers, which we refer to as the Hospital Products. On June 30, 2020, we sold the Hospital Products. See *Note 4: 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.

For a complete discussion of the accounting for net product revenue, see *Note 5: Revenue Recognition*.

Accounts Receivable. Prior to the sale of the Hospital Products on June 30, 2020, accounts receivable are stated at amounts invoiced and certain other gross to net variable consideration deductions. An allowance for credit losses is established based on expected losses. Expected losses are estimated by reviewing individual accounts, considering aging, financial condition of the debtor, payment history, current and forecast economic conditions and other relevant factors. A majority of our accounts receivable are due from four significant customers. As of September 30, 2020, we have collected all of the accounts receivable outstanding as of June 30, 2020.

NOTE 2: Newly Issued Accounting Standards

Recent Accounting Guidance Not Yet Adopted

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 will be effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years and early adoption is permitted. We are currently evaluating the impact of adopting ASU 2019-12.

NOTE 3: Subsidiary Bankruptcy and Deconsolidation

Bankruptcy Filing and Deconsolidation

As a result of Specialty Pharma’s bankruptcy filing on February 6, 2019, Avadel has ceded authority for managing the business to the Bankruptcy Court, and Avadel management cannot carry on Specialty Pharma’s activities in the ordinary course of business without Bankruptcy Court approval. Avadel manages the day-to-day operations of Specialty Pharma but does not have discretion to make significant capital or operating budgetary changes or decisions and purchase or sell significant assets, as Specialty Pharma’s material decisions are subject to review by the Bankruptcy Court. For these reasons, we concluded that Avadel has lost control of Specialty Pharma, and no longer has significant influence over Specialty Pharma during the pendency of the bankruptcy. Therefore, we deconsolidated Specialty Pharma effective with the filing of the Chapter 11 bankruptcy in February 2019.

In order to deconsolidate Specialty Pharma, the carrying values of the assets and certain liabilities of Specialty Pharma were removed from our unaudited condensed consolidated balance sheet as of February 5, 2019, and we recorded our investment in Specialty Pharma at its estimated fair value of \$0. As the estimated fair value of our investment in Specialty Pharma was lower than its net book value immediately prior to the deconsolidation, we recorded a non-cash charge of approximately \$2,840 for the nine months ended September 30, 2019 associated with the deconsolidation of Specialty Pharma. Subsequent to the deconsolidation of Specialty Pharma, we are accounting for our investment in Specialty Pharma using the cost method of accounting because Avadel does not exercise significant influence over the operations of Specialty Pharma due to the Chapter 11 filing.

On April 26, 2019, Specialty Pharma sold its intangible assets and remaining inventory to an unaffiliated third party in exchange for aggregate cash proceeds of approximately \$250, pursuant to an order approving such sale which was issued by the Bankruptcy Court on April 15, 2019. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business.

On July 2, 2019, Specialty Pharma was made aware of a \$50,695 claim made by the Internal Revenue Service (IRS) as part of the bankruptcy claims process against Specialty Pharma. On October 2, 2019 the IRS amended the original claim filed in July, reducing the claim to \$9,302. Specialty Pharma files its U.S. federal tax return as a member of the Company’s consolidated U.S. tax group. As such, the IRS claim was filed against Specialty Pharma in the bankruptcy proceedings due to IRS tax law requirements for joint and several liability of all members in a consolidated U.S. tax group. On November 19, 2019, Specialty Pharma and the IRS resolved their dispute, subject to the Bankruptcy Court’s approval of Specialty Pharma’s Chapter 11 plan, and without prejudice to the claims, rights and defenses of the IRS and other Avadel entities outside of the bankruptcy case. The resolution provided for allowance of the IRS claim as a priority claim but for the IRS to receive a distribution of 50% of the proceeds, but in no event less than \$125 from Specialty Pharma following confirmation of its disclosure statement and Chapter 11 plan of liquidation.

On July 24, 2020, Specialty Pharma sought bankruptcy court approval of a settlement agreement by and between it, Avadel US Holdings, Inc. and Serenity Pharmaceuticals, LLC (“Serenity”) (the “Serenity Settlement Agreement”). Before the commencement of Specialty Pharma’s bankruptcy case, Serenity asserted claims against Specialty Pharma and Avadel US Holdings collectively in an amount no less than \$50,000, and after the commencement of the bankruptcy case, Serenity asserted a \$3,096 claim against Specialty Pharma and voted to reject its Chapter 11 plan of liquidation. The Serenity Settlement Agreement provides for a global resolution of these disputes by way of an \$800 payment from Avadel US Holdings to Serenity, a mutual exchange of general releases, and the withdrawal of Serenity’s claim and vote in Specialty Pharma’s bankruptcy case. The Serenity Settlement Agreement was approved by order of the Bankruptcy Court on August 12, 2020.

At a hearing conducted on October 6, 2020, the Bankruptcy Court granted final approval of Specialty Pharma's disclosure statement and confirmed its Chapter 11 plan of liquidation. Pursuant to the plan, the appointment of a Plan Administrator was also approved. The Plan Administrator will be responsible for making distributions to creditors, managing the final windup and dissolution of Specialty Pharma, and taking other steps in accordance with the plan of liquidation. The plan of liquidation became effective on October 20, 2020.

Debtor in Possession ("DIP") Financing – Related Party Relationship

In connection with the bankruptcy filing, Specialty Pharma entered into a Debtor in Possession Credit and Security Agreement with Avadel US Holdings ("DIP Credit Agreement") dated as of February 8, 2019, in an aggregate amount of up to \$2,700, of which the funds are to be used by Specialty Pharma solely to fund operations through February 6, 2020. As of September 30, 2020, the Company had funded \$407 under the DIP Credit Agreement. As the Company has assessed that it is unlikely that Specialty Pharma will pay back the loan to Avadel, the \$407 was recorded as part of the loss on deconsolidation of subsidiary within the unaudited condensed consolidated statements of (loss) income for the nine months ended September 30, 2019.

NOTE 4: Disposition of the Hospital Products

On the Closing Date, we announced the sale of our Hospital Products, to the Exela Buyer pursuant to the Purchase Agreement.

Pursuant to the Purchase Agreement, the Exela Buyer paid \$14,500 on the Closing Date and will pay an additional \$27,500 in ten equal monthly installments beginning 90 days following the Closing Date for total aggregate consideration of \$42,000. During the three months ended September 30, 2020, we collected the first installment payment of \$2,750. 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.

We recorded a net gain on the sale of the Hospital Products of \$45,760 during the nine months ended September 30, 2020 which has been recorded on the unaudited condensed consolidated statement of income (loss). The \$45,760 gain represents the aggregate consideration of \$42,000, transaction fees of \$2,928, plus the assets and liabilities either transferred to the Exela Buyer or eliminated by us due to the sale of the Hospital Products, which are listed below.

	September 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 financial statements included below are being provided for information purposes only and are not necessarily indicative of the results of operations or financial position 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 Balance Sheets				
As of December 31, 2019				
	As Reported	Pro Forma Adjustments	Notes	Pro Forma
ASSETS				
Cash and cash equivalents	\$ 9,774	\$ 12,935	(a)	\$ 22,709
Inventories	3,570	(3,570)	(b)	—
Prepaid expenses and other current assets	4,264	27,500	(c)	31,764
Goodwill	18,491	(1,654)	(d)	16,837
Intangible assets, net	813	(813)	(e)	—
Other non-current assets	39,274	(9,702)	(f)	29,572
Total assets	\$ 151,436	\$ 24,696		\$ 176,132
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)				
Current portion of long-term contingent consideration payable	\$ 5,554	\$ (5,054)	(g)	\$ 500
Accrued expenses	19,810	2,800	(h)	22,610
Long-term contingent consideration payable, less current portion	11,773	(11,773)	(g)	—
Total liabilities	180,635	(14,027)		166,608
Shareholders' equity (deficit):				
Accumulated deficit	(391,215)	38,723	(i)	(352,492)
Total shareholders' (deficit) equity	(29,199)	38,723		9,524
Total liabilities and shareholders' equity (deficit)	\$ 151,436	\$ 24,696		\$ 176,132

Adjustments to the pro forma unaudited condensed combined balance sheet

(a) This adjustment represents the receipt of \$14,500 cash consideration from the Exela Buyer at the closing of the Transaction less \$1,565 placed into escrow for the estimated earn outs and royalties payable to Breaking Stick Holdings L.L.C., Horizon Santé FLML, Sarl, Deerfield Private Design Fund II, L.P., all affiliates of Deerfield Capital L.P. ("Deerfield") and Broadfin Healthcare Master Fund ("Broadfin") for the current quarter ended.

(b) This adjustment reflects the elimination of Inventories that were purchased as part of the Transaction.

(c) This adjustment reflects the Transaction consideration in the form of ten monthly installment payments of \$2,750 (totaling \$27,500) beginning 90 days from the Closing date.

(d) This adjustment reflects the elimination of \$1,654 of Goodwill based on the relative fair value of the Hospital Products as a portion of the overall value of the Company.

(e) This adjustment reflects the elimination of the unamortized balance of the Intangible asset on acquired developed technology for Vazculep.

(f) This adjustment reflects the elimination of \$1,228 of other long-term assets and \$8,474 of deferred tax assets at December 31, 2019. The eliminated deferred tax assets are tax attributes of the Hospital Products.

(g) This adjustment reflects the elimination of short and long term related party payables, less the expected amounts due to Deerfield and Broadfin after taking into consideration the escrow discussed in Note (a). As part of the Transaction, the buyer agreed to assume the quarterly earn-out and royalty payments for periods after the close of the Transaction. The Company will no longer be responsible for these payments.

(h) This adjustment reflects the estimated transaction fees payable related to the Transaction.

(i) This adjustment reflects the estimated gain of \$38,723 arising from the Transaction for the year ended December 31, 2019. This estimated gain has not been reflected in the pro forma unaudited condensed combined statements of loss as it is considered to be nonrecurring in nature. No adjustment has been made to the sale proceeds to give effect to any potential post-closing adjustments under the terms of the Purchase Agreement.

