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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2021

☐ **TRANSITION REPORT UNDER SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to .

Commission File Number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification Number)

210 Main Street West
Baudette, Minnesota 56623
(Address of principal executive offices)

(218) 634-3500
(Registrant's telephone number including area code)

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

Title of each class:	Trading Symbol(s)	Name of each exchange on which registered:
Common Stock	ANIP	Nasdaq Global Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

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

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

As of October 25, 2021 there were 12,740,853 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended September 30, 2021

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such statements include, but are not limited to, the announcement and pendency of the acquisition of Novitium Pharma LLC ("Novitium"), statements about future operations, strategies and growth potential, the revenue potential (licensing, royalty and sales) of products we sell, development timelines, expected timeframe for submission of new drug applications or supplemental new drug applications to the U.S. Food and Drug Administration (the "FDA"), pipeline or potential markets for our products, selling and marketing strategies and associated costs to commercially launch Purified Cortrophin™ Gel,, impact of accounting principles, litigation expenses, liquidity and capital resources, the impact of the novel coronavirus ("COVID-19") global pandemic on our business, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words, and the use of future dates. Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including those discussed in the "Risk Factors" section in Part I, Item 1A.of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 and our Quarterly Reports on Form 10-Q for the three months ended March 31, 2021 and June 30, 2021, as well as those discussed elsewhere in this Quarterly Report on Form 10-Q, and the following factors:

- *the ability of the parties to complete the announced acquisition of Novitium or delay in the completion of the acquisition;*
- *risks that we may face with respect to importing raw materials;*
- *delays or failure in obtaining approvals by the FDA of the products we sell;*
- *changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls;*
- *the ability of our manufacturing partners to meet our product demands and timelines;*
- *our dependence on single source suppliers of ingredients due to the time and cost to validate a second source of supply;*
- *acceptance of our products at levels that will allow us to achieve profitability;*
- *our ability to develop, license or acquire, and commercialize new products;*
- *the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products;*
- *our ability to protect our intellectual property rights;*
- *the impact of legislative or regulatory reform on the pricing for pharmaceutical products;*
- *the impact of any litigation to which we are, or may become, a party;*
- *our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries;*

- *our ability to maintain the services of our key executives and other personnel; and*

- *general business and economic conditions and the effects and duration of outbreaks of public health emergencies, such as COVID-19.*

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2020, including the factors described in "Item 1A. Risk Factors." Other risks may be described from time to time in our filings made under the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

The Company may use its investor relations website as a distribution channel of material company information. Financial and other important information regarding the Company is routinely posted on and accessible through the Company's investor relations website. We encourage investors and others interested in our company to review the information we post on our investor relations website in addition to filings with the Securities and Exchange Commission, press releases, public conference calls and webcasts. Information contained on the Company's website is not included as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

NOTE REGARDING TRADEMARKS

Apexicon®, Cortenema®, Purified Cortrophin™ Gel, Cortrophin-Zinc®, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, Vancocin®, and VEREGEN® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries. Atacand® and Atacand HCT® are the property of AstraZeneca AB and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Arimidex® and Casodex® are the property of AstraZeneca UK Limited and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. OXISTAT® is the property of Fougera Pharmaceuticals Inc. and licensed to ANI Pharmaceuticals, Inc. for U.S. sales of OXISTAT® Lotion. Pandel® is property of Taisho Pharmaceutical Co, Ltd. and licensed to ANI Pharmaceuticals for U.S. sales of Pandel® creme.

Part I — FINANCIAL INFORMATION

Item 1. Financial Statements

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	September 30, 2021	*December 31, 2020*
Assets		
Current Assets		
Cash and cash equivalents	$ 15,254	$ 7,864
Accounts receivable, net of $108,456 and $100,328 of adjustments for chargebacks and other allowances at September 30, 2021 and December 31, 2020, respectively	106,714	95,793
Inventories, net	61,684	60,803
Prepaid income taxes	3,030	—
Prepaid expenses and other current assets	4,702	5,861
Total Current Assets	191,384	170,321
Property and equipment	60,816	58,797
Accumulated depreciation	(21,290)	(17,528)
Property and equipment, net	39,526	41,269
Restricted cash	5,001	5,003
Deferred tax assets, net of deferred tax liabilities and valuation allowance	60,196	51,704
Intangible assets, net	170,141	188,511
Goodwill	3,580	3,580
Other non-current assets	626	802
Total Assets	$ 470,454	$ 461,190
Liabilities and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 15,927	$ 13,243
Accounts payable	11,513	11,261
Accrued royalties	3,996	6,407
Accrued compensation and related expenses	4,539	6,231
Current income taxes payable, net	—	3,906
Accrued government rebates	11,713	7,826
Returned goods reserve	32,229	27,155
Deferred revenue	62	80
Accrued expenses and other	4,893	2,456
Total Current Liabilities	84,872	78,565
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	186,063	172,443
Derivatives and other non-current liabilities	8,116	14,482
Total Liabilities	$ 279,051	$ 265,490
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 12,823,515 shares issued and 12,740,853 outstanding at September 30, 2021; 12,429,916 shares issued and 12,354,398 shares outstanding at December 31, 2020	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	—	—
Treasury stock, 82,662 shares of common stock, at cost, at September 30, 2021 and 75,518 shares of common stock, at cost, at December 31, 2020	(3,135)	(2,246)
Additional paid-in capital	222,211	214,354
Accumulated deficit	(23,439)	(4,972)
Accumulated other comprehensive loss, net of tax	(4,235)	(11,437)
Total Stockholders' Equity	191,403	195,700
Total Liabilities and Stockholders' Equity	$ 470,454	$ 461,190

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	2021	***2020***	***2021***	***2020***
Net Revenues	$ 52,061	$ 52,979	$ 155,207	$ 151,223
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	24,413	20,118	66,712	62,617
Research and development	2,456	2,939	8,229	12,318
Selling, general, and administrative	17,181	15,725	53,588	50,621
Depreciation and amortization	11,346	11,358	33,568	33,739
Legal settlement expense	—	—	8,400	—
Purified Cortrophin Gel pre-launch charges	227	37	780	8,275
Total Operating Expenses	55,623	50,177	171,277	167,570
Operating (Loss)/Income	(3,562)	2,802	(16,070)	(16,347)
Other Expense, net				
Interest expense, net	(2,497)	(2,510)	(7,482)	(6,898)
Other expense, net	(1,071)	(229)	(1,653)	(335)
(Loss)/Income Before Benefit for Income Taxes	(7,130)	63	(25,205)	(23,580)
Benefit for income taxes	2,683	371	6,738	4,667
Net (Loss)/Income	$ (4,447)	$ 434	$ (18,467)	$ (18,913)
Basic and Diluted (Loss)/Earnings Per Share:				
Basic (Loss)/Earnings Per Share	$ (0.37)	$ 0.04	$ (1.53)	$ (1.58)
Diluted (Loss)/Earnings Per Share	$ (0.37)	$ 0.04	$ (1.53)	$ (1.58)
Basic Weighted-Average Shares Outstanding	12,107	11,991	12,066	11,953
Diluted Weighted-Average Shares Outstanding	12,107	12,003	12,066	11,953

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Comprehensive Income/(Loss)
(in thousands)
(unaudited)

	Three Months Ended September 30,		***Nine Months Ended September 30,***	
	2021	***2020***	***2021***	***2020***
Net (loss)/income	$ (4,447)	$ 434	$ (18,467)	$ (18,913)
Other comprehensive income/(loss), net of tax:				
Gains/(losses) on interest rate swap, net of tax	1,198	939	7,202	(8,239)
Total other comprehensive income/(loss), net of tax	1,198	939	7,202	(8,239)
Total comprehensive (loss)/income, net of tax	$ (3,249)	$ 1,373	$ (11,265)	$ (27,152)

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Three Months Ended September 30, 2021 and 2020
(in thousands)
(unaudited)

	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Other Comprehensive Gain/(Loss), Net of Tax	Accumulated Deficit	Total
Balance, June 30, 2020	$ 1	12,380	$ —	$ 209,409	58	$ (2,246)	$ (14,049)	$ (1,771)	$191,344
Stock-based Compensation Expense	—	—	—	2,383	—	—	—	—	2,383
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	18	—	—	—	—
Issuance of Restricted Stock Awards	—	43	—	—	—	—	—	—	—
Gains on Interest Rate Swap	—	—	—	—	—	—	939	—	939
Net Income	—	—	—	—	—	—	—	434	434
Balance, September 30, 2020	$ 1	12,423	$ —	$ 211,792	76	$ (2,246)	$ (13,110)	$ (1,337)	$195,100
Balance, June 30, 2021	$ 1	12,826	$ —	$ 219,403	80	$ (3,062)	$ (5,433)	$ (18,992)	$191,917
Stock-based Compensation Expense	—	—	—	2,808	—	—	—	—	2,808
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	3	(73)	—	—	(73)
Issuance of Restricted Stock Awards	—	6	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	(8)	—	—	—	—	—	—	—
Gains on Interest Rate Swap	—	—	—	—	—	—	1,198	—	1,198
Net Loss	—	—	—	—	—	—	—	(4,447)	(4,447)
Balance, September 30, 2021	$ 1	12,824	$ —	$ 222,211	83	$ (3,135)	$ (4,235)	$ (23,439)	$191,403

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Nine Months Ended September 30, 2021 and 2020
(in thousands)
(unaudited)

	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Other Comprehensive (Loss)/Gain, Net of Tax	Retained Earnings/ (Accumulated Deficit)	Total
Balance, December 31, 2019	$ 1	12,105	$ —	$ 200,800	15	$ (723)	$ (4,871)	$ 17,584	$212,791
Cumulative Effect of Change in Accounting Principle, Net of Tax	—	—	—	—	—	—	—	(8)	(8)
Stock-based Compensation Expense	—	—	—	10,543	—	—	—	—	10,543
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	61	(1,523)	—	—	(1,523)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	14	—	449	—	—	—	—	449
Issuance of Restricted Stock Awards	—	304	—	—	—	—	—	—	—
Losses on Interest Rate Swap	—	—	—	—	—	—	(8,239)	—	(8,239)
Net Loss	—	—	—	—	—	—	—	(18,913)	(18,913)
Balance, September 30, 2020	$ 1	12,423	$ —	$ 211,792	76	$ (2,246)	$ (13,110)	$ (1,337)	$195,100
Balance, December 31, 2020	$ 1	12,430	$ —	$ 214,354	76	$ (2,246)	$ (11,437)	$ (4,972)	$195,700
Stock-based Compensation Expense	—	—	—	7,521	—	—	—	—	7,521
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	28	(889)	—	—	(889)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	12	—	336	—	—	—	—	336
Issuance of Restricted Stock Awards	—	463	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	(81)	—	—	(21)	—	—	—	—
Gains on Interest Rate Swap	—	—	—	—	—	—	7,202	—	7,202
Net Loss	—	—	—	—	—	—	—	(18,467)	(18,467)
Balance, September 30, 2021	$ 1	12,824	$ —	$ 222,211	83	$ (3,135)	$ (4,235)	$ (23,439)	$191,403

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Nine Months Ended September 30, 2021	2020
Cash Flows From Operating Activities		
Net loss	$ (18,467)	$ (18,913)
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	7,521	10,543
Deferred taxes	(8,665)	(9,032)
Depreciation and amortization	33,568	33,739
Acquired in-process research and development ("IPR&D")	—	3,753
Non-cash interest	1,718	1,288
Asset impairment charge	—	104
Changes in operating assets and liabilities, net of acquisitions:		
Accounts receivable, net	(10,921)	(11,616)
Inventories, net	8,773	(1,151)
Prepaid expenses and other current assets	1,421	637
Accounts payable	396	(146)
Accrued royalties	(2,411)	1,004
Current income taxes payable, net	(6,936)	(545)
Accrued government rebates	3,887	2,777
Returned goods reserve	5,091	6,456
Accrued expenses, accrued compensation, and other	532	2,078
Net Cash and Cash Equivalents Provided by Operating Activities	15,507	20,976
Cash Flows From Investing Activities		
Acquisition of product rights, IPR&D, and other related assets	(21,069)	(62,178)
Acquisition of property and equipment, net	(2,201)	(4,025)
Net Cash and Cash Equivalents Used in Investing Activities	(23,270)	(66,203)
Cash Flows From Financing Activities		
Payments on Term Loan and Delayed Draw Term Loan agreements	(8,034)	(5,657)
Borrowings under Revolver agreement	24,000	15,000
Payments on Revolver agreement	—	(7,500)
Proceeds from stock option exercises and ESPP purchases	336	449
Payments of debt issuance costs	(262)	—
Treasury stock purchases for restricted stock vests	(889)	(1,523)
Net Cash and Cash Equivalents Provided by Financing Activities	15,151	769
Net Change in Cash and Cash Equivalents	7,388	(44,458)
Cash and cash equivalents, beginning of period	12,867	67,361
Cash and cash equivalents, end of period	$ 20,255	$ 22,903
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	$ 7,864	$ 62,332
Restricted cash	5,003	5,029
Cash, cash equivalents, and restricted cash, beginning of period	$ 12,867	$ 67,361
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	$ 15,254	$ 17,900
Restricted cash	5,001	5,003
Cash, cash equivalents, and restricted cash, end of period	$ 20,255	$ 22,903
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 5,922	$ 5,080
Cash paid for income taxes	$ 8,360	$ 4,878
Supplemental non-cash investing and financing activities:		
Acquisition of product rights, IPR&D, and other related assets included in returned goods reserve and derivatives and other non-current liabilities	$ —	$ 399
Property and equipment purchased and included in accounts payable	$ 28	$ 223

The accompanying notes are an integral part of these condensed consolidated financial statements.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (together, "ANI," the "Company," "we," "us," or "our"), is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. We focus on niche and high barrier to entry opportunities, including controlled substances, oncology products (anti-cancer), hormones and steroids, and complex formulations. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations, comprehensive income, and cash flows. The consolidated balance sheet at December 31, 2020 has been derived from audited financial statements as of that date. The unaudited interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the U.S. Securities and Exchange Commission (the "SEC"). We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our Annual Report on Form 10-K for the year ended December 31, 2020.

