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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, 2020

☐ **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 29, 2020, there were 12,347,554 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, 2020

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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 Exchange Act. Such statements include, but are not limited to, statements about future operations, 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 , 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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 and our Quarterly Reports on Form 10-Q for the three months ended June 30, 2020 and March 31, 2020, as well as those discussed elsewhere in this Quarterly Report on Form 10-Q, and the following factors:

- *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 outbreak 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, 2019, 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.

NOTE REGARDING TRADEMARKS

Cortenema®, Cortrophin® Gel, Cortrophin-Zinc®, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, and Vancocin® 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.

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, 2020	*December 31, 2019*
Assets		
Current Assets		
Cash and cash equivalents	$ 17,900	$ 62,332
Accounts receivable, net of $86,418 and $59,946 of adjustments for chargebacks and other allowances at September 30, 2020 and 2019, respectively	83,745	72,129
Inventories, net	59,195	48,163
Prepaid income taxes	1,621	1,076
Prepaid expenses and other current assets	3,358	3,995
Total Current Assets	165,819	187,695
Property and equipment, net	40,444	40,551
Restricted cash	5,003	5,029
Deferred tax assets, net of deferred tax liabilities and valuation allowance	48,130	38,326
Intangible assets, net	198,620	180,388
Goodwill	3,580	3,580
Other non-current assets	985	1,220
Total Assets	$ 462,581	$ 456,789
Liabilities and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 12,785	$ 9,941
Accounts payable	13,460	14,606
Accrued expenses and other	2,534	2,362
Accrued royalties	6,088	5,084
Accrued compensation and related expenses	5,993	3,736
Accrued government rebates	11,678	8,901
Returned goods reserve	23,250	16,595
Deferred revenue	112	451
Total Current Liabilities	75,900	61,676
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	175,161	175,808
Derivatives and other non-current liabilities	16,420	6,514
Total Liabilities	$ 267,481	$ 243,998
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 12,423,061 shares issued and 12,347,543 outstanding at September 30, 2020; 12,104,875 shares issued and 12,089,565 shares outstanding at December 31, 2019	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	—	—
Treasury stock, 75,518 shares of common stock, at cost, at September 30, 2020 and 15,310 shares of common stock, at cost, at December 31, 2019	(2,246)	(723)
Additional paid-in capital	211,792	200,800
(Accumulated deficit)/retained earnings	(1,337)	17,584
Accumulated other comprehensive loss, net of tax	(13,110)	(4,871)
Total Stockholders' Equity	195,100	212,791
Total Liabilities and Stockholders' Equity	$ 462,581	$ 456,789

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,*	
	2020	*2019*	*2020*	*2019*
Net Revenues	$ 52,979	$ 51,337	$ 151,223	$ 158,581
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	20,118	15,002	62,617	45,359
Research and development	2,939	4,982	12,318	15,128
Selling, general, and administrative	15,725	14,357	50,621	41,829
Depreciation and amortization	11,358	9,473	33,739	35,048
Cortrophin pre-launch charges	37	195	8,275	195
Total Operating Expenses	50,177	44,009	167,570	137,559
Operating Income/(Loss)	2,802	7,328	(16,347)	21,022
Other Expense, net				
Interest expense, net	(2,510)	(3,336)	(6,898)	(10,096)
Other expense, net	(229)	(33)	(335)	(117)
Income/(Loss) Before Benefit/(Provision) for Income Taxes	63	3,959	(23,580)	10,809
Benefit/(provision) for income taxes	371	(64)	4,667	120
Net Income/(Loss)	$ 434	$ 3,895	$ (18,913)	$ 10,929
Basic and Diluted Earnings/(Loss) Per Share:				
Basic Earnings/(Loss) Per Share	$ 0.04	$ 0.32	$ (1.58)	$ 0.91
Diluted Earnings/(Loss) Per Share	$ 0.04	$ 0.32	$ (1.58)	$ 0.89
Basic Weighted-Average Shares Outstanding	11,991	11,879	11,953	11,826
Diluted Weighted-Average Shares Outstanding	12,003	12,085	11,953	12,060

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

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

	Three Months Ended September 30,		***Nine Months Ended September 30,***	
	2020	***2019***	***2020***	***2019***
Net income/(loss)	$ 434	$ 3,895	$ (18,913)	$ 10,929
Other comprehensive income/(loss), net of tax:				
Change in fair value of interest rate swap, net of tax	939	(1,024)	(8,239)	(5,658)
Total other comprehensive income/(loss), net of tax	939	(1,024)	(8,239)	(5,658)
Total comprehensive income/(loss), net of tax	$ 1,373	$ 2,871	$ (27,152)	$ 5,271