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)	(j)	\$ 159
Total operating expense	2,259	(8,489)	(k)	(6,230)
Operating income	20,075	(13,686)		6,389
Income (loss) before income taxes	\$ 9,048	\$ (13,251)	(l)	\$ (4,203)

Unaudited Pro Forma Condensed Combined Statement of Loss

Nine Months Ended September 30, 2019

	As Reported	Pro Forma Adjustments	Notes	Pro Forma
Product sales	\$ 48,220	\$ (48,007)	(j)	\$ 213
Total operating expense	64,985	(14,398)	(m)	50,587
Operating loss	(16,765)	(33,609)		(50,374)
Loss before income taxes	\$ (26,846)	\$ (33,113)	(n)	\$ (59,959)

Adjustments to the pro forma unaudited condensed combined statements of income (loss)

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

(k) 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.

(l) This amount reflects the adjustments noted in (j) and (k) 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.

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

- Cost of products of \$8,972.
- Research and Development expenses of \$1,604.
- Selling, general and administrative expenses of \$828.
- Intangible asset amortization on acquired development technology for Vazculep of \$610.
- Changes in fair value of related party contingent consideration of \$2,384. The Company will no longer be responsible for these payments.

(n) This amount reflects the adjustments noted in (j) and (m) above, as well as the reversal of estimated Changes in fair value of related party payable of \$496 attributable to the Hospital Products. The Company will no longer be responsible for these payments.

NOTE 5: 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 4: Disposition of the Hospital Products*.

Product Sales

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

Reserves to Reduce Gross Revenues to Net Revenues

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

Product Returns

Consistent with industry practice, the Company maintains a returns policy that generally offers customers a right of return for product that has been purchased from the Company. The Company estimates the amount of product returns and records this estimate as a reduction of revenue in the period the related product revenue is recognized. The Company currently estimates 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 19: Revenue by Product*.

Contract Balances

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

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

There were no material deferred contract costs at September 30, 2020.

Transaction Price Allocated to the Remaining Performance Obligation

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

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

NOTE 6: Fair Value Measurement

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

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

- Income approach, which is based on the present value of a future stream of net cash flows.

- Market approach, which is based on market prices and other information from market transactions involving identical or comparable assets or liabilities.

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

- Level 1 - Quoted prices for identical assets or liabilities in active markets.
- Level 2 - Quoted prices for similar assets or liabilities in active markets, or quoted prices for identical or similar assets or liabilities in markets that are not active, or inputs other than quoted prices that are directly or indirectly observable, or inputs that are derived principally from, or corroborated by, observable market data by correlation or other means.
- Level 3 - Unobservable inputs that reflect estimates and assumptions.

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

Fair Value Measurements:	As of September 30, 2020			As of December 31, 2019		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Marketable securities (see Note 7)						
Equity securities	\$ —	\$ —	\$ —	\$ 4,404	\$ —	\$ —
Money market and mutual funds	104,186	—	—	38,799	—	—
Corporate bonds	—	20,415	—	—	4,098	—
Government securities - U.S.	—	20,216	—	—	5,446	—
Other fixed-income securities	50	3,600	—	—	1,637	—
Total assets	\$ 104,236	\$ 44,231	\$ —	\$ 43,203	\$ 11,181	\$ —
Contingent consideration payable (see Note 10)	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 17,327
Total liabilities	\$ —	\$ —	\$ —	\$ —	\$ —	\$ 17,327

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, 2020 and December 31, 2019, respectively, there were no transfers in and out of Level 1, 2, or 3. During the three and nine month periods ended September 30, 2020 and 2019, respectively, we did not recognize any other-than-temporary impairment loss.

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

Debt

We estimate the fair value of our \$143,750 aggregate principal amount of 4.50% exchangeable senior notes due 2023 (the "2023 Notes"), a Level 2 input, 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. The estimated fair value of the 2023 Notes at September 30, 2020 is \$116,636 compared to a book value of \$126,520.

See Note 11: Long-Term Debt for additional information regarding our debt obligations.

NOTE 7: Marketable Securities

The Company has investments in equity and 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 (deficit), net of income tax effects. As of September 30, 2020, 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, 2020 and December 31, 2019, respectively:

September 30, 2020				
Marketable Securities:	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market and mutual funds	\$ 103,204	\$ 1,041	\$ (59)	\$ 104,186
Corporate bonds	20,212	227	(24)	20,415
Government securities - U.S.	20,015	202	(1)	20,216
Other fixed-income securities	3,625	29	(4)	3,650
Total	\$ 147,056	\$ 1,499	\$ (88)	\$ 148,467

December 31, 2019				
Marketable Securities:	Adjusted Cost	Unrealized Gains	Unrealized Losses	Fair Value
Equity securities	\$ 4,234	\$ 170	\$ —	\$ 4,404
Money market and mutual funds	38,028	771	—	38,799
Corporate bonds	4,021	77	—	4,098
Government securities - U.S.	5,341	110	(5)	5,446
Other fixed-income securities	1,614	23	—	1,637
Total	\$ 53,238	\$ 1,151	\$ (5)	\$ 54,384

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 in the accompanying unaudited condensed consolidated statements of (loss) income.

We recognized gross realized gains of \$136 and \$71 for the three months ended September 30, 2020, and 2019, respectively. These realized gains were offset by realized losses of \$8 and \$64 for the three months ended September 30, 2020, and 2019, respectively. We recognized gross realized gains of \$426 and \$339 for the nine months ended September 30, 2020, and 2019, respectively. These realized gains were offset by realized losses of \$886 and \$211 for the nine months ended September 30, 2020 and 2019, respectively. We reflect these gains and losses as a component of investment income in the accompanying unaudited condensed consolidated statements of (loss) income.

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, 2020:

Marketable Debt Securities:	Maturities				Total
	Less than 1 Year	1-5 Years	5-10 Years	Greater than 10 Years	
Corporate bonds	\$ 4,355	\$ 14,274	\$ 1,786	\$ —	\$ 20,415
Government securities - U.S.	—	17,749	739	1,728	20,216
Other fixed-income securities	50	3,600	—	—	3,650
Total	\$ 4,405	\$ 35,623	\$ 2,525	\$ 1,728	\$ 44,281

The Company has 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.

The following table shows the gross unrealized losses and fair value of our available-for-sale debt securities at September 30, 2020. The unrealized losses in the table below are driven by factors other than credit risk and have been in a 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.

Marketable Debt Securities:	Fair Value	Unrealized Losses
Corporate bonds	\$ 8,371	\$ 24
Government securities - U.S.	267	1
Other fixed-income securities	2,151	4
Total	\$ 10,789	\$ 29

NOTE 8: Inventories

The principal categories of inventories, net of reserves of \$0 and \$914 at September 30, 2020 and December 31, 2019, respectively, are comprised of the following:

Inventory:	September 30, 2020	December 31, 2019
Finished goods	\$ —	\$ 3,020
Raw materials	—	550
Total	\$ —	\$ 3,570

The decrease in inventory at September 30, 2020 is a result of the June 30, 2020 disposition of the Hospital Products. See *Note 4: Disposition of the Hospital Products*.

NOTE 9: Goodwill and Intangible Assets

The Company's amortizable and unamortizable intangible assets at September 30, 2020 and December 31, 2019 are as follows:

Goodwill and Intangible Assets:	September 30, 2020			December 31, 2019		
	Gross Value	Accumulated Amortization	Net Carrying Amount	Gross Value	Accumulated Amortization	Net Carrying Amount
Amortizable intangible assets - Acquired developed technology - Vazculep ⁽¹⁾	\$ —	\$ —	\$ —	\$ 12,061	\$ (11,248)	\$ 813
Unamortizable intangible assets - Goodwill ⁽²⁾	\$ 16,836	\$ —	\$ 16,836	\$ 18,491	\$ —	\$ 18,491

⁽¹⁾ This intangible asset was assumed by the Exela Buyer as part of the disposition of the Hospital Products on June 30, 2020. See *Note 4: Disposition of the Hospital Products*.

⁽²⁾ In connection with the disposition of the Hospital Products (see *Note 4: Disposition of the Hospital Products*), the Company allocated goodwill of \$1,655 on a relative fair value basis to the Hospital Products and included this amount in the net gain on the disposition of the Hospital Products on the unaudited condensed consolidated statements of (loss) income during the nine months ended September 30, 2020.

The Company recorded amortization expense related to amortizable intangible assets of \$0 and \$205 for the three months ended September 30, 2020 and 2019, respectively, and \$406 and \$610 for the nine months ended September 30, 2020 and 2019, respectively.