Principles of Consolidation

The unaudited interim condensed consolidated financial statements include the accounts of ANI Pharmaceuticals, Inc. and its subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

Foreign Currency

We have a subsidiary located in Canada. The subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar. The results of any non-U.S. dollar transactions are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. Our gain or loss on transactions denominated in foreign currencies was immaterial for the three and nine months ended September 30, 2021 and 2020. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited interim condensed consolidated financial statements, estimates are

used for, but not limited to, stock-based compensation, revenue recognition, allowance for credit losses, variable consideration determined based on accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, income tax provision or benefit, deferred taxes and valuation allowance, determination of right-of-use assets and lease liabilities, purchase price allocations, and the depreciable lives of long-lived assets. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

We are subject to risks and uncertainties as a result of the novel coronavirus ("COVID-19") pandemic. We are unable to predict the impact that the COVID-19 pandemic will continue to have on our future business, financial condition, and results of operations due to numerous uncertainties. These uncertainties include the occurrence of recurring outbreaks and their severity and the duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. We remain unable to predict the future impact on our estimates and assumptions. There was no material impact to these estimates or assumptions in our consolidated financial statements as of and for the three and nine months ended September 30, 2021 and 2020. Actual results could differ from those estimates, which may change our estimates in future periods. We continue to closely monitor the impact of the COVID-19 pandemic on our business.

Geographic Information

Based on the distinct nature of our operations, our internal management structure, and the financial information that is evaluated regularly by our Chief Operating Decision Maker, we determined that we operate in one reportable segment. Our operations are located in the United States and Canada. The majority of the assets of the Company are located in the United States.

The following table depicts the Company's revenue by geographic operations during the following periods:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
Location of Operations	2021	2020	2021	2020
United States	$ 51,100	$ 52,094	$ 152,007	$ 146,602
Canada	961	885	3,200	4,621
Total Revenue	$ 52,061	$ 52,979	$ 155,207	$ 151,223

The following table depicts the Company's property and equipment, net according to geographic location as of:

(in thousands)	September 30, 2021	December 31, 2020
United States	$ 25,512	$ 26,960
Canada	14,014	14,309
Total property and equipment, net	$ 39,526	$ 41,269

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

We have evaluated all issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our condensed consolidated statements of operations, comprehensive income, balance sheets, or cash flows.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued guidance simplifying the accounting for certain financial instruments with characteristics of liabilities and equity, including certain convertible instruments and contracts on an entity's own equity. The new standard removes the separation models required for convertible debt with cash conversion features and convertible instruments with beneficial conversion features. It also removes certain settlement conditions that are currently required for equity contracts to qualify for the derivative scope exception and simplifies the diluted earnings per share calculation for convertible instruments. We early adopted this guidance as of January 1, 2021. The adoption of this guidance did not have a material impact on our consolidated financial statements but will impact how we account for newly issued convertible instruments in future periods.

In November 2019, the FASB issued guidance simplifying the accounting for income taxes by removing the following exceptions: 1) exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items, 2) exception requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes an equity method investment, 3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary, and 4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss for the year. The amendments also simplify accounting for income taxes by doing the following: 1) requiring that an entity recognize a franchise tax or similar tax that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, 2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction, 3) specifying that an entity is not required to allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements, 4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, and 5) making minor Codification improvements for income taxes related to employee stock ownership plans and investments in qualified affordable housing projects accounted for using the equity method. Most of the provisions of this guidance were to be adopted on a prospective basis. Items 2) and 3) of the "removal" provisions were to be adopted on either a full or modified retrospective basis and item 4) of the "simplifying" provisions was to be adopted on a full retrospective basis. The guidance was effective for reporting periods beginning after December 15, 2020, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2021. The adoption of this guidance did not have a material impact on our consolidated financial statements.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

We recognize revenue using the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price, including the identification and estimation of variable consideration;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when we satisfy a performance obligation.

We derive our revenues primarily from sales of generic and branded pharmaceutical products. Revenue is recognized when our obligations under the terms of our contracts with customers are satisfied, which generally occurs when control of the products we sell is transferred to the customer. We estimate variable consideration after considering applicable information that is reasonably available. We generally do not have incremental costs to

obtain contracts that would otherwise not have been incurred. We do not adjust revenue for the promised amount of consideration for the effects of a significant financing component because our customers generally pay us within 100 days.

All revenue recognized in the accompanying unaudited interim condensed consolidated statements of operations is considered to be revenue from contracts with customers. The following table depicts the disaggregation of revenue:

	Three Months Ended		Nine Months Ended	
Products and Services (in thousands)	**September 30, 2021**	**September 30, 2020**	**September 30, 2021**	**September 30, 2020**
Sales of generic pharmaceutical products	$ 35,140	$ 37,712	$ 101,952	$ 108,607
Sales of branded pharmaceutical products	14,313	12,411	32,868	32,201
Sales of contract manufactured products	2,382	2,152	7,277	7,026
Royalties from licensing agreements	—	339	11,210	1,120
Product development services	77	289	332	1,751
Other	149	76	1,568	518
Total net revenues	$ 52,061	$ 52,979	$ 155,207	$ 151,223

	Three Months Ended		Nine Months Ended	
Timing of Revenue Recognition (in thousands)	**September 30, 2021**	**September 30, 2020**	**September 30, 2021**	**September 30, 2020**
Performance obligations transferred at a point in time	$ 51,984	$ 52,690	$ 154,875	$ 149,472
Performance obligations transferred over time	77	289	332	1,751
Total	$ 52,061	$ 52,979	$ 155,207	$ 151,223

In the three and nine months ended September 30, 2021 and 2020, we did not incur, and therefore did not defer, any material incremental costs to fulfill contracts. We recognized an increase of $11.0 million to net revenue from performance obligations satisfied in prior periods during the nine months ended September 30, 2021, consisting primarily of a final $11.2 million royalty revenue related to the Kite license agreement pursuant to the Tripartite Agreement as defined and described herein in *Royalties from Licensing Agreements,* which was partially offset by a decrease related to revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We recognized a decrease of $8.7 million of net revenue from performance obligations satisfied in prior periods during the nine months ended September 30, 2020, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We provide technical transfer services to customers, for which services are transferred over time. As of September 30, 2021 and December 31, 2020, we did not have any contract assets related to revenue recognized based on percentage of completion but not yet billed. We had $0.1 million of deferred revenue at September 30, 2021 and December 31, 2020. For the three and nine months ended September 30, 2021, we recognized less than $0.1 million of revenue that was included in deferred revenue as of December 31, 2020. For the three and nine months ended September 30, 2020, we recognized $0.1 million and $0.3 million, respectively, of revenue that was included in deferred revenue as of December 31, 2019.

Revenue from Sales of Generic and Branded Pharmaceutical Products

Product sales consists of sales of our generic and brand pharmaceutical products. Our sole performance obligation in our contracts is to provide pharmaceutical products to customers. Our products are sold at pre-determined

standalone selling prices and our performance obligation is considered to be satisfied when control of the product is transferred to the customer. Control is generally transferred to the customer upon delivery of the product to the customer, as our pharmaceutical products are generally sold on an FOB destination basis and because inventory risk and risk of ownership passes to the customer upon delivery. Payment terms for these sales are generally less than 100 days.

Sales of our pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative and other rebates, and cash discounts. Estimates for these elements of variable consideration require significant judgment. A comprehensive discussion of variable consideration is included in Part II, Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2020.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the nine months ended September 30, 2021 and 2020, respectively:

	Accruals for Chargebacks, Returns, and Other Allowances				
(in thousands)	**Chargebacks**	**Government Rebates**	**Returns**	**Administrative Fees and Other Rebates**	**Prompt Payment Discounts**
Balance at December 31, 2019 (1)	$ 49,882	$ 8,901	$ 16,595	$ 8,281	$ 2,549
Accruals/Adjustments	288,538	14,288	22,744	27,383	10,248
Credits Taken Against Reserve	(262,531)	(11,511)	(16,089)	(27,287)	(9,442)
Balance at September 30, 2020 (1)	$ 75,889	$ 11,678	$ 23,250	$ 8,377	$ 3,355
Balance at December 31, 2020 (1)	$ 88,746	$ 7,826	$ 27,155	$ 8,906	$ 3,839
Accruals/Adjustments	343,117	31,515	16,043	74,594	31,138
Credits Taken Against Reserve	(333,867)	(27,628)	(10,969)	(75,877)	(30,876)
Balance at September 30, 2021 (1)	$ 97,996	$ 11,713	$ 32,229	$ 7,623	$ 4,101

(1) Chargebacks are included as an offset to accounts receivable in the unaudited condensed consolidated balance sheets. Administrative Fees and Other Rebates and Prompt Payment Discounts are included as an offset to accounts receivable or as accrued expenses and other in the unaudited condensed consolidated balance sheets. Returns are included in returned goods reserve in the unaudited condensed consolidated balance sheets. Government Rebates are included in accrued government rebates in the unaudited condensed consolidated balance sheets.

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consist of agreements in which we manufacture a pharmaceutical product on behalf of a third party. Our performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The contract manufactured products are sold at pre-determined standalone selling prices and our performance obligations are considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves our dock to be shipped to the customer, as our contract manufactured pharmaceutical products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally fewer than two months. We estimate returns based on historical experience. Historically, we have not had material returns for contract manufactured products.

As of September 30, 2021, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $3.0 million, which consists of firm orders

for contract manufactured products. We will recognize revenue for these performance obligations as they are satisfied, which is anticipated within six months.

Royalties from Licensing Agreements

From time to time, we enter into transition agreements with the sellers of products we acquire, under which we license to the seller the right to sell the acquired products. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the sellers. Upon full transition of the products and upon launching the products under our own labels, we recognize revenue for the products as sales of generic or branded pharmaceutical products, as described above. From time to time, we enter into supply and distribution agreements with contract manufacturing customers, under which we license to the contract manufacturing customer the right to sell our products, and we are entitled to a royalty on sales made by the contract manufacturing customer under these arrangements. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the contract manufacturing customers.

Pursuant to a 2012 Tripartite Agreement (the "Tripartite Agreement") between the Company, The Regents of the University of California ("The Regents"), and Cabaret Biotech Ltd., an Israeli corporation ("Cabaret") (as assignee of Dr. Zelig Eshhar's rights under the Tripartite Agreement), and subsequent amendments thereto and assignments thereof, we were entitled to receive a percentage of the milestone and sales royalty payments paid to Cabaret by Kite Pharma, Inc. ("Kite"), a subsidiary of Gilead Sciences, Inc., under a license agreement. Under such license agreement, Kite licensed from Dr. Eshhar and Cabaret the patent rights covered by the Tripartite Agreement and agreed to make certain payments to Cabaret based on, among other things, Kite's sales of Yescarta®. Under the Tripartite Agreement, portions of these payments were to be distributed to The Regents and to us.

Historically, we recorded royalty income related to Yescarta® on an accrual basis utilizing our best estimate of royalties earned based upon information available in the public domain, our understanding of the various agreements governing the royalty, and other information received from time to time from the relevant parties. Generally, cash was received directly from Cabaret once a year. The agreements governing this royalty were subject to multiple actions in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, ANI and Cabaret. In the first quarter of 2021, we became aware that the litigation between Cabaret and Kite was dismissed. In April 2021, Cabaret and the Company settled all amounts due for amounts actually received by Cabaret or Eshhar for the licensing or use of the patent rights governed by the Kite license agreement. As a result, we recognized $11.2 million as royalties from licensing agreements in our net revenues during the three month period ended March 31, 2021. In addition, we agreed to reimburse Cabaret $0.4 million, which has been recorded as other expense, net in the accompanying unaudited interim condensed consolidated statement of operations, related to certain legal expenditures incurred. We received final payment from Cabaret in May 2021. Based upon the events that led to the dismissal of the litigation between Cabaret and Kite, the Company does not expect to receive any future royalty income related to the Kite license agreement. In conjunction with payment of amounts due to us, all outstanding litigation between the Company and Cabaret were dismissed.

Product Development Services Revenue

We provide product development services to customers, which are performed over time. These services primarily relate to the technical transfer of product development to our facility in Oakville, Ontario. The duration of these technical transfer projects can be up to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a percentage of completion basis, which results in contract assets on our balance sheet. As of September 30, 2021, the aggregate

amount of the transaction price allocated to the remaining performance obligations for all open product development services contracts was $0.4 million. We expect to satisfy these performance obligations within the next six months.