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, 2020 and 2019
(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	Retained Earnings (Accumulated Deficit)/	Total
Balance, June 30, 2019	$ 1	12,086	$ —	$ 194,867	12	$ (723)	$ (5,013)	$ 18,524	$207,656
Stock-based Compensation Expense	—	—	—	2,470	—	—	—	—	2,470
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	3	—	133	—	—	—	—	133
Change in Fair Value of Interest Rate Swap, Net of Tax	—	—	—	—	—	—	(1,024)	—	(1,024)
Net Income	—	—	—	—	—	—	—	3,895	3,895
Balance, September 30, 2019	$ 1	12,089	$ —	$ 197,470	12	$ (723)	$ (6,037)	$ 22,419	$213,130
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	—	—	—	—	—	—	—
Change in Fair Value of Interest Rate Swap, Net of Tax	—	—	—	—	—	—	939	—	939
Net Income	—	—	—	—	—	—	—	434	434
Balance, September 30, 2020	$ 1	12,423	$ —	$ 211,792	76	$ (2,246)	$ (13,110)	$ (1,337)	$195,100

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Nine Months Ended September 30, 2020 and 2019
(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, Net of Tax	Retained Earnings (Accumulated Deficit)/	Total
Balance, December 31, 2018	$ 1	11,863	$ —	$ 186,812	11	$ (659)	$ (379)	$ 11,488	$197,263
Cumulative Effect of Change in Accounting Principle, Net of Tax	—	—	—	—	—	—	—	2	2
Stock-based Compensation Expense	—	—	—	6,773	—	—	—	—	6,773
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	17	(1,031)	—	—	(1,031)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	120	—	4,852	—	—	—	—	4,852
Issuance of Restricted Stock Awards	—	106	—	(967)	(16)	967	—	—	—
Change in Fair Value of Interest Rate Swap, Net of Tax	—	—	—	—	—	—	(5,658)	—	(5,658)
Net Income	—	—	—	—	—	—	—	10,929	10,929
Balance, September 30, 2019	$ 1	12,089	$ —	$ 197,470	12	$ (723)	$ (6,037)	$ 22,419	$213,130
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	—	—	—	—	—	—	—
Change in Fair Value of Interest Rate Swap, Net of Tax	—	—	—	—	—	—	(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

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,	
	2020	***2019***
Cash Flows From Operating Activities		
Net (loss)/income	$ (18,913)	$ 10,929
Adjustments to reconcile net income/(loss) to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	10,543	6,773
Deferred taxes	(9,032)	(6,433)
Depreciation and amortization	33,739	35,048
Acquired in-process research and development ("IPR&D")	3,753	2,653
Non-cash interest	1,288	5,679
Asset impairment charge	104	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(11,616)	(5,858)
Inventories, net	(1,151)	(5,671)
Prepaid expenses and other current assets	637	(510)
Accounts payable	(146)	2,130
Accrued royalties	1,004	(2,929)
Current income taxes, net	(545)	(5,836)
Accrued government rebates	2,777	210
Returned goods reserve	6,456	3,393
Accrued expenses, accrued compensation, and other	2,078	1,250
Net Cash and Cash Equivalents Provided by Operating Activities	20,976	40,828
Cash Flows From Investing Activities		
Acquisition of product rights, IPR&D, and other related assets	(62,178)	(21,243)
Acquisition of property and equipment, net	(4,025)	(4,932)
Net Cash and Cash Equivalents Used in Investing Activities	(66,203)	(26,175)
Cash Flows From Financing Activities		
Payments on Term Loan and Delayed Draw Term Loan agreements	(5,657)	(1,805)
Borrowings under Revolver agreement	15,000	—
Payments on Revolver agreement	(7,500)	—
Proceeds from stock option exercises and ESPP purchases	449	4,852
Treasury stock purchases for restricted stock vests	(1,523)	(1,031)
Net Cash and Cash Equivalents Provided by Financing Activities	769	2,016
Net Change in Cash and Cash Equivalents	(44,458)	16,669
Cash and cash equivalents, beginning of period	67,361	48,029
Cash and cash equivalents, end of period	$ 22,903	$ 64,698
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	$ 62,332	$ 43,008
Restricted cash	5,029	5,021
Cash, cash equivalents, and restricted cash, beginning of period	$ 67,361	$ 48,029
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	$ 17,900	$ 59,673
Restricted cash	5,003	5,025
Cash, cash equivalents, and restricted cash, end of period	$ 22,903	$ 64,698
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 5,080	$ 3,627
Cash paid for income taxes	$ 4,878	$ 9,893
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	$ 223	$ 479

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. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), 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. Our strategy is to use our assets to develop, acquire, manufacture, and market branded and generic specialty prescription pharmaceuticals. By executing this strategy, we believe we will be able to continue to grow our business, expand and diversify our product portfolio, and create long-term value for our investors.

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, 2019, 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 United States Securities and Exchange Commission. 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, 2019.

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/(loss). Our gain or loss on transactions denominated in foreign currencies was immaterial for the three and nine months ended September 30, 2020 and 2019. 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 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, 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 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. While we experienced a negative impact to our net revenues during the nine months ended September 30, 2020 in part due to the COVID-19 pandemic, we remain unable to predict the future impact on our estimates and assumptions. There was not a material impact to these estimates or assumptions in our condensed consolidated financial statements as of and for the three and nine months ended September 30, 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.