NOTE 10: Contingent Consideration Payable

Contingent consideration payable and related activity are reported at fair value and consist of the following at September 30, 2020 and December 31, 2019:

Contingent Consideration Payable:	Balance, December 31, 2019	Activity during the nine months ended September 30, 2020				Disposition of the Hospital Products	Balance, September 30, 2020
		Payments	Changes in Fair Value of Contingent Consideration Payable				
			Operating Expense	Other Expense			
Acquisition-related contingent consideration:							
Earn-out payments - Éclat Pharmaceuticals (a) (d)	\$ 15,472	\$ (5,323)	\$ 3,327	\$ —	(13,476)	\$ —	
Financing-related:							
Royalty agreement - Deerfield (b) (d)	1,251	(587)	—	272	(936)	—	
Royalty agreement - Broadfin (c) (d)	604	(279)	—	163	(488)	—	
Total contingent consideration payable	17,327	\$ (6,189)	\$ 3,327	\$ 435	\$ (14,900)	—	
Less: current portion	(5,554)					—	
Long-term contingent consideration payable	\$ 11,773					\$ —	

Long-term related party payable and related activity are reported at fair value and consist of the following at September 30, 2020 and June 30, 2020:

Contingent Consideration Payable:	Balance, June 30, 2020	Activity during the three months ended September 30, 2020			Balance, September 30, 2020
		Payments	Changes in Fair Value of Contingent Consideration Payable		
			Operating Expense	Other Expense	
Acquisition-related contingent consideration:					
Earn-out payments - Éclat Pharmaceuticals (a) (d)	\$ 1,656	\$ (1,587)	\$ (69)	\$ —	\$ —
Financing-related:					
Royalty agreement - Deerfield (b) (d)	175	(175)	—	—	—
Royalty agreement - Broadfin (c) (d)	83	(83)	—	—	—
Total contingent consideration payable	1,914	\$ (1,845)	\$ (69)	\$ —	—
Less: current portion	—				—
Long-term contingent consideration payable	\$ 1,914				\$ —

(a) In March 2012, the Company acquired all of the membership interests of Éclat from Breaking Stick Holdings, L.L.C. (“Breaking Stick”, formerly Éclat Holdings), an affiliate of Deerfield. Breaking Stick is majority owned by Deerfield, with a minority interest owned by the Company’s former CEO, and certain other current and former employees. As part of the consideration, the Company committed to provide quarterly earn-out payments equal to 20% of any gross profit generated by certain Éclat products. These payments will continue in perpetuity, to the extent gross profit of the related products also continue in perpetuity. In connection with the disposition of the Hospital Products on June 30, 2020 as discussed in *Note 4: Disposition 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 and the Company under the Deerfield Royalty Agreement.

- (b) As part of a February 2013 debt financing transaction conducted with Deerfield, the Company received cash of \$2,600 in exchange for entering into a royalty agreement whereby the Company is obligated to pay quarterly a 1.75% royalty on the net sales of certain Éclat products until December 31, 2024. In connection with such debt financing transaction, the Company granted Deerfield a security interest in the product registration rights of the Éclat products. In connection with the disposition of the Hospital Products on June 30, 2020 as discussed in *Note 4: Disposition 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 and the Company under the Deerfield Royalty Agreement.
- (c) As part of a December 2013 debt financing transaction conducted with Broadfin Healthcare Master Fund, a former related party and shareholder, the Company received cash of \$2,200 in exchange for entering into a royalty agreement whereby the Company is obligated to pay quarterly a 0.834% royalty on the net sales of certain Éclat products until December 31, 2024. In connection with the disposition of the Hospital Products on June 30, 2020 as discussed in *Note 4: Disposition 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 the Company under the Broadfin Royalty Agreement.
- (d) Deerfield and Broadfin Healthcare Master Trust disposed of their 2023 Notes and ordinary shares in the Company during the six months ended June 30, 2020 and are no longer considered related parties.

Before the sale of the Hospital Products on June 30, 2020, the fair value of each contingent consideration payable listed in (a), (b) and (c) above was estimated using a discounted cash flow model based on estimated and projected annual net revenues or gross profit, as appropriate, of each of the specified Éclat products using an appropriate risk-adjusted discount rate of 14%. These fair value measurements are based on significant inputs not observable in the market and thus represent a Level 3 measurement as defined in ASC 820. Subsequent changes in the fair value of the acquisition-related contingent consideration payables, resulting primarily from management’s revision of key assumptions, will be recorded in the unaudited condensed consolidated statements of (loss) income in the line items entitled “Changes in fair value of contingent consideration” for items noted in (b) above and in “Other expense - changes in fair value of contingent consideration payable” for items (b) and (c) above. See *Note 1: Summary of Significant Accounting Policies* under the caption Acquisition-related Contingent Consideration and Financing-related Royalty Agreements in Part II, Item 8 of the Company’s 2019 Annual Report on Form 10-K for more information on key assumptions used to determine the fair value of these liabilities.

Prior to June 30, 2020, the Company chose to make a fair value election pursuant to ASC 825, “Financial Instruments” for its royalty agreements detailed in items (b) and (c) above. These financing-related liabilities are recorded at fair market value on the unaudited condensed consolidated balance sheets and the periodic change in fair market value is recorded as a component of “Other expense – change in fair value of contingent consideration payable” on the unaudited condensed consolidated statements of (loss) income.

The following table summarizes changes to the contingent consideration payables, a recurring Level 3 measurement, for the nine-month periods ended September 30, 2020 and 2019, respectively:

Contingent Consideration Payable Rollforward:	Balance
Balance, December 31, 2018	\$ 28,840
Payments of contingent consideration	(10,014)
Fair value adjustments ⁽¹⁾	2,880
Balance, September 30, 2019	<u>\$ 21,706</u>
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	<u>\$ —</u>

⁽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 11: Long-Term Debt

Long-term debt is summarized as follows:

	September 30, 2020	December 31, 2019
Principal amount of 4.50% exchangeable senior notes due 2023	\$ 143,750	\$ 143,750
Less: unamortized debt discount and issuance costs, net	(17,230)	(22,064)
Net carrying amount of liability component	126,520	121,686
Less: current maturities	—	—
Long-term debt	\$ 126,520	\$ 121,686
Equity component:		
Equity component of exchangeable notes, net of issuance costs	\$ (26,699)	\$ (26,699)

NOTE 12: Income Taxes

The Coronavirus Aid, Relief and Economic Security Act (the “CARES Act”), enacted on March 27, 2020, includes significant business tax provisions. In particular, the CARES Act modified the rules associated with net operating losses (“NOLs”). Under the temporary provisions of the CARES Act, NOL carryforwards and carrybacks may offset 100% of taxable income for taxable years beginning before 2021. In addition, NOLs arising in 2018, 2019 and 2020 taxable years may be carried back to each of the preceding five years to generate a refund. During the nine months ended September 30, 2020, the income tax benefit includes a discrete tax benefit of \$9,124 as a result of our ability under the CARES Act to carry back NOLs incurred to periods when the statutory U.S. Federal tax rate was 35% versus our current U.S. Federal tax rate of 21%. During the nine months ended September 30, 2020, the Company received \$3,351 in cash tax refunds from carryback claims related to the CARES Act from the carryback of 2018 tax losses. During the three months ended September 30, 2020 the Company filed refund claims for \$18,753 associated with the carryback of 2019 tax losses.

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 income tax expense was \$2,234 for the three months ended September 30, 2019 resulting in an effective tax rate of (33.6)%. The net increase in the effective income tax rate for the three months ended September 30, 2020, as compared to the same period in 2019, was primarily due to decreased income in the U.S. due to the sale of the Hospital Products.

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 income tax provision was \$3,641 for the nine months ended September 30, 2019 resulting in an effective tax rate of (13.7)%. The net decrease in the effective income tax rate for the nine months ended September 30, 2020, as compared to the same period in 2019, is primarily due to the discrete tax benefits recognized under the CARES Act as described above, favorable income tax benefits from the U.S. Orphan Drug and Research & Development Tax Credit, which did not occur during the nine months ended September 30, 2019, partially offset by increased income in the U.S. due to the sale of the Hospital Products during the nine months ended September 30, 2020.

During the nine months ended September 30, 2020, the Company substantially completed the 2015 through 2017 U.S. Federal Tax Audit. Completion of the audit resulted in an assessment of \$1,937 for the 2015 through 2017 U.S. Federal Tax Returns compared to the IRS Claims of \$50,695 made on July 2, 2019 and the updated IRS Claims of \$9,302 on October 2, 2019 made as part of the Specialty Pharma bankruptcy proceedings, which at this time does not include interest and penalties. The Company settled the \$1,937 assessment.

NOTE 13: Other Assets and Liabilities

Various other assets and liabilities are summarized as follows:

Prepaid Expenses and Other Current Assets:	September 30, 2020	December 31, 2019
Valued-added tax recoverable	\$ 353	\$ 1,051
Prepaid and other expenses	1,426	2,116
Short-term deposit	1,477	—
Guarantee from Armistice	364	454
Income tax receivable	18,593	536
Short term note receivable from Exela (see Note 4)	24,750	—
Other	91	107
Total	\$ 47,054	\$ 4,264

Other Non-Current Assets:	September 30, 2020	December 31, 2019
Deferred tax assets, net	\$ 15,479	\$ 29,427
Long-term deposits	—	1,477
Guarantee from Armistice	1,117	1,367
Right of use assets at contract manufacturing organizations	5,201	6,428
Other	467	575
Total	\$ 22,264	\$ 39,274

Accrued Expenses	September 30, 2020	December 31, 2019
Accrued compensation	\$ 1,897	\$ 3,944
Accrued social charges	394	592
Accrued restructuring (see Note 15)	728	2,949
Customer allowances	6,588	6,470
Accrued transaction fees related to the disposition of the Hospital Products	2,500	—
Accrued contract research organization charges	361	2,098
Accrued contract manufacturing organization costs	1,009	735
Other	2,921	3,022
Total	\$ 16,398	\$ 19,810

Other Current Liabilities:	September 30, 2020	December 31, 2019
Accrued interest	\$ 1,078	\$ 2,695
Due to Exela	1,817	—
Guarantee to Deerfield	365	455
Other	171	725
Total	\$ 3,431	\$ 3,875

Other Non-Current Liabilities:	September 30, 2020	December 31, 2019
Customer allowances	\$ 659	\$ 981
Unrecognized tax benefits	3,143	6,465
Guarantee to Deerfield	1,121	1,372
Other	15	55
Total	\$ 4,938	\$ 8,873

NOTE 14: Equity Transactions

Shelf Registration Statement on Form S-3

In February 2020, we filed with the SEC a new shelf registration statement on Form S-3 (the 2020 Shelf Registration Statement) (File No. 333-236258) that allows issuance and sale by us, from time to time, of:

- (a) up to \$250,000 in aggregate of ordinary shares, nominal value US\$0.01 per share (the “Ordinary Shares”), each of which may be represented by American Depositary Shares (“ADSs”), preferred shares, nominal value US\$0.01 per share (the “Preferred Shares”), debt securities (the “Debt Securities”), warrants to purchase Ordinary Shares, ADSs, Preferred Shares and/or Debt Securities (the “Warrants”), and/or units consisting of Ordinary Shares, ADSs, Preferred Shares, one or more Debt Securities or Warrants in one or more series, in any combination, pursuant to the terms of the 2020 Shelf Registration Statement, the base prospectus contained in the 2020 Shelf Registration Statement (the “Base Prospectus”), and any amendments or supplements thereto (together, the “Securities”); including
- (b) up to \$50,000 of ADSs that may be issued and sold from time to time pursuant to the terms of an Open Market Sale AgreementSM, entered into with Jefferies LLC on February 4, 2020 (the “Sales Agreement”), the 2020 Shelf Registration Statement, the Base Prospectus and the terms of the sales agreement prospectus contained in the 2020 Shelf Registration Statement.