Credit Concentration

Our customers are primarily wholesale distributors, chain drug stores, group purchasing organizations, and pharmaceutical companies.

During the three and nine months ended September 30, 2021 and 2020 we had three customers that accounted for 10% or more of net revenues. As of September 30, 2021, accounts receivable from these customers totaled 85% of accounts receivable, net.

The three customers represent the total percentage of net revenues as follows:

	Three Months Ended		Nine Months Ended	
	September 30, 2021	September 30, 2020	September 30, 2021	September 30, 2020
Customer 1	31 %	30 %	29 %	31 %
Customer 2	23 %	25 %	22 %	24 %
Customer 3	17 %	19 %	15 %	19 %

3. PENDING BUSINESS COMBINATION

On March 8, 2021, we entered into a definitive agreement to acquire Novitium Pharma LLC ("Novitium"), a privately held New Jersey-based pharmaceutical company with development, manufacturing, and commercial capabilities (the "Acquisition"). The closing of the Acquisition will occur (a) within five business days after all of the conditions to the closing set forth in the merger agreement are satisfied or waived or (b) at such other time, date and place as may be agreed by us and Novitium, subject to the completion of a minimum period. The closing is subject to the satisfaction of customary closing conditions and necessary regulatory approvals.

Consideration will consist of a combination of (i) an estimated cash amount of $89.5 million, subject to various adjustments and expected to be financed by a $25.0 million private placement of preferred stock (the "PIPE Investment") and by new debt financing, both described below, (ii) an aggregate of 2,466,667 shares of ANI common stock, and (iii) up to $46.5 million in contingent future earn-out payments.

We will finance the transaction with a new $340.0 million Senior Secured Credit Facility (the "New Facility"), consisting of a $300.0 million term loan and a $40.0 million revolving credit facility, the issuance of 2,466,667 shares of ANI common stock (approximately $74.0 million in value based on a $30.00 stock price) (the "Stock Consideration"), and a $25.0 million PIPE Investment by Ampersand 2020 Limited Partnership ("Ampersand"), an affiliate of Ampersand Capital Partners of which ANI's Chairman of the Board is an operating partner and as such Ampersand is a related party. At closing, we intend to use the proceeds from the New Facility to fund a portion of the Acquisition and repay all of the outstanding debt under the existing senior secured credit facility discussed in Note 4.

The New Facility will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI's existing senior credit facilities. The term loan portion of the New Facility, which was successfully syndicated on May 24, 2021, represents fully committed capital and, as such, carries a customary ticking fee that commences 45 days and 90 days post allocation. During the three and nine months ended September 30, 2021, we incurred $2.4 million in expense related to the ticking fee, all of which was recognized as other expense, net, on the unaudited interim condensed consolidated statement of operations. Amounts drawn on the

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$300.0 million term loan will bear an interest rate equal to 1-month LIBOR rate plus an applicable margin of 6.00% per annum, or an alternative base rate plus an applicable base rate margin of 5.00% per annum. Amounts drawn on the $40.0 million revolving credit facility will bear an interest rate equal to 1-month LIBOR rate plus an applicable margin of 4.75% per annum, or an alternative base rate plus an applicable base rate margin of 3.75% per annum. On the revolving credit facility, we will incur a commitment fee on any unused portion at a rate of 0.50% per annum.

As discussed in Note 5, we currently have an interest rate swap to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under our Term Loan and DDTL. We intend to retain an interest rate swap with similar structure and terms in order to manage our exposure to changes in LIBOR-based interest rates underlying a portion of borrowings under the New Facility.

Concurrently with the execution of the definitive agreement, on March 8, 2021, we entered into an Equity Commitment and Investment Agreement with Ampersand (the "PIPE Investor"), pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock (the "PIPE Shares"), for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million PIPE Investment. The issuance of shares of ANI common stock into which PIPE Shares will be convertible and the Stock Consideration for the Acquisition were approved by the ANI stockholders in June 2021.

During the three and nine months ended September 30, 2021, we incurred $0.5 million and $5.1 million, respectively, in transaction costs related to this pending Acquisition, all of which were expensed and recognized as selling, general, and administrative expenses on the unaudited interim condensed consolidated statements of operations.

4. INDEBTEDNESS

Credit Facility

Our five-year Senior Secured Credit Facility (the "Credit Facility") is comprised of a $72.2 million term loan (the "Term Loan"), a $118.0 million delayed draw term loan ("DDTL"), and a $75.0 million revolving credit facility (the "Revolver"), all of which mature in December 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse event. The Term Loan includes a repayment schedule, pursuant to which $6.8 million of the loan will be paid in quarterly installments during the 12 months ending September 30, 2022. As of September 30, 2021, $6.8 million of the Term Loan is recorded as current borrowings in the consolidated balance sheets. The DDTL includes a repayment schedule, pursuant to which $9.6 million will be paid in quarterly installments during the 12 months ending September 30, 2022. As of September 30, 2021, $9.6 million of the DDTL is recorded as current borrowings in the consolidated balance sheets. As of September 30, 2021, there is $31.5 million outstanding and payable on our Revolver, all of which is recorded as a long-term borrowing on the consolidated balance sheets. As of September 30, 2021, $43.5 million remained available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver bear an interest rate equal to, at our option, either a 1-month LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending on our total leverage ratio. On the Revolver, we incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. As of September 30, 2021, our interest rate on outstanding borrowings was 1-month LIBOR plus 2.00% and our commitment fee rate was 0.4%.

The Credit Facility is secured by a lien on substantially all of ANI Pharmaceuticals, Inc.'s and its principal domestic subsidiary's assets and any future domestic subsidiary guarantors' assets. The Credit Facility is subject to customary financial and nonfinancial covenants.

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The carrying value of the current and non-current components of the Term Loan and DDTL as of September 30, 2021 and December 31, 2020 are:

	Current	
(in thousands)	**September 30, 2021**	**December 31, 2020**
Current borrowing on debt	$ 16,355	$ 13,691
Deferred financing costs	(428)	(448)
Current debt, net of deferred financing costs	$ 15,927	$ 13,243

	Non-Current	
(in thousands)	**September 30, 2021**	**December 31, 2020**
Non-current borrowing on debt	$ 155,057	$ 165,755
Deferred financing costs	(494)	(812)
Non-current debt, net of deferred financing costs and current component	$ 154,563	$ 164,943

As of September 30, 2021, we had a $62.3 million balance on the Term Loan, $109.2 million balance on the DDTL, and $31.5 million balance on the Revolver. Of the $0.6 million of deferred debt issuance costs allocated to the Revolver, $0.3 million is included in other non-current assets in the accompanying unaudited interim condensed consolidated balance sheets and $0.3 million is included in prepaid expenses and other current assets in the accompanying unaudited interim condensed consolidated balance sheets.

The contractual maturity of our Term Loan, DDTL, and Revolver is as follows for the years ending December 31:

(in thousands)	**Term Loan**	**DDTL**	**Revolver**
2021	$ 2,707	$ 2,950	$ —
2022	5,414	8,850	—
2023	54,141	97,350	31,500
Total	$ 62,262	$ 109,150	$ 31,500

The following table sets forth the components of total interest expense related to the Term Loan, DDTL, and Revolver recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three and nine months ended September 30, 2021 and 2020:

	Three Months Ended		Nine Months Ended	
(in thousands)	**September 30, 2021**	**September 30, 2020**	**September 30, 2021**	**September 30, 2020**
Contractual coupon	$ 2,342	$ 2,351	$ 7,032	$ 6,450
Amortization of finance fees	175	180	527	542
Capitalized interest	(17)	(18)	(74)	(67)
	$ 2,500	$ 2,513	$ 7,485	$ 6,925

5. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

At times we use derivative financial instruments to hedge our exposure to interest rate risks. All derivative financial instruments are recognized as either assets or liabilities at fair value on the consolidated balance sheet and are classified as current or non-current based on the scheduled maturity of the instrument.

When we enter into a hedge arrangement and intend to apply hedge accounting, we formally document the hedge relationship and designate the instrument for financial reporting purposes as a fair value hedge, a cash flow hedge,

or a net investment hedge. When we determine that a derivative financial instrument qualifies as a cash flow hedge and is effective, the changes in fair value of the instrument are recorded in accumulated other comprehensive loss, net of tax in our consolidated balance sheets and will be reclassified to earnings when the hedged item affects earnings.

In December 2018, we refinanced our previous credit agreement and, at the same time, entered into an interest rate swap, which was considered a derivative financial instrument, with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our Term Loan. In February 2019, we entered into an interest rate swap, which was considered a derivative financial instrument, with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our DDTL. The hedges had been designated as effective cash flow hedges and qualified for hedge accounting. The interest rate swaps related to the Term Loan and DDTL had a weighted average fixed rate of 2.60% and 2.47%, respectively, with a maturity in December 2023. In April 2020, we terminated the remaining $184.2 million notional value of these interest rate swaps and are recognizing the net loss in accumulated other comprehensive loss at the time of the termination to interest expense over the remaining terms through December 2023.

At the same time in April 2020, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under our Term Loan and DDTL. The interest rate swap matures in December 2026. As of September 30, 2021, the notional amount of the interest rate swap was $171.4 million and decreases in line with maturities of our Term Loan and DDTL until December 2023, after which it remains static until maturity in 2026. The interest rate swap provides an effective fixed rate of 1.99% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. The interest rate swap effectively provides a fixed rate of interest throughout the life of our Term Loan and DDTL. As of September 30, 2021, the fair value of the interest rate swap liability was valued at $7.9 million and was recorded in derivatives and other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of September 30, 2021, $4.2 million was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets.

During the three and nine months ended September 30, 2021, the change in the fair value of the interest rate swap of $0.6 million, net of $0.3 million of tax and $4.7 million, net of $0.2 million of tax, was recorded in accumulated other comprehensive income, net of tax in our unaudited interim condensed consolidated statements of comprehensive income/(loss). Differences between the hedged 1-month LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Loan and DDTL based on the 1-month LIBOR rate. In the three and nine months ended September 30, 2021, $1.3 million and $3.7 million of interest expense was recognized in relation to the interest rate swap, respectively.

6. EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing net income (loss) available to common shareholders by the weighted-average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, we calculate diluted earnings (loss) per share by dividing net income available to common shareholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options, shares to be purchased under our Employee Stock Purchase Plan (“ESPP”), unvested restricted stock awards, and stock purchase warrants, using the treasury stock method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share.

Our unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; in periods of net income, the calculation of basic and diluted earnings (loss) per share excludes from the numerator net income (but not net loss) attributable to the unvested restricted shares, and excludes the impact of those shares from the denominator.

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Earnings (loss) per share for the three and nine months ended September 30, 2021 and 2020 are calculated for basic and diluted earnings (loss) per share as follows:

(in thousands, except per share amounts)	Basic Three Months Ended September 30,		Diluted Three Months Ended September 30,		Basic Nine Months Ended September 30,		Diluted Nine Months Ended September 30	
	2021	2020	2021	2020	2021	2020	2021	2020
Net (loss)/income	$ (4,447)	$ 434	$ (4,447)	$ 434	$ (18,467)	$ (18,913)	$ (18,467)	$ (18,913
Net income allocated to restricted stock	—	(12)	—	(13)	—	—	—	—
Net (loss)/income allocated to common shares	$ (4,447)	$ 422	$ (4,447)	$ 421	$ (18,467)	$ (18,913)	$ (18,467)	$ (18,913
Basic Weighted-Average Shares Outstanding	12,107	11,991	12,107	11,991	12,066	11,953	12,066	11,953
Dilutive effect of stock options and ESPP			—	12			—	—
Diluted Weighted-Average Shares Outstanding			12,107	12,003			12,066	11,953
(Loss)/Income per share	$ (0.37)	$ 0.04	$ (0.37)	$ 0.04	$ (1.53)	$ (1.58)	$ (1.53)	$ (1.58

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, was 1.6 million and 1.1 million for the three months ended September 30, 2021 and 2020, and was 1.7 million and 1.3 million for the nine months ended September 30, 2021 and 2020, respectively. For the three months ended September 30, 2021 and the nine months ended September 30, 2021 and 2020, all potentially dilutive shares were anti-dilutive and excluded from the calculation of diluted loss per share because we recognized a net loss. For the three months ended September 30, 2020, anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, and unvested restricted stock awards and common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the two-class or treasury stock method.

7. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2021	December 31, 2020
Raw materials	$ 33,995	$ 41,591
Packaging materials	3,631	3,194
Work-in-progress	814	886
Finished goods	28,460	20,363
	66,900	66,034
Reserve for excess/obsolete inventories	(5,216)	(5,231)
Inventories, net	$ 61,684	$ 60,803

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Vendor Concentration

We source the raw materials for our products, including active pharmaceutical ingredients ("API"), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. As a result, we are dependent upon our current vendors to reliably supply the API required for on-going product manufacturing. During the three and nine months ended September 30, 2021, no single vendor represented at least 10% of inventory purchases. During the three months ended September 30, 2020, we purchased approximately 14% of our inventory from one supplier. During the nine months ended September 30, 2020, we purchased approximately 12% of our inventory from one supplier. purchases.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. ("BioSante"), we recorded goodwill of $1.8 million. As a result of our acquisition of WellSpring Pharma Services Inc., we recorded additional goodwill of $1.7 million in 2018. We assess the recoverability of the carrying value of goodwill as of October 31st of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value during the nine months ended September 30, 2021. No impairment losses were recognized during the three and nine months ended September 30, 2021 and 2020.