The transactions costs associated with the 2020 Shelf Registration Statement totaled approximately \$428 of which \$214 was charged against additional paid-in capital during the nine months ended September 30, 2020 as a result of the May 2020 Public Offering, discussed below. The remaining costs of \$214 are recorded as a prepaid asset at September 30, 2020.

February 2020 Private Placement

On February 21, 2020, we announced that we entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares (“Series A Preferred”) in a private placement to a group of institutional accredited investors. The private placement resulted in gross proceeds of approximately \$65,000 before deducting placement agent and other offering expenses, which resulted in net proceeds of \$60,570.

Pursuant to the terms of the private placement, we issued 8,680 ADSs and 488 shares of Series A Preferred at a price of \$7.09 per share, priced at-the-market under Nasdaq rules. Each share of non-voting Series A Preferred is convertible into one ADS, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.99% of the total number of Avadel ADSs outstanding. The closing of the private placement occurred on February 25, 2020.

Issuance costs of \$4,430 have been recorded as a reduction of additional paid-in capital.

May 2020 Public Offering

In connection with the shelf registration statement described above, on April 28, 2020, we announced the pricing of an underwritten public offering of 11,630 Ordinary Shares, in the form of ADSs at a price to the public of \$10.75 per ADS. Each ADS represents the right to receive one Ordinary Share. All of the ADSs were offered by us and the gross proceeds to us from the offering were approximately \$125,000, before deducting underwriting discounts and commissions and offering expenses, which resulted in net proceeds of \$116,924. The offering closed on May 1, 2020.

August 2020 Treasury Shares Retirement

In August 2020, the Company retired all of our 5,407 treasury shares, or \$49,998 previously repurchased ordinary shares. As a result, we reduced additional paid-in capital by \$49,944 and ordinary shares by \$54 during the three and nine months ended September 30, 2020. The portion allocated to additional paid-in capital is determined pro rata by applying a percentage, determined by dividing the number of shares to be retired by the number of shares issued and outstanding as of the retirement date, to the balance of additional paid-in capital as of the retirement date. Based on this calculation, the entirety of the excess of repurchase price over par of \$49,944 was allocated to additional paid-in capital.

NOTE 15: 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 the three months ended June 30, 2020. Restructuring charges associated with this plan recognized during the three and nine months ended September 30, 2020 were immaterial. Restructuring charges associated with this plan of \$1,259 and \$3,198 were recognized during the three and nine months ended September 30, 2019. Included in the 2019 restructuring charges of \$3,198 were charges for employee severance, benefits and other costs of \$2,774, a charge of \$598 related to fixed asset impairment, a charge of \$826 related to the early termination penalty related to the office lease termination as well as a benefit of \$1,000 related to the reversal of the French retirement indemnity obligation.

The following table sets forth activities for the Company’s cost reduction plan obligations for the nine months ended September 30, 2020 and 2019:

2019 French Restructuring Obligation:	2020	2019
Balance of restructuring accrual at January 1,	\$ 1,922	\$ —
Charges for employee severance, benefits and other costs	173	2,774
Payments	(1,813)	(1,837)
Foreign currency impact	(45)	(42)
Balance of restructuring accrual at September 30,	<u>\$ 237</u>	<u>\$ 895</u>

The 2019 French Restructuring liabilities of \$237 are included in the unaudited condensed consolidated balance sheet in accrued expenses at September 30, 2020.

2019 Corporate Restructuring

During the first quarter of 2019, the Company announced a plan to reduce its Corporate workforce by more than 50% (“2019 Corporate Restructuring”). The reduction in workforce is primarily a result of the exit of Noctiva during the first quarter of 2019 (see *Note 3: Subsidiary Bankruptcy and Deconsolidation*), 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 the three months ended September 30, 2020. The restructuring charges associated with this plan recognized during the three and nine months ended September 30, 2020 were immaterial, compared to the restructuring charges of \$607 and \$1,570 recognized during the three and nine months ended September 30, 2019, respectively. Included in the 2019 Corporate Restructuring charges of \$1,570 for the nine months ended September 30, 2019, were charges for employee severance, benefit and other costs of \$2,966, as well as a benefit of \$1,396 related to share based compensation forfeitures related to the employees affected by the global reduction in workforce.

The following table sets forth activities for the Company’s cost reduction plan obligations for the nine months ended September 30, 2020 and 2019:

2019 Corporate Restructuring Obligation:	2020	2019
Balance of restructuring accrual at January 1,	\$ 1,080	\$ —
Charges for employee severance, benefits and other costs	206	2,966
Payments	(794)	(2,113)
Balance of restructuring accrual at September 30,	<u>\$ 492</u>	<u>\$ 853</u>

The 2019 Corporate Restructuring liabilities of \$492 are included in the unaudited condensed consolidated balance sheet in accrued expenses at September 30, 2020.

NOTE 16: Share-Based Compensation*2020 Performance Share Units (“PSUs”)*

At the Annual Meeting of Stockholders held in August 2020, the 2020 Omnibus Incentive Compensation Plan was approved which provided for the grant of PSUs to certain executive officers and employees. These PSUs vest upon the achievement of certain regulatory milestones. As of September 30, 2020 152 PSUs were outstanding, none had vested and the weighted-average grant date fair value of all shares was \$8.29 per share. The Company has not yet recognized any PSU-related stock-based compensation expense as the regulatory milestones have not yet been met; however, in the event the performance conditions are met before a certain date, approximately 150% of the outstanding shares, or \$1,900 of compensation expense will be recognized by the Company for the PSUs outstanding as of September 30, 2020.

On October 20, 2020, we granted 105 of PSUs to current employees, with the weighted-average grant date fair value of the PSUs of \$5.36 per share.

NOTE 17: 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 warrants, stock options, restricted stock units, preferred shares and ordinary shares expected to be issued under or ESPP has been calculated using the treasury stock method. The dilutive effect of the PSUs will be calculated using the treasury stock method, if and when the contingent vesting condition is achieved.

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

Net (Loss) Income Per Share:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net (loss) income	\$ (11,703)	\$ (8,864)	\$ 18,306	\$ (30,487)
Weighted average shares:				
Basic shares	58,213	37,436	51,206	37,382
Effect of dilutive securities—employee and director equity awards outstanding, preferred shares and 2023 Notes	—	—	1,643	—
Diluted shares	58,213	37,436	52,849	37,382
Net (loss) income per share - basic	\$ (0.20)	\$ (0.24)	\$ 0.36	\$ (0.82)
Net (loss) income per share - diluted	\$ (0.20)	\$ (0.24)	\$ 0.35	\$ (0.82)

Potential common shares of 15,969 and 19,544 were excluded from the calculation of weighted average shares for the three months ended September 30, 2020 and 2019, respectively, and potential common shares of 15,789 and 20,512 were excluded from the calculation of weighted average shares for the nine months ended September 30, 2020 and 2019, 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 months ended September 30, 2020 and for the three and nine months ended September 30, 2019, the effects of dilutive securities were entirely excluded from the calculation of net loss per share as a net loss was reported in this period.

NOTE 18: Comprehensive Loss

The following table shows the components of accumulated other comprehensive loss for the three and nine months ended September 30, 2020 and 2019, respectively, net of tax effects:

Accumulated Other Comprehensive Loss:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Foreign currency translation adjustment:				
Beginning balance	\$ (23,733)	\$ (23,720)	\$ (23,738)	\$ (23,621)
Net other comprehensive income (loss)	534	(210)	539	(309)
Balance at September 30,	\$ (23,199)	\$ (23,930)	\$ (23,199)	\$ (23,930)
Unrealized gain on marketable debt securities, net				
Beginning balance	\$ 1,215	\$ 872	\$ 932	\$ 205
Net other comprehensive income, net of \$(1), \$(5), \$(131) and \$(46) tax, respectively	66	86	349	753
Balance at September 30,	\$ 1,281	\$ 958	\$ 1,281	\$ 958
Accumulated other comprehensive loss at September 30,	\$ (21,918)	\$ (22,972)	\$ (21,918)	\$ (22,972)

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 19: 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 its 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 are 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.

The following table presents a summary of total product sales by these products:

Product Sales by Product:	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Bloxiverz	\$ —	\$ 1,466	\$ 2,201	\$ 6,392
Vazculep	—	8,786	10,429	27,669
Akovaz	—	4,208	9,545	13,946
Other	—	(231)	159	213
Total product sales	\$ —	\$ 14,229	\$ 22,334	\$ 48,220

On June 30, 2020, we sold the Hospital Products. See *Note 4: Disposition of the Hospital Products*.

NOTE 20: 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, 2020 and December 31, 2019, 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.

Litigation Related to Noctiva

Note 3: Subsidiary Bankruptcy and Deconsolidation briefly describes the Chapter 11 bankruptcy case which our subsidiary Specialty Pharma commenced on February 6, 2019, and which on April 26, 2019 resulted in the bankruptcy court-approved sale of all of Specialty Pharma's intangible assets and inventory to an unaffiliated third party. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business. During the pendency of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and any new litigation against Specialty Pharma is precluded unless the bankruptcy court orders otherwise. There is currently no pending or threatened litigation or disputes to which Specialty Pharma is or would be a party. All prior litigation and disputes involving Specialty Pharma have been dismissed or resolved.

Material Commitments

We have been relieved of all purchase commitments disclosed in *Note 16: Contingent Liabilities and Commitments* to the Company's audited consolidated financial statements included in Part II, Item 8 of the Company's 2019 Annual Report on Form 10-K due to the sale of the Hospital Products described in *Note 4: Disposition of the Hospital Products*.

During the three months ended September 30, 2020, we entered into a commitment with a contract manufacturer related to the purchase and validation of equipment to be used in the manufacture of FT218. The total cost of this commitment is estimated to be approximately \$3,800 and is expected to be completed by the end of 2021.

Material commitments in the normal course of business include long-term debt obligations which are disclosed in *Note 11: Long-Term Debt* to the Company's unaudited condensed consolidated financial statements. Our long-term contingent consideration payable as disclosed in *Note 10: Contingent Consideration Payable* has also been relieved due to the sale of the Hospital Products.

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 \$1,486 at September 30, 2020. 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 \$1,481 at September 30, 2020. 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, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K.

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

Management's Discussion and Analysis

(In thousands, except per share data)

(Unaudited)

You should read the discussion and analysis of our financial condition and results of operations set forth in this Item 2 together with our unaudited condensed consolidated financial statements and the related notes appearing elsewhere in this quarterly report on Form 10-Q. Some of the information contained in this discussion and analysis or set forth elsewhere in this quarterly report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties, and reference is made to the "Cautionary Note Regarding Forward-Looking Statements" set forth immediately following the Table of Contents of this Quarterly Report on Form 10-Q for further information on the forward looking statements herein. In addition, you should read the "Risk Factors" section in Part I, Item 1A of our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission ("SEC") on March 16, 2020 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 an emerging biopharmaceutical company. Our lead product candidate, FT218, is an investigational once-nightly formulation of sodium oxybate for the treatment of excessive daytime sleepiness ("EDS") and cataplexy in narcolepsy patients. FT218 uses our Micropump controlled release drug-delivery technology.

We are primarily focused on the development and potential United States ("U.S.") Food and Drug Administration ("FDA") approval of FT218. Outside of our lead product candidate, we continue to evaluate opportunities to expand our product portfolio.

Recent Developments

Disposition of the Hospital 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, which is approved by the FDA to Exela Sterile Medicines LLC ("Exela Buyer") (the "Transaction") pursuant to an asset purchase agreement between Avadel U.S. Holdings Inc., Avadel Legacy Pharmaceuticals, LLC, Exela Holdings, Inc. and the Exela Buyer ("Purchase Agreement"). Pursuant to the Purchase Agreement, Exela Buyer paid us \$14,500 on the Closing Date and will pay an additional \$27,500 in ten equal monthly installments which began in September 2020 for total aggregate consideration of \$42,000. During the three months ended September 30, 2020, we received the first installment payment of \$2,750. For more information, see our Current Report on Form 8-K filed with the SEC on July 2, 2020.

Subsidiary Bankruptcy

At a hearing conducted on October 6, 2020, the Bankruptcy Court granted final approval of Specialty Pharma's disclosure statement and confirmed its Chapter 11 plan of liquidation. Pursuant to the plan, the appointment of a Plan Administrator was also approved. The Plan Administrator will be responsible for making distributions to creditors, managing the final windup and dissolution of Specialty Pharma, and taking other steps in accordance with the plan of liquidation. The plan of liquidation became effective on October 20, 2020.

FT218 (Micropump sodium oxybate)

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 patients 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 Europe and the U.S. as a twice-nightly formulation indicated for the treatment of EDS and cataplexy in patients with narcolepsy.

The REST-ON trial was a randomized, double-blind, placebo-controlled study that enrolled 212 patients and was conducted in clinical sites in the U.S., Canada, Western Europe and Australia. The last patient, last visit was completed at the end of the first quarter of 2020 and positive top line data from the REST-ON trial was announced on April 27, 2020. Patients who received 9g of once-nightly FT218 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. We observed the 9g 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%, enuresis 9%) and 3.9% of the patients who received 9g of FT218 discontinued the trial due to adverse reactions. We also assessed the three co-primary endpoints in patients who received 7.5g and 6g of once-nightly FT218. Patients who received either 7.5g or 6g of once-nightly FT218 also demonstrated statistically significant, clinically meaningful improvements compared to placebo for each of the three co-primary endpoints.

In January 2018, the FDA granted FT218 Orphan Drug Designation, which makes the drug eligible for certain development and commercial incentives, including a potential U.S. market exclusivity for up to seven years. Additionally, in April 2019, our first FT218 patent was issued, providing intellectual property protection into mid-2037. One or more FT218-related U.S. patents have issued since, 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 excessive daytime sleepiness and cataplexy in patients with narcolepsy. The OLE/switch study will examine 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 if they participated in REST-ON or not. We anticipate that the study will enroll about 250 patients at most of the North American clinical trial sites that participated in the REST-ON study.

We believe FT218 has the potential to demonstrate improved dosing compliance, safety and patient satisfaction over the current standard of care for EDS and cataplexy in patients with narcolepsy, which is a twice-nightly sodium oxybate formulation. If approved, we believe FT218 has the potential to take a significant share of the sodium oxybate market. The current market size for the twice-nightly administration of sodium oxybate is estimated at an annualized revenue run rate of \$1.6 billion.

Micropump Drug-Delivery Technology

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

Previously Approved FDA Products

On June 30, 2020, we announced the sale of our portfolio of sterile injectable drugs used in the hospital setting, including our three commercial products, Akovaz, Bloxiverz and Vazculep, as well as Nouress, which is approved by the U.S. FDA to Exela Sterile Medicines LLC. This sale included the following FDA approved products:

- **Bloxiverz (neostigmine methylsulfate injection)** - Bloxiverz was approved by the FDA in May 2013 and was launched in July 2013. Bloxiverz is a drug used intravenously in the operating room to reverse the effects of non-depolarizing neuromuscular blocking agents after surgery. Bloxiverz was the first FDA-approved version of neostigmine methylsulfate. Today, neostigmine is one of the two most frequently used products for the reversal of the effects of other agents used for neuromuscular blocks. There are approximately 2,500 vials of neostigmine sold annually in the U.S.
- **Vazculep (phenylephrine hydrochloride injection)** - Vazculep was approved by the FDA in June 2014 and was launched in October 2014. Vazculep is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. There are approximately 7,400 vials of *Vazculep* sold annually in the U.S.
- **Akovaz (ephedrine sulfate injection)** - Akovaz, was approved by the FDA in April 2016 and was launched in August 2016. 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. There are approximately 6,800 vials of *Akovaz* sold annually in the U.S.

- **Nouress (cysteine hydrochloride injection)** - Nouress was approved by the FDA in December 2019. Nouress is a sterile injectable product for use in the hospital setting, and two issued U.S. patents currently cover that product. Several additional patent applications for Nouress are pending with the U.S. Patent and Trademark Office (“USPTO”).

Corporate Information

We were incorporated on December 1, 2015 as an Irish private limited company, and re-registered as an Irish public limited company (“plc”), on November 21, 2016. 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 U.S. Securities and Exchange Commission (“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, 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 (currently the subject of a voluntary Chapter 11 bankruptcy proceeding), (ii) Avadel Legacy Pharmaceuticals, LLC, (iii) Avadel Management Corporation, (iv) FSC Holding Company, (v) Avadel Operations Company, Inc. and (vi) Avadel CNS Pharmaceuticals LLC. Avadel Finance Ireland Designated Activity Company is the holding entity of Avadel Finance Cayman Limited. Flamel Ireland Limited (operating under the trade name Avadel Ireland) is an Irish corporation. Avadel France Holding SAS, a French société par actions simplifiée, is the holding entity of Avadel Research SAS through which Avadel conducts substantially all of its R&D activities. 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 16, 2020.

References in these unaudited condensed consolidated financial statements and the notes thereto to “Avadel,” the “Company,” “we,” “our,” “us,” and similar terms shall be deemed to be references to Flamel prior to the completion of the Merger, unless the context otherwise requires.

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 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 our 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. Specifically, we have seen, or likely will see, additional generic competition to our current and future products and we continue to expect generic competition 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 and/or expensive and, as a result, could create liquidity challenges for the Company.
- **Net Loss from Operations in 2020:** Since we sold our Hospital Products at June 30, 2020 and will no longer generate revenue from sales and we will incur substantial expenses to further the clinical development of FT218, we expect to incur a net loss in 2020, which we are unable to estimate at this time.

Impact of COVID-19

Since early 2020, we have seen the profound impact that the novel coronavirus (“COVID-19”) is having on human health, the global economy and society at large. We have been actively monitoring the COVID-19 situation and have taken measures to mitigate the potential impacts to our employees and business, such as implementing 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 submission of our NDA for FT218 to the FDA, 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 that we use; and iii) requiring our employees to work from home for an extended period of time. An extended period of global supply chain and economic disruption could materially affect our business, results of operations, access to sources of liquidity and financial condition.