Definite-lived Intangible Assets

The components of net definite-lived intangible assets are as follows:

	September 30, 2021		December 31, 2020		Weighted Average
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	Amortization Period
Acquired ANDA intangible assets	$ 106,415	$ (51,684)	$ 106,415	$ (42,367)	8.8 years
NDAs and product rights	242,372	(132,146)	230,974	(112,483)	9.9 years
Marketing and distribution rights	17,157	(12,107)	17,157	(11,386)	5.7 years
Non-compete agreement	624	(490)	624	(423)	7.0 years
	$ 366,568	$ (196,427)	$ 355,170	$ (166,659)	9.4 years

Definite-lived intangible assets are stated at cost, net of amortization, generally using the straight-line method over the expected useful lives of the intangible assets. In the case of certain New Drug Application ("NDA") and product rights assets, we use an accelerated amortization method to better match the anticipated economic benefits expected to be provided. Amortization expense was $10.1 million for the three months ended September 30, 2021 and 2020. Amortization expense was $29.8 million and $30.2 million for the nine months ended September 30, 2021 and 2020, respectively. Refer to Note 12 for more details on acquired definite-lived intangible assets.

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three and nine months ended September 30, 2021 and 2020 and therefore no impairment loss was recognized in the three and nine months ended September 30, 2021 and 2020.

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Expected future amortization expense is as follows:

(in thousands)	
2021	$ 10,057
2022	36,828
2023	36,080
2024	33,103
2025	29,755
2026 and thereafter	24,318
Total	$ 170,141

9. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of September 30, 2021, we had 0.2 million shares of common stock available under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount.

The following table summarizes ESPP expense incurred under the 2016 Employee Stock Purchase Plan and included in our accompanying unaudited interim condensed consolidated statements of operations:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of sales	$ 3	$ 3	$ 11	$ 14
Research and development	5	6	16	25
Selling, general, and administrative	20	23	66	79
	$ 28	$ 32	$ 93	$ 118

Stock Incentive Plan

Equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"). As of September 30, 2021, 0.6 million shares of our common stock were available for issuance under the 2008 Plan.

From time to time, we may grant stock options to employees through an inducement grant outside of our 2008 Plan to induce prospective employees to accept employment with us (the "Inducement Grants"). The options are granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant date and are generally exercisable in four equal annual installments beginning on the first anniversary of the respective grant date. The grants are made pursuant to inducement grants outside of our stockholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

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The following table summarizes stock-based compensation expense incurred under the 2008 Plan and Inducement Grants included in our accompanying unaudited interim condensed consolidated statements of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2021	2020	2021	2020
Cost of sales	$ 2	$ 34	$ 4	$ 93
Research and development	144	117	407	450
Selling, general, and administrative	2,634	2,200	7,017	9,882
	$ 2,780	$ 2,351	$ 7,428	$ 10,425

A summary of stock option and restricted stock activity under the 2008 Plan and Inducement Grants during the nine months ended September 30, 2021 and 2020 is presented below:

(in thousands)	Options	Inducement Grants	RSAs
Outstanding at December 31, 2019	757	—	192
Granted	42	180	305
Options Exercised/RSAs Vested	(8)	—	(128) (1)
Forfeited	(44)	—	(17)
Expired	—	—	—
Outstanding at September 30, 2020	747	180	352
Outstanding at December 31, 2020	756	180	352
Granted	97	61	463
Options Exercised/RSAs Vested	(5)	—	(126) (2)
Forfeited	(74)	—	(61)
Expired	—	—	—
Outstanding at September 30, 2021	774	241	628

(1) Includes 43 thousand shares purchased from employees to cover employee income taxes related to income earned upon vesting of restricted stock. The shares purchased are held in treasury and the $1.5 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

(2) Includes 28 thousand shares purchased from employees to cover employee income taxes related to income earned upon vesting of restricted stock. The shares purchased are held in treasury and the $0.9 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

10. INCOME TAXES

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of September 30, 2021, we have

provided a valuation allowance against consolidated net deferred tax assets of $0.4 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any such amounts accrued as of September 30, 2021 and December 31, 2020. We are subject to taxation in various U.S. jurisdictions and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate, calculated on a worldwide consolidated basis, expected for the entire year. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and estimated permanent differences, and excludes certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discrete items result in variances to the effective tax rate from period to period. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. Prior to the adoption of new accounting guidance that we adopted on a prospective basis on January 1, 2021, during periods when we incurred net losses before income taxes, our annual estimated effective tax rate was at times adjusted based on the "loss limitation" requirements applicable to interim tax provisions, resulting in a limited income tax benefit recognized in that period. Under these provisions, our income tax benefit for the three months ended March 31, 2020 (but not for the three and nine month periods ended September 30, 2020) was limited. The "loss limitation" requirements were removed by the new accounting guidance and, therefore, we were not required to assess any such limitation for 2021. Our estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discrete items occur. Global Intangible Low-Taxed Income ("GILTI"), as defined in the Tax Cuts and Jobs Act of 2017, generated from our Canadian operations is subject to U.S. taxes, with certain defined exemptions, thresholds and credits. For financial reporting purposes we have elected to treat GILTI inclusions as a period cost.

For the three months ended September 30, 2021, we recognized an income tax benefit of $2.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 37.6% to pre-tax consolidated loss of $7.1 million reported during the period, as well as the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended September 30, 2021.

For the three months ended September 30, 2020, we recognized an income tax benefit of $0.4 million. The income tax benefit for this period is the incremental benefit generated from applying the estimated annual worldwide effective tax benefit rate of 19.8% to consolidated pre-tax losses for the nine months ended September 30, 2020 as compared to the consolidated income tax benefit as of June 30, 2020. The estimated annual effective rate varies from the statutory rate as a result of permanent differences as well as the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items during the three months ended September 30, 2020.

For the nine months ended September 30, 2021, we recognized an income tax benefit of $6.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 26.7% to pre-tax consolidated loss of $25.2 million reported during the period, as well as the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the nine months ended September 30, 2021.

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For the nine months ended September 30, 2020, we recognized an income tax benefit of $4.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 19.8% to pre-tax consolidated loss of $23.6 million reported during the period, as well as the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items during the nine months ended September 30, 2020.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

All our existing leases as of September 30, 2021 are classified as operating leases. As of September 30, 2021, we have nine material operating leases for facilities and office equipment with remaining terms expiring from 2022 through 2026 and a weighted average remaining lease term of 2.5 years. Many of our existing leases have fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. Discount rates used in the calculation of our lease liability ranged between 3.99% and 8.95%.

Rent expense for the three and nine months ended September 30, 2021 and 2020 consisted of the following:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease costs	$ 40	$ 57	$ 132	$ 166
Variable lease costs	9	15	30	44
Total lease costs	$ 49	$ 72	$ 162	$ 210

A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2021	$ 35
2022	127
2023	82
2024	56
2025 and thereafter	42
Total	$ 342
Discount	(22)
Lease liability	320
Current lease liability	(130)
Non-current lease liability	$ 190

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies, such as the Drug Enforcement Administration ("DEA"), the U.S. Food and Drug Administration ("FDA"), the Centers for Medicare and Medicaid Services ("CMS"), and Health Canada. The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The DEA and Health Canada maintain oversight over our products that are considered controlled substances.

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Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone ("EEMT") and Opium Tincture, are marketed without approved NDAs or Abbreviated New Drug Applications ("ANDAs"). During the three months ended September 30, 2021 and 2020, net revenues for these products totaled $4.2 million and $4.3 million, respectively. During the nine months ended September 30, 2021 and 2020, net revenues for these products totaled $12.2 million and $12.4 million, respectively.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the three months ended September 30, 2021 and 2020 were $0.7 million. Our contract manufacturing revenues for the group of unapproved products for the nine months ended September 30, 2021 and 2020 were $2.1 million and $2.3 million, respectively.

Legal Proceedings

We are involved, and from time to time may become involved, in various disputes, governmental and/or regulatory inquiries, investigations, government reimbursement related actions and litigation. These matters are complex and subject to significant uncertainties. As such, we cannot accurately predict the outcome, or the effects of the legal proceedings described below. While we believe that we have valid claims and/or defenses in the litigation and other matters described below, litigation is inherently unpredictable, and the outcome of the proceedings could result in losses, including substantial damages, fines, civil or criminal penalties and injunctive or administrative remedies. We intend to vigorously prosecute and/or defend these matters, as appropriate, however, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations, and legal proceedings, individually or in the aggregate, could have a material adverse effect on our results of operations and/or cash flows in any given accounting period or on our overall financial condition.

Some of these matters with which we are involved are described below, and unless otherwise disclosed, we are unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. We record accruals for loss contingencies to the extent we conclude it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

From time to time, we are also involved in other pending proceedings for which, in our opinion based upon facts and circumstances known at the time, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to our results, and therefore remain undisclosed. If and when any reasonably possible losses associated with the resolution of such other pending proceedings, in our opinion, become material, we will disclose such matters.

Furthermore, like all pharmaceutical manufacturers, we are periodically exposed to product liability claims. The prevalence of these claims could limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial condition, and operating results. Recent trends in the product liability and director and officer insurance markets is to exclude matters related to certain classes of drugs. Our policies have been subject to such exclusions which place further potential risk of financial loss on us.

Legal fees for litigation-related matters are expensed as incurred and included in the consolidated statements of operations under the selling, general, and administrative expense line item.

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Commercial Litigation

In November of 2017, we were served with a complaint filed by Arbor Pharmaceuticals, LLC, in the United States District Court for the District of Minnesota. The complaint alleged false advertising and unfair competition in violation of Section 43(a) of the Lanham Act, Section 1125(a) of Title 15 of the United States Code, and Minnesota State law, under the premise that we sold an unapproved Erythromycin Ethylsuccinate ("EES") product during the period between September 27, 2016 and November 2, 2018. The complaint sought a trial by jury and monetary damages (inclusive of actual and consequential damages, treble damages, disgorgement of ANI profits, and legal fees) of an unspecified amount. Discovery in this action closed on March 31, 2019 and trial was scheduled to commence on August 25, 2021. On August 3, 2021, the Company entered into a Settlement Agreement with Arbor Pharmaceuticals, LLC to resolve all claims related to Civil Action 17-4910, Arbor Pharmaceuticals, LLC ("Arbor") v. ANI Pharmaceuticals, Inc., which was pending trial in the United States District Court for the District of Minnesota. Under the terms of the agreement, ANI paid Arbor $8.4 million and Arbor dismissed the action with prejudice. Neither party admitted wrongdoing in reaching this settlement. The Company paid the settlement from cash on the balance sheet.

On December 3, 2020, class action complaints were filed against the Company on behalf of putative classes of direct and indirect purchasers of the drug Bystolic. On December 23, 2020, six individual purchasers of Bystolic, CVS, Rite Aid, Walgreen, Kroger, Albertsons, and H-E-B, filed complaints against the Company. On March 15, 2021, the plaintiffs in these actions filed amended complaints. All amended complaints are substantively identical. The plaintiffs in these actions allege that, beginning in 2012, Forest Laboratories, the manufacturer of Bystolic, entered into anticompetitive agreements when settling patent litigation related to Bystolic with seven potential manufacturers of a generic version of Bystolic: Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, Watson, and various of their corporate parents, successors, subsidiaries, and affiliates. ANI itself was not a party to patent litigation with Forest concerning Bystolic and did not settle patent litigation with Forest. The plaintiffs named the Company as a defendant based on the Company's January 8, 2020 Asset Purchase Agreement with Amerigen. The complaints allege that the 2013 patent litigation settlement agreement between Forest and Amerigen violates federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs allege they paid higher prices as a result of delayed generic competition. Plaintiffs seek damages, trebled or otherwise multiplied under applicable law, injunctive relief, litigation costs and attorneys' fees. The complaints do not specify the amount of damages sought from the Company or other defendants and the Company at this early stage of the litigation cannot reasonably estimate the potential damages that the plaintiffs will seek. The cases have been consolidated in the United States District Court for the Southern District of New York as In re Bystolic Antitrust Litigation, Case No. 20-cv-005735 (LJL). On April 23, 2021, the Company and other defendants filed motions to dismiss the amended complaints, which are pending before the court for decision. The Company disputes any liability in these matters.

On March 24, 2021, Azurity Pharmaceuticals, Inc. ("Azurity") filed a complaint in the United States District Court for the District of Minnesota against ANI Pharmaceuticals, Inc., asserting that ANI's vancomycin hydrochloride oral solution drug product infringes U.S. Patent No. 10,688,046. The complaint seeks injunctive relief, damages, including lost profits and/or royalty, treble damages, and attorneys' fee and costs. ANI filed its answer on August 31, 2021, and is currently engaged in discovery. ANI intends to dispute any and all liability in this case.