Financial Highlights

Highlights of our consolidated results for the three and nine months ended September 30, 2020 are as follows:

- Revenue was \$0 and \$22,334 for the three and nine months ended September 30, 2020, respectively, compared to \$14,229 and \$48,220 in the same periods last year, respectively. The quarter over quarter and year over year decreases were primarily the result of the sale of the Hospital Products on June 30, 2020.
- Operating loss was \$13,697 for the three months ended September 30, 2020 and operating income was \$20,075 for the nine months ended September 30, 2020, respectively, compared to an operating loss of \$4,147 and \$16,765 and for the same period last year, respectively. The increase in operating loss for the three months ended September 30, 2020 was driven by a decline in gross margin (*i.e.*, total revenues minus cost of products) of \$11,406 driven by the sale of the Hospital Products and higher selling, general and administrative expense of \$3,107. The increase in operating income for the nine months ended September 30, 2020 was driven by the gain on the disposition of Hospital Products of \$45,760, lower R&D expense of \$10,004, lower restructuring costs of \$4,643, partially offset by lower gross margin of \$21,917.
- Gain on the disposition of the Hospital Products was \$45,760 for the nine months ended September 30, 2020. The net gain included sale proceeds of \$42,000 (\$27,500 was recorded as a current note receivable at June 30, 2020), write-off of our inventory, intangible asset, a portion of goodwill and other related assets of \$8,212, estimated transaction fees of \$2,928 and the reversal of our contingent consideration liability of \$14,900.
- Net loss was \$11,703 for the three months ended September 30, 2020 and net income was \$18,306 for the nine months ended September 30, 2020, respectively, compared to net loss of \$8,864 and \$30,487 in the same periods last year, respectively. Included in the net income during the nine months ended September 30, 2020 was a gain on the disposition of the Hospital Products of \$45,760.
- Diluted net loss per share was \$0.20 for the three months ended September 30, 2020 and diluted net income was \$0.35 for the nine months ended September 30, 2020, respectively, compared to diluted net loss per share of \$0.24 and \$0.82 in the same periods last year, respectively.
- Cash and marketable securities increased \$167,418 to \$231,576 at September 30, 2020, from \$64,158 at December 31, 2019. This increase was driven by the February private placement which resulted in proceeds, net of placement fees of approximately \$61,000, the May public offering, which resulted in proceeds, net of placement fees of approximately \$117,000, cash proceeds from the disposition of the Hospital Products of \$17,250, partially offset by \$29,609 use of cash in operations during the nine months ended September 30, 2020.

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, 2019 (the "2019 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 MD&A in our 2019 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, 2020 and 2019, respectively:

Comparative Statements of (Loss) Income	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Product sales	\$ —	\$ 14,229	\$ (14,229)	(100.0)%
Operating expenses:				
Cost of products	—	2,823	(2,823)	(100.0)%
Research and development expenses	5,569	7,539	(1,970)	(26.1)%
Selling, general and administrative expenses	8,423	5,316	3,107	58.4 %
Intangible asset amortization	—	205	(205)	(100.0)%
Changes in fair value of contingent consideration	(69)	627	(696)	(111.0)%
Restructuring (income) costs	(226)	1,866	(2,092)	(112.1)%
Total operating expense	13,697	18,376	(4,679)	(25.5)%
Operating loss	(13,697)	(4,147)	(9,550)	(230.3)%
Investment and other income, net	213	781	(568)	(72.7)%
Interest expense	(3,259)	(3,125)	(134)	(4.3)%
Other expense - changes in fair value of contingent consideration payable	—	(139)	139	100.0 %
Loss before income taxes	(16,743)	(6,630)	(10,113)	(152.5)%
Income tax (benefit) provision	(5,040)	2,234	(7,274)	(325.6)%
Net loss	\$ (11,703)	\$ (8,864)	\$ (2,839)	(32.0)%
Net loss per share - diluted	\$ (0.20)	\$ (0.24)	\$ 0.04	16.7 %

The following is a summary of our financial results (in thousands, except per share amounts) for the nine months ended September 30, 2020 and 2019, respectively:

Comparative Statements of Income (Loss)	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Product sales	\$ 22,334	\$ 48,220	\$ (25,886)	(53.7)%
Operating expenses:				
Cost of products	5,742	9,711	(3,969)	(40.9)%
Research and development expenses	15,156	25,160	(10,004)	(39.8)%
Selling, general and administrative expenses	23,431	22,520	911	4.0 %
Intangible asset amortization	406	610	(204)	(33.4)%
Changes in fair value of contingent consideration	3,327	2,384	943	39.6 %
Gain on sale of Hospital Products	(45,760)	—	(45,760)	(100.0)%
Restructuring (income) costs	(43)	4,600	(4,643)	(100.9)%
Total operating expense	2,259	64,985	(62,726)	(96.5)%
Operating income (loss)	20,075	(16,765)	36,840	219.7 %
Investment and other (expense) income, net	(906)	2,548	(3,454)	(135.6)%
Interest expense	(9,686)	(9,293)	(393)	(4.2)%
Loss on deconsolidation of subsidiary	—	(2,840)	2,840	100.0 %
Other expense - changes in fair value of contingent consideration payable	(435)	(496)	61	12.3 %
Income (loss) before income taxes	9,048	(26,846)	35,894	133.7 %
Income tax (provision) benefit	(9,258)	3,641	(12,899)	(354.3)%
Net income (loss)	\$ 18,306	\$ (30,487)	\$ 48,793	160.0 %
Net income (loss) per share - diluted	\$ 0.35	\$ (0.82)	\$ 1.17	142.7 %

Product sales for each of the Company's significant products for the three months ended September 30, 2020 and 2019 were as follows:

Product sales:	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Bloxiverz	\$ —	\$ 1,466	(1,466)	(100.0)%
Vazculep	—	8,786	(8,786)	(100.0)%
Akovaz	—	4,208	(4,208)	(100.0)%
Other	—	(231)	231	100.0 %
Product sales	\$ —	\$ 14,229	\$ (14,229)	(100.0)%

Product sales were \$0 for the three months ended September 30, 2020, compared to \$14,229 for the same prior year period. The decrease in product sales was due to the sale of the Hospital Products on June 30, 2020.

Product sales for each of the Company's significant products for the nine months ended September 30, 2020 and 2019 were as follows:

Product sales:	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Bloxiverz	\$ 2,201	\$ 6,392	\$ (4,191)	(65.6)%
Vazculep	10,429	27,669	(17,240)	(62.3)%
Akovaz	9,545	13,946	(4,401)	(31.6)%
Other	159	213	(54)	(25.4)%
Product sales	\$ 22,334	\$ 48,220	\$ (25,886)	(53.7)%

Product sales were \$22,334 for the nine months ended September 30, 2020, compared to \$48,220 for the same prior year period. The decline in product sales is driven by the sale of the Hospital Products on June 30, 2020 as well as lower units volumes and net selling prices for Bloxiverz through the first six months of 2020 as compared to the prior year and lower unit volumes for Vazculep during the first six months of the year as compared to the prior year. due to new competitors that entered the market.

Cost of Products:	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Cost of products	\$ —	\$ 2,823	\$ (2,823)	(100.0)%
Percentage of total revenues	n/a	19.8 %		

Cost of products decreased \$2,823 or 100.0% during the three months ended September 30, 2020 compared to the same prior year period driven by June 30, 2020 sale of the Hospital Products.

Cost of Products:	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Cost of products	\$ 5,742	\$ 9,711	\$ (3,969)	(40.9)%
Percentage of total revenues	25.7 %	20.1 %		

Cost of products decreased \$3,969 or 40.9% during the nine months ended September 30, 2020 compared to the same prior year period driven by lower sold units due to the June 30, 2020 sale of the Hospital Products.

Research and Development Expenses:	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Research and development expenses	5,569	7,539	\$ (1,970)	(26.1)%

Research and development ("R&D") expenses decreased \$1,970 or 26.1% during the three months ended September 30, 2020 as compared to the same period in 2019. This decline was driven by the completion of the FT218 clinical study during the three months ending March 31, 2020, as well as lower payroll, benefits and share-based compensation of \$400 related to the 2019 Corporate and French restructuring plans partially offset by higher API purchases of \$1,700 in the current quarter. The Company continues to invest a substantial portion of R&D in its FT218 development program.

Research and Development Expenses:	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Research and development expenses	\$ 15,156	\$ 25,160	\$ (10,004)	(39.8)%

R&D expenses decreased \$10,004 or 39.8% during the nine months ended September 30, 2020 as compared to the same period in 2019. This decline was driven by the completion of the FT218 clinical study during the three months ending March 31, 2020 and lower payroll, benefits and share-based compensation of approximately \$3,300 related to the 2019 Corporate and French restructuring plans. The Company continues to invest a substantial portion of R&D in its FT218 development program.

Selling, General and Administrative Expenses:	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Selling, general and administrative expenses	\$ 8,423	\$ 5,316	\$ 3,107	58.4 %

Selling, general and administrative (“SG&A”) expenses increased \$3,107 or 58.4% during the three months ended September 30, 2020 as compared to the same prior year period. This increase was due to an increase in consulting and professional fees of approximately \$900, an increase in market research costs of \$900, higher share-based compensation costs of \$800 and higher legal fees of \$800.

Selling, General and Administrative Expenses:	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Selling, general and administrative expenses	\$ 23,431	\$ 22,520	\$ 911	4.0 %

SG&A expenses increased \$911 or 4.0% during the nine months ended September 30, 2020 as compared to the same prior year period. This increase was primarily due to an increase in market research costs, consulting and professional fees and legal costs of approximately \$1,300, \$1,200 and \$900 respectively, partially offset by a decrease of \$2,200 of sales and marketing costs related to the exit of Noctiva during the first quarter 2019.

Intangibles Asset Amortization:	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Intangible asset amortization	\$ —	\$ 205	\$ (205)	(100.0)%

Intangible asset amortization expense for the three months ended September 30, 2019 related to the amortization of our acquired developed technology - Vazculep. This intangible asset was transferred to Exela Sterile Medicines LLC on June 30, 2020 as part of the disposition of the Hospital Products. See Note 4: Disposition of the Hospital Products.

Intangibles Asset Amortization:	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Intangible asset amortization	\$ 406	\$ 610	\$ (204)	(33.4)%

Intangible asset amortization expense for the nine months ended September 30, 2020 and 2019 relates to the amortization of our acquired developed technology - Vazculep. This intangible asset was transferred to Exela Sterile Medicines LLC on June 30, 2020 as part of the disposition of the Hospital Products. See *Note 4: Disposition of the Hospital Products*.

Changes in Fair Value of Contingent Consideration:	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Changes in fair value of contingent consideration	\$ (69)	\$ 627	\$ (696)	(111.0)%

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 these assumptions change, 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 can, and often do, change based on adjustments in current market conditions, competition and other factors. These changes can have a material impact on our unaudited condensed consolidated statements of (loss) income and balance sheet.

As a result of changes in the underlying assumptions used to determine the estimated fair values of our acquisition-related contingent consideration earn-out payments - Éclat, we recorded an expense of \$69 and income of \$627 and increased and decreased the fair value of the acquisition-related contingent consideration earn-out payments - Éclat for the three months ended September 30, 2020 and 2019, respectively. As noted in our critical accounting estimates included in the 2019 Form 10-K, there are numerous assumptions and estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These assumptions include estimates of pricing, market size, the market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows.

For the three months ended September 30, 2020, as a result of changes to these estimates when compared to the same estimates at December 31, 2019, we recorded an increase in the fair value of our contingent consideration liabilities due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

For the three months ended September 30, 2019, as a result of changes to these estimates when compared to the same estimates at December 31, 2018, we recorded a decrease in the fair value of our contingent consideration liabilities, largely due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

Changes in Fair Value of Contingent Consideration:	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Changes in fair value of contingent consideration	\$ 3,327	\$ 2,384	\$ 943	39.6 %

We compute the fair value of the contingent consideration using several significant assumptions and when these assumptions change, due to underlying market conditions, the fair value of these liabilities change as well. Each of the underlying assumptions used to determine the fair values of these contingent liabilities can, and often do, change based on adjustments in current market conditions, competition and other factors. These changes can have a material impact on our unaudited condensed consolidated statements of (loss) income and balance sheet.

As a result of changes in the underlying assumptions used to determine the estimated fair values of our acquisition-related contingent consideration earn-out payments - Éclat, we recorded an expense of \$3,327 and \$2,384 and increased the fair value of the acquisition-related contingent consideration earn-out payments - Éclat for the nine months ended September 30, 2020 and 2019, respectively. As noted in our critical accounting estimates included in the 2019 Form 10-K, there are numerous assumptions and estimates we use when determining the fair value of the acquisition-related earn-out payments - Éclat. These assumptions include estimates of pricing, market size, the market share the related products are forecast to achieve, the cost of goods related to such products and an appropriate discount rate to use when present valuing the related cash flows.

For the nine months ended September 30, 2020, as a result of changes to these estimates when compared to the same estimates at December 31, 2019, we recorded an increase in the fair value of our contingent consideration liabilities due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

For the nine months ended September 30, 2019, as a result of changes to these estimates when compared to the same estimates at December 31, 2018, we recorded an increase in the fair value of our contingent consideration liabilities, largely due to changes in certain underlying market conditions of the acquisition-related contingent consideration earn-out payments - Éclat.

	Nine Months Ended September 30,		Nine Months Ended	
			Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
Gain on Sale of Hospital Products			\$	%
Gain on sale of Hospital Products	\$ 45,760	\$ —	\$ 45,760	100.0 %

On June 30, 2020, we sold our assets, rights and interests related to Bloxiverz, Vazculep, Akovaz and Nouress to the Exela Buyer pursuant to an asset purchase agreement by and among us and the Exela Buyer. We recognized a net \$45,760 gain on this transaction. See *Note 4: Disposition of the Hospital Products*.

	Three Months Ended September 30,		Three Months Ended	
			Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
Restructuring (Income) Costs			\$	%
Restructuring (income) costs	\$ (226)	\$ 1,866	\$ (2,092)	(112.1)%

Restructuring income of \$226 and restructuring costs of \$1,866 were recognized during the three months ended September 30, 2020 and 2019, respectively. Restructuring income during the three months ended September 30, 2020, was related to share-based compensation forfeitures related to the 2019 Corporate Restructuring actions. Restructuring costs during the three months ended September 30, 2019 were primarily related to the 2019 French and Corporate Restructuring actions and mainly included severance and legal costs, see *Note 15: Restructuring Costs* for further details.

	Nine Months Ended September 30,		Nine Months Ended	
			Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
Restructuring (Income) Costs			\$	%
Restructuring (income) costs	\$ (43)	\$ 4,600	\$ (4,643)	(100.9)%

Restructuring income of \$43 and costs of \$4,600 were recognized during the nine months ended September 30, 2020 and 2019, respectively. Restructuring (income) costs were primarily related to the 2019 French and Corporate Restructuring actions and mainly included severance and legal costs, see *Note 15: Restructuring Costs* for further details.

Investment and Other (Expense) Income, net	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Investment and other (expense) income, net	\$ 213	\$ 781	\$ (568)	(72.7)%

Investment and other (expense) income, net decreased for the three months ended September 30, 2020 when compared to the same period in the prior year driven by lower realized gains on our marketable securities during the current period when compared to the prior period.

Investment and Other (Expense) Income, net	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Investment and other (expense) income, net	\$ (906)	\$ 2,548	\$ (3,454)	(135.6)%

Investment and other (expense) income, net decreased for the nine months ended September 30, 2020 when compared to the same period in the prior year driven by a \$800 legal settlement related to a bankruptcy claim, an increase in net unrealized losses on our marketable equity securities and net realized losses on our marketable securities during the current period when compared to net unrealized gains on our marketable securities during the prior period.

Interest Expense	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Interest expense	\$ 3,259	\$ 3,125	\$ 134	4.3 %

Interest expense of \$3,259 and \$3,125 for the three months end September 30, 2020 and 2019 is related to interest on the 2023 Notes that were issued in February 2018.

Interest Expense	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Interest expense	\$ 9,686	\$ 9,293	\$ 393	4.2 %

Interest expense of \$9,686 and \$9,293 for the nine months end September 30, 2020 and 2019 is related to interest on the 2023 Notes that were issued in February 2018.

Loss on Deconsolidation of Subsidiary	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020 vs. 2019			
	2020	2019	\$	%
Loss on deconsolidation of subsidiary	\$ —	\$ (2,840)	\$ 2,840	100.0 %

As a result of Specialty Pharma's bankruptcy filing on February 6, 2019, the Company concluded that it no longer controls its operations and accordingly deconsolidated this subsidiary. The Company recorded a loss on the deconsolidation during the nine months ended September 30, 2019 as a result of removing the net assets and certain liabilities of this subsidiary from our unaudited condensed consolidated financial statements. See Note 3: *Subsidiary Bankruptcy and Deconsolidation* for more discussion.

Other Expense - Changes in Fair Value of Contingent Consideration Payable	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
			2020 vs. 2019	
	2020	2019	\$	%
Other expense - changes in fair value of contingent consideration payable	\$ —	\$ (139)	\$ 139	100.0 %

We recorded expense of \$139 to increase of the fair value of these liabilities during the three months ended September 30, 2019, due to the same reasons associated with the Éclat product sales forecasts as described in the section “Changes in Fair Value of Related Party Contingent Consideration” for these periods. As noted in our critical accounting estimates section included in our 2019 Form 10-K, there are a number of assumptions and estimates we use when determining the fair value of the contingent consideration payable payments. These estimates include pricing, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates often do change based on changes in current market conditions, competition and other factors.

The items accounting for the difference between the income tax benefit computed at the statutory rate and the Company’s effective tax rate for the three months ended September 30, 2020 and 2019, are as follows:

Other Expense - Changes in Fair Value of Contingent Consideration Payable	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
			2020 vs. 2019	
	2020	2019	\$	%
Other expense - changes in fair value of contingent consideration payable	\$ (435)	\$ (496)	\$ 61	12.3 %

We recorded expense of \$435 and \$496 to increase the fair value of these liabilities during the nine months ended September 30, 2020 and 2019, respectively, due to the same reasons associated with the Éclat product sales forecasts as described in the section “Changes in Fair Value of Related Party Contingent Consideration” for these periods. As noted in our critical accounting estimates section included in our 2019 Form 10-K, there are a number of assumptions and estimates we use when determining the fair value of the contingent consideration payable payments. These estimates include pricing, market size, the market share the related products are forecast to achieve and an appropriate discount rate to use when present valuing the related cash flows. These estimates often do change based on changes in current market conditions, competition and other factors.

Income Tax (Benefit) Provision:	Three Months Ended September 30,		Three Months Ended Increase / (Decrease)	
			2020 vs. 2019	
	2020	2019	\$	%
Income tax (benefit) provision	\$ (5,040)	\$ 2,234	\$ (7,274)	(325.6)%
Percentage of loss before income taxes	(30.1)%	33.6 %		

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 income tax expense was \$2,234 for the three months ended September 30, 2019 resulting in an effective tax rate of (33.6%). The net increase in the effective income tax rate for the three months ended September 30, 2020, as compared to the same period in 2019, was primarily due to decreased income in the U.S. due to the sale of the Hospital Products.

Income Tax (Benefit) Provision:	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Income tax (benefit) provision	\$ (9,258)	\$ 3,641	\$ (12,899)	(354.3)%
Percentage of income before income taxes	(102.3)%	(13.7)%		

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 income tax provision was \$3,641 for the nine months ended September 30, 2019 resulting in an effective tax rate of (13.7%). The net decrease in the effective income tax rate for the nine months ended September 30, 2020, as compared to the same period in 2019, is primarily due to the discrete tax benefits recognized under the CARES Act as described above, favorable income tax benefits from the U.S. Orphan Drug and Research & Development Tax Credit, which did not occur during the nine months ended September 30, 2019, partially offset by increased income in the U.S. due to the sale of the Hospital Products during the nine months ended September 30, 2020.

Liquidity and Capital Resources

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

Net cash (used in) provided by:	Nine Months Ended September 30,		Nine Months Ended Increase / (Decrease)	
	2020	2019	2020 vs. 2019	
			\$	%
Operating activities	\$ (29,609)	\$ (30,072)	\$ 463	1.5 %
Investing activities	(76,962)	33,553	(110,515)	(329.4)%
Financing activities	179,500	14	179,486	1,282,042.9 %

Operating Activities

Net cash used in operating activities of \$29,609 for the nine months ended September 30, 2020 decreased \$463 compared to the same prior year period. This decrease in cash used in operating cash flow is driven by cash collection on all outstanding accounts receivable subsequent to the sale of the hospital products, as well as the \$2,750 installment payment received from Exela during the three months ended September 30, 2020.