On April 1, 2021, United Therapeutics Corp. and Supernus Pharmaceuticals, Inc. ("UTC/Supernus") filed a complaint in the United States District Court for the District of Delaware against ANI Pharmaceuticals, Inc., asserting that ANI's proposed Treprostinil extended release drug product, which is subject to ANI's Abbreviated New Drug Application No. 215667, infringes U.S. Patent Nos. 7,417,070, 7,544,713, 8,252,839, 8,349,892, 8,410,169, 8,747,897, 9,050,311, 9,278,901, 9,393,203, 9,422,223, 9,593,066 and 9,604,901 ("the Asserted Patents"). The complaint seeks injunctive relief, attorneys' fee and costs. ANI filed its answer and counterclaims on May 28, 2021, denying UTC/Supernus' allegations and seeking declaratory judgment that ANI has not infringed any valid and enforceable claim of the Asserted Patents, that the Asserted Patents are invalid, and an award of attorneys' fees and costs. Trial is set for May 8, 2023.

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Industry Related Litigation

In July 2020, we were served with a complaint brought by the Office of the Attorney General of the State of New Mexico against manufacturers and sellers of ranitidine products. The complaint asserts a public nuisance claim and a negligence claim against the generic ranitidine manufacturer defendants, including the Company. The public nuisance claim asserts that the widespread sale of ranitidine products in the state created a public nuisance that requires a state-wide medical monitoring program of New Mexico residents for the development of colorectal cancer, stomach cancer, gastrointestinal disorders and liver disease. As damages, New Mexico asks that the defendants fund this medical monitoring program. The negligence claims assert that the defendants were negligent in selling the product, essentially alleging that it was unreasonable to have the product on the market. With respect to that claim, New Mexico asserts that it paid for ranitidine products through state-funded insurance and health-care programs. On December 15, 2020, the case was removed to federal court and transferred to the In re Zantac multidistrict litigation ("MDL") pending in the United States District Court for the Southern District of Florida. New Mexico moved for remand to state court. The MDL court granted the remand motion on February 25, 2021. On April 16, 2021, New Mexico filed an amended complaint in the New Mexico First Judicial District Court in Santa Fe County. It did not name ANI in the amended complaint, effectively voluntarily dismissing ANI from the action. In December 2020, the City of Baltimore served ANI with a complaint against manufacturers and sellers of ranitidine products. The City of Baltimore complaint tracks the allegations of the New Mexico complaint. The Baltimore action was removed to federal court and transferred to the In re Zantac MDL on February 1, 2021. The City of Baltimore moved for remand, which was granted on April 1, 2021. The parties stipulated to allow the City of Baltimore to file an amended complaint in the Circuit Court of Maryland for Baltimore City in "due course," without a specific filing deadline. On June 23, 2021, the City of Baltimore filed an amended complaint. The City of Baltimore did not name ANI in its amended complaint, effectively voluntarily dismissing ANI from the action. We dispute any liability in these matters.

Product Liability Related Litigation

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, have faced allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA's February 2009 Black Box warning requirement ("legacy claims"). All these original legacy claims were settled or closed out, including a series of claims in California that were resolved by coordinated proceeding and settlement. Our insurance company assumed the defense of the legacy claims and paid all losses in settlement of the California legacy claims. In March 2019, we were served with a lawsuit in the Superior Court of California, County of Riverside, adding us as a defendant in a complaint filed in July 2017 that is alleged not to have been part of the original settled legacy claims. This new claim was dismissed with prejudice in July 2021 and the matter is now closed.

In June 2020, we were served with a personal injury complaint in the case of Koepsel v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-80882-RLR, filed in the United States District Court for Southern District of Florida, in which the plaintiff alleges that he developed kidney cancer in 2018 as a result of taking over the counter medication containing ranitidine. The Koepsel action was filed within an existing multidistrict litigation concerning ranitidine-containing drugs pending in the Southern District of Florida before Judge Robin L. Rosenberg, In re Zantac MDL, 20 MDL 2924. A Master Personal Injury Complaint ("MPIC") in that MDL that was filed on June 22, 2020 also named the Company as a defendant. The Company was dismissed from the Koepsel case on August 21, 2020 and was dismissed from the MPIC on September 8, 2020. On December 31, 2020, after ANI was dismissed, the district court dismissed the MPIC claims against generic manufacturer defendants partially with prejudice and partially with leave to replead. The failure to warn and design defect claims were dismissed with prejudice on preemption grounds. An Amended Master Personal Injury Complaint was filed on February 8, 2021, which does not name ANI. The Company has been named in other individual personal injury complaints filed in MDL 20 MD 2924 in which plaintiffs allege that they developed cancer after taking prescription and over the counter medication containing ranitidine. To date, the Company has been served with complaints in

five of those additional cases: Cooper v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81130-RLR (served September 30, 2020), Lineberry v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81079-RLR (served August 20, 2020), Lovette v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81040-RLR (served August 26, 2020), Hightower v. Pfizer, et al, MDL No. 20-MD-2924, Case No. 9-20-cv-82214-RLR (served December 16, 2020) and Bird v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9-20-cv-80837-RLR (served December 30, 2020). We have informed counsel for the plaintiffs that we did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited two-month period of time, from July 2019 to September 2019. Our product was voluntarily recalled in January 2020. Each of the plaintiffs in the five pending cases alleges a cancer diagnosis prior to the time that ANI sold ranitidine, and we have informally sought dismissal from these cases on that basis. ANI was voluntarily dismissed from the Cooper, Lineberry and Lovette actions on November 20, 2020. ANI was voluntarily dismissed from the Bird action on March 15, 2021 and from the Hightower action on March 29, 2021. After ANI had been voluntarily dismissed from all complaints served on it in the MDL, the district court dismissed all claims against the generic manufacturer defendants with prejudice on preemption grounds by opinion dated July 8, 2021. We dispute any liability in these MDL matters.

Other Industry Related Matters

On or about September 20, 2017, the Company and certain of its employees were served with search warrants and/or grand jury subpoenas to produce documents and possibly testify relating to a federal investigation of the
generic pharmaceutical industry. We have been cooperating and intend to continue cooperating with the investigation. However, no assurance can be given as to the timing or outcome of the investigation.

12. FAIR VALUE DISCLOSURES

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework that prioritizes and ranks the level of observability of inputs used in measuring fair value.

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Loan, DDTL, and Revolver bear an interest rate that fluctuates with the changes in LIBOR and, because the variable interest rates approximate market borrowing rates available to us, we believe the carrying values of these borrowings approximated their fair values at September 30, 2021.

Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

Our contingent value rights (“CVRs”), which were granted coincident with our merger with BioSante and expire in June 2023, are considered contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of our projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs was immaterial as of September 30, 2021 and December 31, 2020. We also determined that the changes in such fair value were immaterial in the three and nine months ended September 30, 2021 and 2020.

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The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 5, the fair value of the interest rate swap was a $7.9 million liability at September 30, 2021.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of September 30, 2021 and December 31, 2020, by level within the fair value hierarchy:

(in thousands) Description	Fair Value at September 30, 2021	Level 1	Level 2	Level 3
Liabilities				
Interest rate swaps	$ 7,926	$ —	$ 7,926	$ —
CVRs	$ —	$ —	$ —	$ —

Description	Fair Value at December 31, 2020	Level 1	Level 2	Level 3
Liabilities				
Interest rate swaps	$ 14,109	$ —	$ 14,109	$ —
CVRs	$ —	$ —	$ —	$ —

Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

We do not have any financial assets and liabilities that are measured at fair value on a non-recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Recurring Basis

We do not have any non-financial assets and liabilities that are measured at fair value on a recurring basis.

Non-Financial Assets and Liabilities Measured at Fair Value on a Non-Recurring Basis

We measure our long-lived assets, including property, plant, and equipment, ROU assets, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three and nine months ended September 30, 2021 and 2020.

Acquired Non-Financial Assets Measured at Fair Value

In April 2021, we acquired three NDAs and an ANDA and certain related inventories from Sandoz, Inc. for total consideration of $20.7 million. We also incurred and paid $0.4 million in transaction costs directly related to the acquisition. The acquisition was funded via borrowings under our Revolver. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $11.4 million as acquired intangible assets and $9.7 million of inventory at fair value, including $0.6 million of API, $1.0 million of sample inventory, and $8.1 million in finished goods inventory. In order to determine the fair value of the intangible assets, we used the present value of the estimated cash flows related to the product rights using a discount rate of 10%, which are level 3 unobservable inputs. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. The intangible assets are being amortized in full over a useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to September 30, 2021 and therefore no impairment loss was recognized for the nine months ended September 30, 2021.

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In July 2020, we acquired an ANDA and certain related inventories from a private company for total consideration of $4.3 million. We also incurred and paid $0.1 million in transaction costs directly related to the acquisition. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $3.0 million as an acquired ANDA intangible asset and $1.4 million in inventory at fair value. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. The ANDA is being amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to June 30, 2021 and therefore no impairment loss was recognized for the nine months ended September 30, 2021.

In January 2020, we completed the acquisition of the U.S. portfolio of 23 generic products and API and finished goods related to certain of those products from Amerigen Pharmaceuticals, Ltd. ("Amerigen") for a purchase consideration of $56.8 million and up to $25.0 million in contingent payments over the next four years. Payments were made using cash on hand and through borrowings of $15.0 million under our Revolver. We also incurred and paid $0.7 million in transaction costs directly related to the acquisition. We accounted for the transaction as an asset acquisition and capitalized the transactions costs directly related to the acquisition. We recognized $38.5 million as acquired ANDA intangible assets and $6.7 million as acquired marketing and distribution rights related to the licensed products, which are being amortized over their useful lives of seven years. We also recognized $3.8 million of the purchase price as research and development expense because certain of the generic products had significant remaining work required in order to be commercialized and the products did not have an alternative future use. The payment was allocated to the two asset categories and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. To determine the fair value of the acquired intangible assets and in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 8%. We also recognized $8.4 million in inventory at fair value, including $1.7 million of API and $6.7 million of finished goods. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. Contingent liabilities will be accrued when they are both estimable and probable. The intangible assets will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to September 30, 2021 and therefore no impairment loss was recognized for the nine months ended September 30, 2021.

13. PURIFIED CORTROPHIN GEL PRE-LAUNCH CHARGES

In January 2016, we acquired the right, title and interest in the NDAs for Cortrophin Gel and Cortrophin-Zinc. Subsequently, we have assembled a Cortrophin Gel re-commercialization team of scientists, executed a long-term supply agreement with a supplier of pig pituitary glands, our primary raw material for corticotrophin API, executed a long-term supply agreement with an API manufacturer, with whom we have advanced the manufacture of corticotropin API via manufacture of commercial-scale batches, and executed a long-term commercial supply agreement with a current good manufacturing practice ("cGMP") aseptic fill contract manufacturer.

Prior to the third quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts were consumed in research and development activities and recognized as research and development expense in the period in which they were incurred. In the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. The FDA granted approval of the sNDA of this product on October 29, 2021. Prior to FDA approval, under U.S. GAAP, we were prohibited from capitalizing these pre-launch purchases of materials as inventory, and accordingly, they were charged to expense in the period in which they were incurred. Subsequent to approval, these purchases will be recorded as inventory at net realizable value. During the three and nine months ended September 30, 2021, we incurred $0.2 million and $0.8 million, respectively, of charges for the purchase of materials. During the three and nine months ended September 30, 2020, we incurred $0.1 million and $8.3 million,

respectively in charges for the purchase of materials. We also incurred other charges directly related to the Cortrophin pre-launch commercialization efforts, including, but not limited to, sales and marketing and consulting expenses. During the three and nine months ended September 30, 2021, we incurred $2.1 million and $4.7 million, respectively, of these charges, which are included on the unaudited interim condensed consolidated statements of operations as a selling, general, and administrative expense. There were no comparable expenses in 2020.

14. SUBSEQUENT EVENT

On October 29, 2021, the FDA approved the Company's Supplemental New Drug Application ("sNDA") for Purified Cortrophin™ Gel (Repository Corticotropin Injection USP) (Cortrophin Gel) for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis ("MS") and rheumatoid arthritis ("RA"), in addition to excess urinary protein due to nephrotic syndrome. Cortrophin Gel is an adrenocorticotropic hormone ("ACTH"), also known as purified corticotropin.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, the audited consolidated financial statements and the accompanying notes thereto in our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (the "2020 Annual Report"), as well as the information contained under Management's Discussion and Analysis of Financial Condition and Results of Operations and "Risk Factors" contained in the 2020 Annual Report, and Part II, Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q , and other information provided from time to time in our other filings with the SEC. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" in our 2020 Annual Report and this Quarterly Report on Form 10-Q.

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (together, "ANI," the "Company," "we," "us," or "our"), is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. We focus on niche and high barrier to entry opportunities, including controlled substances, oncology products (anti-cancer), hormones and steroids, and complex formulations. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment.