Investing Activities

Cash used in investing activities was \$76,962 for the nine months ended September 30, 2020 compared to cash provided by investing activities of \$33,553 for the nine months ended September 30, 2019. Cash used in investing activities for the nine months ended September 30, 2020 was driven by higher net purchases of marketable securities during the current quarter, partially offset by proceeds received from the disposition of the Hospital Products. Cash provided by investing activities for the nine months ended September 30, 2019 was due to net proceeds from the sales of marketable securities.

Financing Activities

Cash provided by financing activities for the nine months ended September 30, 2020 was \$179,500 and was driven by the May public offering that resulted in net proceeds of \$116,924, the February private placement that resulted in net proceeds of \$60,570, and stock option exercises of \$1,829.

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, our Hospital Products revenue stream and other factors set forth in "Risk Factors" within Part I, Item 1A of the 2019 Form 10-K and within Part II, Item 1A of this quarterly report on Form 10-Q. To complete the FT218 clinical development plan and to ensure an adequate and robust NDA for filing with the FDA 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 that COVID-19, which may have a material adverse impact on our business.

In February 2020, we announced that we had entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares (“Series A Preferred”) in a private placement to a group of institutional accredited investors. The private placement resulted in gross proceeds of approximately \$65,000 before deducting placement agent and other offering expenses, which resulted in net proceeds of \$60,570.

Also, in February 2020, we filed a shelf registration statement on Form S-3 that allows issuance and sale by us, from time to time, of :

- up to \$250,000 in aggregate of ordinary shares, nominal value US\$0.01 per share (the “Ordinary Shares”), each of which may be represented by ADSs, preferred shares, nominal value US\$0.01 per share (the “Preferred Shares”), debt securities (the “Debt Securities”), warrants to purchase Ordinary Shares, ADSs, Preferred Shares and/or Debt Securities (the “Warrants”), and/or units consisting of Ordinary Shares, ADSs, Preferred Shares, one or more Debt Securities or Warrants in one or more series, in any combination, pursuant to the terms of the 2020 Shelf Registration Statement, the base prospectus contained in the 2020 Shelf Registration Statement (the “Base Prospectus”), and any amendments or supplements thereto (together, the “Securities”); including
- up to \$50,000 of ADSs that may be issued and sold from time to time pursuant to the terms of an Open Market Sale AgreementSM (“the Sales Agreement”), entered into with Jefferies LLC on February 4, 2020, the 2020 Shelf Registration Statement, the Base Prospectus and the terms of the sales agreement prospectus contained in the 2020 Shelf Registration Statement.

On April 28, 2020, we announced the pricing of an underwritten public offering of 11,630 ordinary shares, in the form of American Depositary Shares (“ADSs”) at a price to the public of \$10.75 per ADS. Each ADS represents the right to receive one ordinary share. All of the ADSs are being offered by Avadel. The gross proceeds to us from the offering was approximately \$125,000, before deducting underwriting discounts and commissions and estimated offering expenses, which resulted in net proceeds of approximately \$116,924.

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, 2020 and unused financing sources are expected to provide the Company with the flexibility to meet its liquidity needs in 2020, 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, 2020 and December 31, 2019, 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.

Litigation Related to Noctiva

Note 3: Subsidiary Bankruptcy and Deconsolidation briefly describes the Chapter 11 bankruptcy case which our subsidiary Specialty Pharma commenced on February 6, 2019, and which on April 26, 2019 resulted in the bankruptcy court-approved sale of all of Specialty Pharma’s intangible assets and inventory to an unaffiliated third party. As a result of such sale, Specialty Pharma has completed its divestment of the assets of the Noctiva business. During the pendency of the bankruptcy case, all pending litigation against Specialty Pharma is automatically stayed and any new litigation against Specialty Pharma is precluded unless the bankruptcy court orders otherwise. There is currently no pending or threatened litigation or disputes to

which Specialty Pharma is or would be a party. All prior litigation and disputes involving Specialty Pharma have been dismissed or resolved.

Material Commitments

We have been relieved of all purchase commitments disclosed in *Note 16: Contingent Liabilities and Commitments* to the Company's audited consolidated financial statements included in Part II, Item 8 of the Company's 2019 Annual Report on Form 10-K due to the sale of the Hospital Products described in *Note 4: Disposition of the Hospital Products*.

During the three months ended September 30, 2020, we entered into a commitment with a contract manufacturer related to the purchase and validation of equipment to be used in the manufacture of FT218. The total cost of this commitment is estimated to be approximately \$3,800 and is expected to be completed by the end of 2021.

Material commitments in the normal course of business include long-term debt obligations which are disclosed in *Note 11: Long-Term Debt* to the Company's unaudited condensed consolidated financial statements. Our long-term contingent consideration payable as disclosed in *Note 10: Contingent Consideration Payable* has also been relieved due to the sale of the Hospital Products.

Contractual Obligations

Disclosures regarding contractual obligations are included in Part II, Item 7 of the Company's 2019 Annual Report on Form 10-K and updated in *Note 10: Contingent Consideration Payable* to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this Report.

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, 2020, 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, 2020.

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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We continue

to work from home due to the COVID-19 pandemic and will continue to monitor the impact on the design and operating effectiveness of our internal controls.

PART II – OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

The information contained in *Note 20: Commitments and Contingencies* to the Company's unaudited condensed consolidated financial statements included in Part I, Item 1 of this Report is incorporated by reference herein.

ITEM 1A. RISK FACTORS.

Except as set forth below, there have been no material changes in our risk factors from those disclosed in our annual report on Form 10-K for the year ended December 31, 2019 filed with the SEC on March 16, 2020.

COVID-19 may materially and adversely affect our business and our financial results.

The recent COVID-19 pandemic is understood to have originated in Wuhan, China in December 2019 and has since spread globally, including to the United States and European countries. The continued spread of COVID-19 could adversely impact our operations, including our ability to initiate or complete clinical trials, manufacture sufficient supply of our product candidates, file our New Drug Application, or NDA, for FT218 or to manufacture FT218 at sufficient scale for commercialization, if approved. Any delay in submission of our NDA could adversely affect our ability to obtain regulatory approval for and to commercialize FT218, particularly on our current projected timelines, increase our operating expenses and have a material adverse effect on our business and financial results.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions, social distancing and business shutdowns. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely. We have already suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. These measures could negatively affect our business. For instance, temporarily requiring all employees to work remotely may induce absenteeism, disrupt our operations or increase the risk of a cybersecurity incident. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we or our third party suppliers and contract manufacturers, or contract research organizations operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition.

Disruptions at the FDA, the SEC 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 June 23, 2020, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to maintain this pace and delays or setbacks are possible in the future. On July 10, 2020, the FDA announced its goal of restarting domestic on-site inspections during the week of July 20, but such activities will depend on data about the virus' trajectory in a given state and locality and the rules and guidelines that are put in place by state and local governments. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. Should FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel, FDA has stated that it generally intends to issue a complete response letter. Further, if there is inadequate information to make a determination on the acceptability of a facility, FDA may defer action on the application until an inspection can be completed. 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 candidates.

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

Securities Purchase Agreement

On February 21, 2020, we announced that we entered into a definitive agreement for the sale of our ADSs and Series A Non-Voting Convertible Preferred Shares (“Series A Preferred”) in a private placement to a group of institutional accredited investors. The private placement resulted in gross proceeds of approximately \$65,000 before deducting placement agent and other offering expenses which resulted in net proceeds of \$60,570.

Pursuant to the terms of the private placement, we issued 8,680,225 ADSs and 487,614 shares of Series A Preferred at a price of \$7.09 per share, priced at-the-market under Nasdaq rules. Each share of non-voting Series A Preferred is convertible into one ADS, provided that conversion will be prohibited if, as a result, the holder and its affiliates would own more than 9.99% of the total number of Avadel ADSs outstanding. The closing of the private placement occurred on February 25, 2020. Proceeds from the private placement will be used to fund continued clinical and program development of FT218, including our open-label extension study for REST-ON, a switch study to evaluate patients switching from twice-nightly sodium oxybate to once-nightly FT218, as well as for general corporate purposes.

The private placement was exempt from registration pursuant to Section 4(a)(2) of the Securities Act as a transaction by an issuer not involving a public offering.

In connection with the shelf registration statement, on April 28, 2020 we announced the pricing of an underwritten public offering of 11,630,000 ADSs at a price to the public of \$10.75 per ADS. Each ADS represents the right to receive one Ordinary Share. All of the ADSs were offered by us and the gross proceeds to us from the offering were approximately \$125,000, before deducting underwriting discounts and commissions and offering expenses, which resulted in net proceeds of \$116,924. The offering closed on May 1, 2020.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES.

None.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

<u>Exhibit No.</u>	<u>Description</u>
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 9, 2020

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

Date: November 9, 2020

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

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

I, Gregory J. Divis, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2020

/s/ Gregory J. Divis

Gregory J. Divis

Chief Executive Officer

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

I, Thomas S. McHugh, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 9, 2020

/s/ Thomas S. McHugh

Thomas S. McHugh

Senior Vice President and Chief Financial Officer

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

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the “Company”) for the period ended September 30, 2020 (the “Report”), the undersigned hereby certifies in his capacity as Chief Executive Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

Date: November 9, 2020

/s/ Gregory J. Divis

Gregory J. Divis

Chief Executive Officer

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

In connection with the Quarterly Report on Form 10-Q of Avadel Pharmaceuticals plc (the “Company”) for the period ended September 30, 2020 (the “Report”), the undersigned hereby certifies in his capacity as Chief Financial Officer of the Company pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

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

Date: November 9, 2020

/s/ Thomas S. McHugh

Thomas S. McHugh

Senior Vice President and Chief Financial Officer