Strategy

Our objective is to build a sustainable and growing biopharmaceutical company serving patients in need and creating long-term value for our investors. Our growth strategy is driven by the following key pillars:

Building a successful Purified Cortrophin Gel franchise

We acquired the NDAs for Cortrophin gel and Cortrophin-Zinc in January 2016 and executed long-term supply agreements with a supplier of our primary raw material for corticotrophin active pharmaceutical ingredient ("API"), a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin gel fill/finish contract manufacturer. In April 2020, the FDA issued a Refusal to File ("RTF") letter for our Supplemental New Drug Application ("sNDA") for Purified Cortrophin™ Gel. Subsequently, we retained a prominent regulatory consulting firm, restructured the internal Cortrophin Gel development team, and focused our efforts on a comprehensive review of the original sNDA to execute a plan that addressed all gaps for a planned re-submission to the FDA. During the second quarter of 2021, we re-submitted the sNDA to the FDA.

On October 29, 2021, the FDA approved the Company's sNDA for Purified Cortrophin™ Gel (Repository Corticotropin Injection USP) for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis ("MS") and rheumatoid arthritis ("RA"), in addition to excess urinary protein due to nephrotic syndrome. Cortrophin Gel is an adrenocorticotropic hormone ("ACTH"), also known as purified corticotropin.

During 2021, we have begun to invest in leadership, expertise and infrastructure in the areas of commercialization of rare disease therapies and have developed a launch strategy and commercial plan for this product. We anticipate that our expenditures in support of these efforts will materially increase in the fourth quarter of 2021 and in 2022.

Strengthening our generics business with enhanced research and development capability and increased focus on niche opportunities

We have grown our generics business through a combination of market share gains on existing products and new product launches. We have also successfully acquired numerous ANDAs through asset acquisitions, including, most recently, the U.S. portfolio of 23 generic products, including 10 commercial products at the time of the acquisition, from Amerigen Pharmaceuticals, Ltd. We also focus on niche lower competition opportunities such as injectables and Paragraph IV filings. Additionally, we will seek opportunities to enhance our research and development capabilities through strategic partnerships and acquisitions of assets and businesses.

Maximizing the value from our established brands through innovative "go-to-market" ("GTM") strategies and continued programmatic acquisitions

We have acquired the New Drug Applications ("NDAs") for and market Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, InnoPran XL, OXISTAT, VEREGEN, and Pandel. We are innovating in our GTM strategy through creative partnerships. In addition, we will continue to explore opportunities in acquiring new brands to grow our established brands portfolio.

Expansion of contract development and manufacturing organization ("CDMO") business by leveraging our unique manufacturing capabilities

We built a CDMO business through our sites in Baudette and grew it through the acquisition of WellSpring Pharma Services Inc. ("ANI Canada"). Our North America based manufacturing and unique capabilities in high-potency, hormonal, steroid, and oncolytic products can be leveraged to expand our CDMO business.

The pillars of our strategy are enabled by an empowered, collaborative, and purposeful team with high performance-orientation.

Product Development Considerations

We consider a variety of criteria in determining which products to develop, all of which influence the level of competition upon product launch. These criteria include:

- ***Formulation Complexity.*** Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that we intend to leverage in selecting products to develop or manufacture.

- ***Patent Status.*** We seek to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.

- ***Market Size.*** When determining whether to develop or acquire an individual product, we review the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. We endeavor to manufacture products with sufficient market size to enable us to enter the market with a strong likelihood of being able to price our products both competitively and at a profit.

- ***Profit Potential.*** We research the availability and cost of active pharmaceutical ingredients in determining which products to develop or acquire. In determining the potential profit of a product, we forecast our anticipated market share, pricing, including the expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.

- ***Manufacturing.*** We generally seek to develop and manufacture products at our own manufacturing plants in order to optimize the utilization of our facilities, ensure quality control in our products, and maximize profit potential.

- ***Competition.*** When determining whether to develop or acquire a product, we research existing and expected competition. We seek to develop products for which we can obtain sufficient market share and may decline to develop a product if we anticipate significant competition. Our specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies are able to compete.

Recent Developments

Pending Business Acquisition

On March 8, 2021, we entered into a definitive agreement to acquire Novitium Pharma LLC ("Novitium"), a privately held New Jersey-based pharmaceutical company with development, manufacturing, and commercial capabilities (the "Acquisition"). The closing of the acquisition will occur (a) within five business days after all of the conditions to the closing set forth in the merger agreement are satisfied or waived or (b) at such other time, date and place as may be agreed by us and Novitium, subject to the completion of a minimum period. The closing is subject to the satisfaction of customary closing conditions and necessary regulatory approvals, including the approval of the Federal Trade Commission, or FTC. We have engaged in extensive discussions with the FTC over the past several months to obtain the necessary approval of the Acquisition and have agreed as a condition to obtaining such approval, to divest a currently marketed product by the Company and rights to another product under development. We believe that the disposition of these product rights to an unrelated third party, which party has been approved by the staff of the FTC, are immaterial to the Company's business. Currently, the Agreements Containing Consent Orders (ACCO) have been finalized with the FTC staff and are awaiting final approval by the Commissioners. We currently expect to close the Acquisition in November 2021.

Consideration will consist of a combination of (i) an estimated cash amount of $89.5 million, subject to various adjustments and expected to be financed by a $25.0 million private placement of preferred stock (the "PIPE Investment") and new debt financing, both described below, (ii) an aggregate of 2,466,667 shares of ANI common stock, and (iii) up to $46.5 million in contingent future earn-out payments.

We will finance the transaction with a new $340.0 million Senior Secured Credit Facility (the "New Facility"), consisting of a $300.0 million term loan and a $40.0 million revolving credit facility, the issuance of 2,466,667 shares of ANI common stock (approximately $74.0 million in value based on a $30 stock price) (the "Stock Consideration"), and a $25.0 million PIPE Investment by Ampersand 2020 Limited Partnership ("Ampersand"), an affiliate of Ampersand Capital Partners of which our Chairman of the Board is an operating partner. The New Facility will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI's existing senior credit facilities. The term loan portion of the New Facility, which was successfully syndicated on May 24, 2021, represents fully committed capital and, as such, carries a customary ticking fee that commences 45 days and 90 days post allocation. During the three and nine months ended September 30, 2021, we incurred $2.4 million in expense related to the ticking fee, all of which was recognized as other expense, net, on the unaudited interim condensed consolidated statement of operations.

Concurrently with the execution of the definitive agreement, on March 8, 2021, we entered into an Equity Commitment and Investment Agreement with Ampersand (the "PIPE Investor"), pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock (the "PIPE Shares"), for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million PIPE Investment. The issuance of shares of ANI common stock into which PIPE Shares will be convertible and the Stock Consideration for the Acquisition were approved by ANI stockholders in June 2021.

As of the date of filing of this quarterly report on Form 10-Q, the Acquisition remains under review by the U.S. Federal Trade Commission and we remain actively engaged in discussions with the commission.

For more information about the pending Novitium acquisition transaction, please see our Form 8-K filed with the SEC on March 9, 2021 and our definitive proxy statement for the 2021 Annual Meeting of Stockholders filed with the SEC on April 29, 2021.

Product Launches

In September 2021, we launched Nebivolol Tablets, the generic version of the reference listed drug Bystolic®. Nebivolol Tablets are indicated for the treatment of hypertension and may be used alone or in combination with other antihypertensive agents.

NDA Acquisition

On April 1, 2021, we acquired the NDAs for OXISTAT®, VEREGEN®, and Pandel® and the ANDA for Apexicon® from Sandoz Inc. for total consideration of $20.7 million. The acquisition was funded through a $24.0 million borrowing under the Revolver.

Purified Cortrophin Gel Re-commercialization Update

In April 2020, the U.S. Food and Drug Administration ("FDA") issued a Refusal to File ("RTF") letter for our sNDA for Cortrophin Gel. Subsequently, we retained a prominent regulatory consulting firm, restructured the internal Cortrophin development team, and focused our efforts on a comprehensive review of the original sNDA to execute a plan that addressed all gaps for a planned re-submission to the FDA. During the second quarter of 2021, we re-submitted the sNDA and on October 29, 2021, it was approved by the FDA.

During 2021, we have begun to invest in leadership, expertise and infrastructure in the areas of commercialization of rare disease therapies and have developed a launch strategy and commercial plan for this product. We anticipate that our expenditures in support of these efforts will materially increase in the fourth quarter of 2021 and in 2022. In addition, in the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. We expect these pre-launch purchases of material to continue in 2021 as we build raw materials, API and finished goods for the upcoming launch of this product.

COVID-19 Impact

We continue to closely monitor the impact of the novel coronavirus ("COVID-19") pandemic on our business and the geographic regions where we operate. During the three months ended March 31, 2021 per IQVIA/IMS data, total market generic prescriptions in the United States declined when compared to the three months ended December 31, 2020 and March 31, 2020. Over these same periods, total market brand prescriptions were steady or increased. The decline in generic prescriptions, which generally make up greater than 60% of our net revenues, during this period was in part attributable to the COVID-19 pandemic, as subsequent waves impacted patient and customer behavior. The decline in generic prescriptions due to the COVID-19 pandemic negatively impacted our generic net revenues during the three months ended March 31, 2021. During the three-month periods ended June 30, 2021 and September 30, 2021, per IQVIA/IMS data, total market generic and prescriptions increased sequentially during each of these three-month periods and increased against the comparable 2020 three-month periods, in part due to easing of local restrictions and availability of COVID-19 vaccines. We have not experienced a significant impact to our manufacturing operations; however, we continue to see disruptions to our supply chain from the COVID-19 pandemic during 2021. Our manufacturing facilities in Baudette, Minnesota and Oakville, Ontario have remained open throughout the pandemic and have operated in accordance with local, state and national safety guidelines. The pandemic has not impacted our access to capital and has not significantly impacted our use of funds, including but not limited to capital expenditures, spend on research and development activities and business development opportunities.

We are unable to predict the impact that the COVID-19 pandemic will continue to have on our future financial condition, results of operations and cash flows due to numerous uncertainties, including the scope, severity and continued duration of the pandemic, the level of success of continued actions taken to contain the pandemic or mitigate its impact, including the availability and usage of vaccines, and the direct and indirect economic effects of the pandemic and containment measures, among others. Further, the impacts of a potential worsening of global economic conditions and the continued disruptions to, and volatility in, the credit and financial markets, pharmaceutical supply chains, patient access to healthcare as well as other unanticipated consequences remain unknown.

Settlement of Pending Litigation

On August 3, 2021, we entered into a Settlement Agreement with Arbor Pharmaceuticals, LLC ("Arbor") to resolve all claims related to Civil Action 17-4910, Arbor Pharmaceuticals, LLC v. ANI Pharmaceuticals, Inc., which was pending trial in the United States District Court for the District of Minnesota. Under the terms of the agreement, we paid Arbor $8.4 million and Arbor dismissed the action with prejudice. Neither party admitted wrongdoing in reaching this settlement. We paid the $8.4 million settlement from cash on hand and recognized the amount as legal settlement expense on the unaudited interim condensed consolidated statements of operations in the three months ended June 30, 2021.

GENERAL

The following table summarizes our results of operations for the periods indicated:

(in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net revenues	$ 52,061	$ 52,979	$ 155,207	$ 151,223
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	24,413	20,118	66,712	62,617
Research and development	2,456	2,939	8,229	12,318
Selling, general, and administrative	17,181	15,725	53,588	50,621
Depreciation and amortization	11,346	11,358	33,568	33,739
Legal settlement expense	—	—	8,400	—
Purified Cortrophin Gel pre-launch charges	227	37	780	8,275
Operating (loss)/income	(3,562)	2,802	(16,070)	(16,347)
Interest expense, net	(2,497)	(2,510)	(7,482)	(6,898)
Other expense, net	(1,071)	(229)	(1,653)	(335)
(Loss)/income before benefit for income taxes	(7,130)	63	(25,205)	(23,580)
Benefit for income taxes	2,683	371	6,738	4,667
Net (loss)/income	$ (4,447)	$ 434	$ (18,467)	$ (18,913)

The following table sets forth, for all periods indicated, items in our unaudited interim condensed consolidated statements of operations as a percentage of net revenues:

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net revenues	100.0 %	100.0 %	100.0 %	100.0 %
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	46.9 %	38.0 %	43.0 %	41.4 %
Research and development	4.7 %	5.5 %	5.3 %	8.1 %
Selling, general, and administrative	33.0 %	29.7 %	34.5 %	33.5 %
Depreciation and amortization	21.8 %	21.4 %	21.6 %	22.3 %
Legal settlement expense	— %	— %	5.4 %	— %
Purified Cortrophin Gel pre-launch charges	0.4 %	0.1 %	0.5 %	5.5 %
Operating (loss)/income	(6.8)%	5.3 %	(10.3)%	(10.8)%
Interest expense, net	(4.8)%	(4.7)%	(4.8)%	(4.6)%
Other expense, net	(2.1)%	(0.4)%	(1.1)%	(0.2)%
(Loss)/income before benefit for income taxes	(13.7)%	0.2 %	(16.2)%	(15.6)%
Benefit for income taxes	5.2 %	0.7 %	4.3 %	3.1 %
Net (loss)/income	(8.5)%	0.9 %	(11.9)%	(12.5)%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

Net Revenues

(in thousands)	Three Months Ended September 30, 2021	2020	Change	% Change
Generic pharmaceutical products	$ 35,140	$ 37,712	$ (2,572)	(6.8)%
Branded pharmaceutical products	14,313	12,411	1,902	15.3 %
Contract manufacturing	2,382	2,152	230	10.7 %
Royalty and other	226	704	(478)	(67.9)%
Total net revenues	$ 52,061	$ 52,979	$ (918)	(1.7)%

We derive substantially all of our revenues from sales of generic and branded pharmaceutical products, contract manufacturing, and contract services, which include product development services, laboratory services, and royalties on net sales of certain products. Many of our branded products face competition from generic products and we expect them to continue to face competition from generic products in the future. Our generic products face competition from other generic products and we expect them to continue to face competition in the future. The primary means of competition among generic manufacturers are pricing, contract terms, service levels, and reliability. Increased competition generally results in decreased average selling prices of generic and brand products over time.

Net revenues for the three months ended September 30, 2021 were $52.1 million compared to $53.0 million for the same period in 2020, a decrease of 1.7%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $35.1 million during the three months ended September 30, 2021, a decrease of 6.8% compared to $37.7 million for the same period in 2020. From a product perspective, the net decrease was due to declines in sales of Erythromycin Ethylsuccinate ("EES"), Methazolamide, Penicillamine, and Vancomycin. These decreases were partially offset by the second quarter 2021 launch of Nicardipine and the third quarter 2021 launch of Nebivolol. The decrease in net generic revenues was due in part to a decrease in average selling prices tempered by increased volumes among generic products.

- Net revenues for branded pharmaceutical products were $14.3 million during the three months ended September 30, 2021, an increase of 15.3% compared to $12.4 million for the same period in 2020. The primary reason for the increase was the April 2021 launch of the products acquired in the Sandoz, Inc. asset acquisition. These increases were tempered by decreased unit sales of InnoPran XL. The increase in net brand revenues was due in part to higher volumes tempered by a shift in mix towards brand products with lower average selling prices.

- Contract manufacturing revenues were $2.4 million during the three months ended September 30, 2021, an increase of 10.7% compared to $2.2 million for the same period in 2020, due to a current year shift in mix towards customers with higher average selling prices, mostly offset by a decrease in the volume of orders.

- Royalty and other revenues were $0.2 million during the three months ended September 30, 2021, a decrease of $0.5 million from $0.7 million for the same period in 2020, primarily due to decreases in product development revenues earned by ANI Canada and the non-recurrence in royalty revenue during the three months ended September 30, 2021 related to Yescarta®.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended September 30, 2021	2020	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 24,413	$ 20,118	$ 4,295	21.3 %

Cost of sales consists of direct labor, including manufacturing and packaging, active and inactive pharmaceutical ingredients, freight costs, packaging components, and royalties related to profit-sharing arrangements. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on our unaudited interim condensed consolidated statements of operations.

For the three months ended September 30, 2021, cost of sales increased to $24.4 million from $20.1 million for the same period in 2020, an increase of $4.3 million, or 21.3%, primarily as a result of $2.2 million in cost of sales representing the excess of fair value over cost of inventory acquired in the Sandoz, Inc. asset acquisition and subsequently sold during the period and increased volumes in the current year period. The increase was tempered by a $1.1 million decrease related to a decrease in sales of products subject to profit sharing arrangements.

Cost of sales, exclusive of the $2.2 million net impact related to excess of fair value over the cost of inventory sold during the period, as a percentage of net revenues increased to 42.6% during the three months ended September 30, 2021, from 38.0% during same period in 2020, primarily as a result of increased volumes in a period of declining average selling prices across generic products and a shift in mix towards brand products with lower average selling prices. The negative impacts were tempered by a decrease in sales of products subject to profit sharing arrangements and increased average selling prices among brand products.

During the three months ended September 30, 2021, no single vendor represented at least 10% of inventory purchases. During the three months ended September 30, 2020, we purchased approximately 14% of our inventory from one supplier.

Other Operating Expenses

(in thousands)	Three Months Ended September 30, 2021	2020	Change	% Change
Research and development	$ 2,456	$ 2,939	$ (483)	(16.4)%
Selling, general, and administrative	17,181	15,725	1,456	9.3 %
Depreciation and amortization	11,346	11,358	(12)	(0.1)%
Purified Cortrophin Gel pre-launch charges	227	37	190	513.5 %
Total other operating expenses	$ 31,210	$ 30,059	$ 1,151	3.8 %

Other operating expenses consist of research and development costs, selling, general, and administrative expenses, depreciation and amortization, and Cortrophin pre-launch charges.

For the three months ended September 30, 2021, other operating expenses increased to $31.2 million from $30.1 million for the same period in 2020, an increase of $1.2 million, or 3.8%, primarily as a result of the following factors:

- Research and development expenses decreased from $2.9 million to $2.5 million, a decrease of 16.4%, primarily due to a decrease in expenses related to Cortrophin.

- Selling, general, and administrative expenses increased from $15.7 million to $17.2 million, an increase of $1.5 million, or 9.3%, primarily due to the $0.5 million of transaction expenses related to the pending Novitium acquisition and $2.1 million in sales and marketing expenses related to Cortrophin pre-launch activities incurred during the three months ended September 30, 2021.

- Depreciation and amortization expense was $11.3 million for the three months ended September 30, 2021, materially unchanged compared to $11.4 million for the same period 2020.

- As described in Note 13, *Purified Cortrophin Gel Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized Cortrophin Gel pre-launch charges of $0.2 million in the three months ended September 30, 2021. We recognized Cortrophin Gel pre-launch charges of less than $0.1 million in the three months ended September 30, 2020.

Other Expense, net

	Three Months Ended September 30,			
(in thousands)	2021	2020	Change	% Change
Interest expense, net	$ (2,497)	$ (2,510)	$ 13	(0.5)%
Other expense, net	(1,071)	(229)	(842)	367.7 %
Total other expense, net	$ (3,568)	$ (2,739)	$ (829)	30.3 %

For the three months ended September 30, 2021, we recognized total other expense of $3.6 million versus total other expense of $2.7 million for the same period in 2020, an increase of $0.8 million. Interest expense, net for the three months ended September 30, 2021 and 2020 consisted primarily of interest expense on borrowings under our secured term loan ("Term Loan"), delayed draw term loan ("DDTL"), and line of credit ("Revolver"). For the three months ended September 30, 2021, other expense, net primarily consisted of $2.4 million of ticking fee expense related to our new Senior Secured Credit Facility (the "New Facility") that was syndicated on May 24, 2021, which was partially offset by income from the sale of an Abbreviated New Drug Application ("ANDA"). For the three months ended September 30, 2021 and 2020, there was less than $0.1 million of interest capitalized into construction in progress.

Benefit for Income Taxes

	Three Months Ended September 30,			
(in thousands)	2021	2020	Change	% Change
Benefit for income taxes	$ 2,683	$ 371	$ 2,312	623.2 %

Our provision for income taxes consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance.

For the three months ended September 30, 2021, we recognized an income tax benefit of $2.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 37.6% to pre-tax consolidated loss of $7.1 million reported during the period, as well as the net effects of certain discrete items occurring in 2021 which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended September 30, 2021.

For the three months ended September 30, 2020, we recognized an income tax benefit of $0.4 million. The income tax benefit for this period is the incremental benefit generated from applying the estimated annual worldwide effective tax benefit rate of 19.8% to consolidated pre-tax losses for the nine months ended September 30, 2020 as compared to the consolidated income tax benefit as of June 30, 2020. The estimated annual effective rate varies from the statutory rate as a result of permanent differences as well as the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items during the three months ended September 30, 2020.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2021 AND 2020

Net Revenues

(in thousands)	Nine Months Ended September 30, 2021	2020	Change	% Change
Generic pharmaceutical products	$ 101,952	$ 108,607	$ (6,655)	(6.1)%
Branded pharmaceutical products	32,868	32,201	667	2.1 %
Contract manufacturing	7,277	7,026	251	3.6 %
Royalty and other income	13,110	3,389	9,721	286.8 %
Total net revenues	$ 155,207	$ 151,223	$ 3,984	2.6 %

Net revenues for the nine months ended September 30, 2021 were $155.2 million compared to $151.2 million for the same period in 2020, an increase of $4.0 million, or 2.6%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $102.0 million during the nine months ended September 30, 2021, a decrease of 6.1% compared to $108.6 million for the same period in 2020. From a product perspective, the net decrease was driven by declines in sales of Vancomycin, Methazolamide, Propranolol ER, EES, Miglustat, Penicillamine, and Mixed Amphetamine Salts, and tempered by increased revenues from sales of Polyethylene Glycol, Potassium Citrate Extended Release, the second quarter 2021 launch of Nicardipine, and the third quarter 2021 launch of Nebivolol. The decrease in net revenues was due in part to lower average selling prices among generic products and a shift in mix towards generic products with lower average selling prices tempered by increased volumes of generic products.

  During the nine months ended September 30, 2020, and most significantly the three months ended June 30, 2020, the overall generic pharmaceutical product market and our net revenues from generic pharmaceutical products were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in suppressed generic prescriptions during this period. During the nine months ended September 30, 2021, based on IQVIA/IMS data, generic prescription levels continued to be suppressed when compared to pre-pandemic levels. We believe that this overall decline in prescription activity during this period, especially during the three months ended March 31, 2021, was principally due to the COVID-19 pandemic, and it negatively impacted the market for many of our generic pharmaceutical products. Total generic market prescriptions have increased sequentially during the second and third quarterly periods in 2021 and appear to be nearing pre-pandemic levels.

- Net revenues for branded pharmaceutical products were $32.9 million during the nine months ended September 30, 2021, an increase of 2.1% compared to $32.2 million for the same period in 2020. From a product perspective, the primary reason for the increase was the launch of the products acquired in the Sandoz, Inc. asset acquisition in the second quarter 2021 and increased unit sales and revenues of Casodex. These increases were tempered by lower unit sales of Inderal XL and decreased revenues of Atacand. The increase in net revenues was due to increased volumes over these periods partially offset by a shift in mix towards brand products with lower average selling prices over the comparable period.

  During the nine months ended September 30, 2020, the overall brand pharmaceutical product market and our brand revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in suppressed brand prescriptions during the three and nine months ended September 30, 2020. During the nine months ended September 30, 2021, brand prescription levels on a total market basis increased when compared to the prior nine-month period and the comparable nine-month period in 2020.

- Contract manufacturing revenues were $7.3 million during the nine months ended September 30, 2021, an increase of 3.6% compared to $7.0 million for the same period in 2020, due to a shift in mix towards customers with higher average selling prices, mostly offset by a decrease in the volume of orders.

- Royalty and other revenues were $13.1 million during the nine months ended September 30, 2021, an increase of $9.7 million from $3.4 million for the same period in 2020, primarily due to the recognition of the final royalty of $11.2 million under the Kite Pharma, Inc. license agreement (Yescarta®) pursuant to the Tripartite Agreement in the first quarter 2021.

Cost of Sales (Excluding Depreciation and Amortization)

	Nine Months Ended September 30,			
(in thousands)	2021	2020	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 66,712	$ 62,617	$ 4,095	6.5 %

For the nine months ended September 30, 2021, cost of sales increased to $66.7 million from $62.6 million for the same period in 2020, an increase of $4.1 million, or 6.5%. The increase is primarily due to increased volumes of generic and brand products and increased freight charges during the nine months ended September 30, 2021. The decrease was tempered by a $1.7 million decrease in inventory reserve charges related to excess and obsolete inventory and discontinued products and a $1.8 million decrease related to a current period decrease in sales of products subject to profit sharing arrangements. During the nine months ended September 30, 2021, we incurred $3.7 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Sandoz, Inc. asset acquisition and subsequently sold during the period, compared to $4.2 million during the nine months ended September 30, 2020, related to the Amerigen asset acquisition.

Cost of sales as a percentage of net revenues, exclusive of the impacts related to excess of fair value over the cost of inventory sold during the period, increased to 40.6% during the nine months ended September 30, 2021, from 39.0% during same period in 2020, primarily as a result of increased volumes in a period of declining average selling prices across generic products and a shift in mix towards generic and brand products with lower average selling prices. The negative impacts were significantly tempered by $11.2 million of royalty revenue in the first quarter 2021 with no associated cost of sales.

During the nine months ended September 30, 2021, no single vendor represented at least 10% of inventory purchases. During the nine months ended September 30, 2020, we purchased 12% of our inventory from one supplier.

Other Operating Expenses

	Nine Months Ended September 30,			
(in thousands)	2021	2020	Change	% Change
Research and development	$ 8,229	$ 12,318	$ (4,089)	(33.2)%
Selling, general, and administrative	53,588	50,621	2,967	5.9 %
Depreciation and amortization	33,568	33,739	(171)	(0.5)%
Legal settlement expense	8,400	—	8,400	NM [1]
Purified Cortrophin Gel pre-launch charges	780	8,275	(7,495)	(90.6)%
Total other operating expenses	$ 104,565	$ 104,953	$ (388)	(0.4)%

[1] Not Meaningful

For the nine months ended September 30, 2021, other operating expenses decreased to $104.6 million from $105.0 million for the same period in 2020, a decrease of $0.4 million, or 0.4%, primarily as a result of the following factors:

- Research and development expenses decreased from $12.3 million to $8.2 million, a decrease of 33.2%, primarily due to the non-recurrence of the $3.8 million in-process research and development expense from the Amerigen Pharmaceuticals, Ltd. acquisition in the first quarter 2020.

- Selling, general, and administrative expenses increased from $50.6 million to $53.6 million, an increase of $3.0 million, or 5.9%, primarily due to the $5.1 million of transaction expenses related to the pending Novitium acquisition and $4.7 million in sales and marketing expenses related to Cortrophin pre-launch activities incurred in the nine months ended September 30, 2021, as well as increased legal, insurance, and other professional fees. These increases were offset by the non-recurrence of $6.5 million of termination benefit expenses related to the departure of our former President and CEO and non-recurrence of other recruitment and related legal charges associated with our CEO search in the second quarter 2020.

- Depreciation and amortization expense was $33.6 million for the nine months ended September 30, 2021, materially unchanged compared to $33.7 million for the same period 2020.

- As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized Legal settlement expense of $8.4 million in the nine months ended September 30, 2021. No legal settlement expenses were recognized in the nine months ended September 30, 2020.

- As described in Note 13, *Purified Cortrophin Gel Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized Cortrophin Gel pre-launch charges of $0.8 million in the nine months ended September 30, 2021. We recognized Cortrophin Gel pre-launch charges of $8.3 million in the nine months ended September 30, 2020.

Other Expense, net

	Nine Months Ended September 30,			
(in thousands)	2021	2020	Change	% Change
Interest expense, net	$ (7,482)	$ (6,898)	$ (584)	8.5 %
Other expense, net	(1,653)	(335)	(1,318)	393.4 %
Total other expense, net	$ (9,135)	$ (7,233)	$ (1,902)	26.3 %

For the nine months ended September 30, 2021, we recognized Total other expense of $9.1 million versus Total other expense of $7.2 million for the same period in 2020, an increase of $1.9 million. Interest expense, net for the nine months ended September 30, 2021 and 2020 consisted primarily of interest expense on borrowings under our Term Loan, DDTL, and Revolver. The increase in the nine months ended September 30, 2021 is due to increased interest expense related to $24.0 million of additional borrowings under our Revolver in April 2021. For the nine months ended September 30, 2021, other expense, net primarily consisted of the ticking fee expense related to our New Facility that was syndicated on May 24, 2021 and income from the sale of an ANDA. Neither occurred in the comparable period of 2020. For the nine months ended September 30, 2021 and 2020 there was less than $0.1 million of interest capitalized into construction in progress.

Benefit for Income Taxes

	Nine Months Ended September 30,			
(in thousands)	2021	2020	Change	% Change
Benefit for income taxes	$ 6,738	$ 4,667	$ 2,071	44.4 %

For the nine months ended September 30, 2021, we recognized an income tax benefit of $6.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 26.7% to pre-tax consolidated loss of $25.2 million reported during the period, as well as the net effects of certain discrete items occurring in 2021 which

impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the nine months ended September 30, 2021.

For the nine months ended September 30, 2020, we recognized an income tax benefit of $4.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 19.8% to pre-tax consolidated loss of $23.6 million reported during the period, as well as the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the nine months ended September 30, 2020.

LIQUIDITY AND CAPITAL RESOURCES

Our Senior Secured Credit Facility (the "Credit Facility"), which we entered into in 2018, is comprised of a $72.2 million term loan (the "Term Loan"), a $118.0 million delayed draw term loan (the "DDTL") and a $75.0 million revolving credit facility (the "Revolver"), all of which mature in December 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse event. Amounts drawn on the Term Loan, DDTL, and Revolver bear an interest rate equal to, at our option, either a 1-month LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending on our total leverage ratio. On the Revolver, we incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. As of September 30, 2021, we had a $202.9 million outstanding balance on the Credit Facility.

In March 2020, we drew $15.0 million under the Revolver, of which $7.5 million was repaid. In April 2021, we drew $24.0 million under the Revolver, of which $20.7 million was used to fund the acquisition of three NDAs and an ANDA and certain related inventories from Sandoz Inc.

On September 30, 2021, we had $15.3 million in unrestricted cash and cash equivalents. On December 31, 2020, we had $7.9 million in unrestricted cash and cash equivalents. We generated $15.5 million of cash from operations in the nine months ended September 30, 2021. In August 2021, we utilized $8.4 million of cash on hand to settle litigation with Arbor.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue and corresponding collections from customers, and our Revolver, under which $43.5 million remains available for borrowing as of September 30, 2021, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months.

We will finance the pending acquisition of Novitium in part with a new $340.0 million Senior Secured Credit Facility (the "New Facility"), consisting of a $300.0 million term loan and a $40.0 million revolving credit facility. The New Facility will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI's existing senior credit facilities. The acquisition will also be funded in part by a $25.0 million PIPE Investment by Ampersand 2020 Limited Partnership ("Ampersand").

Cash Flows

The following table summarizes the net cash and cash equivalents provided by/(used in) by operating activities, investing activities, and financing activities for the periods indicated:

	Nine Months Ended September 30,	
(in thousands)	2021	2020
Operating Activities	$ 15,507	$ 20,976
Investing Activities	$ (23,270)	$ (66,203)
Financing Activities	$ 15,151	$ 769

Net Cash Provided by Operations

Net cash provided by operating activities was $15.5 million for the nine months ended September 30, 2021, compared to $21.0 million provided by operating activities during the same period in 2020, a decrease of $5.5 million. The decrease was due to net changes in working capital, including payment for litigation settlement of $8.4 million and payments of income taxes of $8.4 million during the nine months ended September 30, 2021, as compared to payments of income taxes of $4.9 million during the nine months ended September 30, 2020.

Net Cash Used in Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2021 was $23.3 million, principally due to the acquisition of three NDAs and an ANDA from Sandoz, Inc. for $20.7 million in consideration and $2.2 million of capital expenditures during the period. Net cash used in investing activities for the nine months ended September 30, 2020 was $66.2 million, principally due to the January 2020 acquisition of 23 generic products and inventory and materials from Amerigen Pharmaceuticals, Ltd. for $57.4 million, cash payments for the July 2020 acquisition of an ANDA and certain inventories of $4.0 million, and $4.0 million of capital expenditures during the period.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $15.2 million for the nine months ended September 30, 2021, principally due to borrowings of $24.0 million on the Revolver, $8.0 million of maturity payments on the Term Loan and DDTL, and $0.9 million of treasury stock purchased in relation to restricted stock vests. Net cash provided by financing activities was $0.8 million for the nine months ended September 30, 2020, principally due to net borrowings of $7.5 million on the Revolver and $0.5 million of proceeds from stock option exercises, partially offset by $5.7 million of maturity payments on the Term Loan and DDTL and $1.5 million of treasury stock purchased in relation to restricted stock vests.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited interim condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, government rebates, returns, and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets.

A summary of our significant accounting policies is included in Part II, Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2020. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Such policies are summarized in Part I, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2020.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

A discussion of the recently issued accounting pronouncements is described in Note 1, *Business, Presentation, and Recent Accounting Pronouncements*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q and is incorporated herein by reference.

OFF-BALANCE SHEET ARRANGEMENTS

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

CONTRACTUAL OBLIGATIONS

As of September 30, 2021, our contractual obligations have not changed materially from the amounts reported in our most recent Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks include interest rate risk, equity risk, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, interest rate risk, equity risk, and foreign currency exchange rate risk could have a significant impact on our results of operations.

In April 2020, we entered into an interest rate swap to manage our exposure to the variable interest rate on our Term Loan and DDTL borrowings. The interest rate swap hedges the variable cash flows associated with interest payments on borrowings under the Term Loan and DDTL, effectively providing a fixed rate of interest throughout the life of these borrowings. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

We are exposed to other risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the year ended September 30, 2021 by less than $1,000.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated transactions from our ANI Pharmaceuticals Canada Inc. subsidiary from the Canadian dollar to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the quarter ended September 30, 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of September 30, 2021. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

Item 1A. Risk Factors

In addition to the other information set forth in this report, please carefully consider the factors described under the heading "Risk Factors" in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2020 in Part I, Item 1A and in our quarterly report on Form 10-Q for the three months ended June 30, 2021 in Part II, Item 1A. The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition, and/or operating results.

The following are new significant risk factors related to the Supplemental New Drug Application ("sNDA") approval of Cortrophin Gel that could materially harm our business, financial position, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report.

Risks Related to our Business

Cortrophin Gel is our first rare disease pharmaceutical product, and we are developing a sales and marketing platform to commercialize this product. To the to the extent our efforts to commercialize this product are unsuccessful, our business, financial condition and results of operations will be negatively impacted.

On October 29, 2021, we received approval from the FDA for our Cortrophin Gel product for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis ("MS") and rheumatoid arthritis ("RA"), in addition to excess urinary protein due to nephrotic syndrome. We have devoted significant time and money over the past five years to the development of this product since we acquired the rights to the product in 2016. We have begun to invest and will continue to invest significantly in the commercialization of this product in the U.S, including building out a sales force and developing a patient support program, with a full-scale commercial launch planned for the first quarter of 2022. The ability for us to generate significant net product revenues from Cortrophin Gel will depend upon our ability to successfully launch sales of the product and numerous other factors, including:

- successfully establishing and maintaining effective sales, marketing, and distribution systems in jurisdictions in which Cortrophin Gel is approved for sale;
- successfully establishing and maintaining manufacturing capabilities and manufacturing adequate commercial quantities of Cortrophin Gel at acceptable cost and quality levels, including maintaining current good manufacturing practice ("cGMP") and quality systems regulation standards required by various regulatory agencies;
- broad acceptance of Cortrophin Gel by physicians, patients and the healthcare community;

- the acceptance of pricing and placement of Cortrophin Gel on payers' formularies and the associated tiers;
- effectively competing with Mallinckrodt which has the only other approved purified corticotropin product on the market, as well as other products that are in development or may be developed in the future as a treatment option;
- continued demonstration of safety and efficacy of Cortrophin Gel in comparison to competing products or treatment options;
- our ability to comply with ongoing regulatory obligations and continued regulatory review which may result in significant additional expense and may require labeling changes based on new safety information, post-market studies or clinical trials to evaluate safety risks related to the use of Cortrophin Gel; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we do not achieve one or more of these factors, we could experience significant delays or an inability to successfully commercialize Cortrophin Gel, which would materially harm our business. In addition, discovery of previously unknown problems with Cortrophin Gel, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or if a regulatory agency disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on Cortrophin Gel or on us, including requiring withdrawal of the product from the market.

We have only recently begun to develop a marketing and sales organization in anticipation of the approval of Cortrophin Gel and have no experience in marketing prescription rare disease drug products. If we are unable to successfully establish marketing and sales capabilities for Cortrophin Gel, our business will suffer.

We currently have no fully established rare disease sales, marketing or distribution capabilities and have no experience in marketing rare disease products. We intend to continue to develop an in-house marketing organization and sales force, which will require significant expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to successfully establish internal sales, marketing and distribution capabilities for Cortrophin Gel, we may pursue collaborative arrangements third parties. However, there can be no assurance that we will establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in-house sales and distribution capabilities or establish or maintain relationships with third-party collaborators to commercialize Cortrophin Gel or any other branded product we may sell in the future.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

The following table provides information about common stock repurchased by us during the third quarter of fiscal 2021:

Period	Total Number of Shares Purchased[1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or approximate dollar value) of Shares that may yet be Purchased Under the Plans or Programs
July 1 - July 31, 2021	—	$ —	—	$ —
August 1 - August 31, 2021	—	$ —	—	$ —
September 1 - September 30, 2021	2,577	$ 28.20	—	$ —
Total	2,577	$ —	—	

[1] Shares purchased during the period were transferred to the Company from employees in satisfaction of minimum tax withholding obligations associated with the vesting of restricted stock awards during the period.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

The exhibits listed in the Index to Exhibits, which is incorporated herein by reference, are filed or furnished as part of this Quarterly Report on Form 10-Q.

INDEX TO EXHIBITS

Exhibit No.	Description
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2021 formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Comprehensive Income; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity; (v) Condensed Consolidated Statements of Cash Flows; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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.

ANI Pharmaceuticals, Inc. (Registrant)

Date: November 1, 2021

By: /s/ Nikhil Lalwani
Nikhil Lalwani
President and
Chief Executive Officer
(principal executive officer)

Date: November 1, 2021

By: /s/ Stephen P. Carey
Stephen P. Carey
Senior Vice President, Finance and
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

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

I, Nikhil Lalwani, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ANI Pharmaceuticals, Inc.;

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 1, 2021

/s/ Nikhil Lalwani
Nikhil Lalwani
President and
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, Stephen P. Carey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ANI Pharmaceuticals, Inc.;

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 1, 2021

/s/ Stephen P. Carey
Stephen P. Carey
Senior Vice President, Finance and Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended September 30, 2021 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is provided solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Dated: November 1, 2021

/s/ Nikhil Lalwani
Nikhil Lalwani
President and Chief Executive Officer
(principal executive officer)

Dated: November 1, 2021

/s/ Stephen P. Carey
Stephen P. Carey
Senior Vice President, Finance and Chief Financial Officer
(principal financial and accounting officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.