Accounts Receivable

We extend credit to customers on an unsecured basis. We measure expected credit losses on our financial assets measured at amortized cost, including trade and unbilled receivables, on a collective basis, based on their similar risk characteristics. Expected credits losses are based on historical credit loss experience, review of the current aging or status of accounts receivable and current and forward-looking views from an economic and industry perspective. We determine trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. Our allowance for credit losses was immaterial as of September 30, 2020. Our allowance for doubtful accounts as of December 31, 2019, as accounted for and reported under previously applicable U.S. GAAP, was also immaterial.

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 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	**2020**	**2019**	**2020**	**2019**
United States	$ 52,094	$ 50,026	$ 146,602	$ 153,088
Canada	885	1,311	4,621	5,493
Total Revenue	$ 52,979	$ 51,337	$ 151,223	$ 158,581

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

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

(in thousands)	September 30, 2020	December 31, 2019
United States	$ 26,560	$ 26,708
Canada	13,884	13,843
Total property and equipment, net	$ 40,444	$ 40,551

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In November 2019, the Financial Accounting Standards Board ("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 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. The guidance is effective for reporting periods beginning after December 15, 2020, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

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.

Recently Adopted Accounting Pronouncements

In November 2018, the FASB issued guidance clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under Accounting Standards Codification Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The guidance was effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2020. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance amending the disclosure requirements on fair value measurements. The amendments add, modify, and eliminate certain disclosure requirements on fair value measurements. The guidance was effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2020. The adoption of this guidance did not have a material impact on our consolidated financial statements.

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In June 2016, the FASB issued guidance under with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate now reflects an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. In April 2019, the FASB further clarified the scope of the credit losses standard and addressed issues related to accrued interest receivable balances, recoveries, variable interest rates, and prepayment. In May 2019, the FASB issued further guidance to provide entities with an option to irrevocably elect the fair value option applied on an instrument-by-instrument basis for eligible financial instruments. We adopted this guidance as of January 1, 2020 using the modified retrospective method for all financial assets measured at amortized cost. Results for reporting periods beginning after January 1, 2020 are presented under the new guidance while prior period amounts continue to be reported in accordance with previously applicable GAAP. We recognized an $8 thousand decrease to retained earnings as of January 1, 2020 for the cumulative effect of adopting the new guidance.

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 according to contract type:

	Three Months Ended		Nine Months Ended	
Products and Services (in thousands)	**September 30, 2020**	**September 30, 2019**	**September 30, 2020**	**September 30, 2019**
Sales of generic pharmaceutical products	$ 37,712	$ 31,753	$ 108,607	$ 99,452
Sales of branded pharmaceutical products	12,411	16,605	32,201	48,300
Sales of contract manufactured products	2,152	2,376	7,026	8,499
Royalties from licensing agreements	339	268	1,120	594
Product development services	289	75	1,751	806
Other[1]	76	260	518	930
Total net revenues	$ 52,979	$ 51,337	$ 151,223	$ 158,581

(1) Primarily includes laboratory services and royalties on sales of contract manufactured products.

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The following table depicts revenue recognized during the following periods:

Timing of Revenue Recognition (in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Performance obligations transferred at a point in time	$ 52,690	$ 51,262	$ 149,472	$ 157,775
Performance obligations transferred over time	289	75	1,751	806
Total	$ 52,979	$ 51,337	$ 151,223	$ 158,581

In the three and nine months ended September 30, 2020 and 2019, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts. We recognized a decrease of $8.7 million to 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 recognized a decrease of $6.5 million of net revenue from performance obligations satisfied in prior periods during the nine months ended September 30, 2019, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales, partially offset by royalties from licensing agreements. We provide technical transfer services to customers, for which services are transferred over time. As a result, we had less than $0.1 million of contract assets related to revenue recognized based on a percentage of completion but not yet billed at both September 30, 2020 and December 31, 2019 and $0.1 million and $0.5 million of deferred revenue at September 30, 2020 and December 31, 2019, respectively. For the nine months ended September 30, 2020, we recognized $0.3 million 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 transferred to the customer upon delivery of the product to the customer, as our pharmaceutical products are 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 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, 2019.

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The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the nine months ended September 30, 2020 and 2019, 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, 2018 (1)	$ 39,007	$ 8,974	$ 12,552	$ 7,353	$ 2,009
Accruals/Adjustments	187,843	12,723	13,392	27,476	7,962
Credits Taken Against Reserve	(188,504)	(12,513)	(9,999)	(26,927)	(7,714)
Balance at September 30, 2019 (1)	$ 38,346	$ 9,184	$ 15,945	$ 7,902	$ 2,257
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

(1) Chargebacks are included as an offset to accounts receivable, net of chargebacks and other allowances in the unaudited condensed consolidated balance sheets. Administrative Fees and Other Rebates and Prompt Payment Discounts are included as an offset to accounts receivable, net of chargebacks and other allowances or 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 consists 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 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 less 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, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $7.8 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 12 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.

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 are 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 are to be distributed to The Regents and to us.

We record 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 is received directly from Cabaret once a year. Currently, the agreements governing this royalty are subject to multiple litigations in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, the Company and Cabaret. In addition, the Israeli Tax Authority has taken the position that any payments from Cabaret to us are subject to mandatory withholding tax. The Company and its tax counsel have disputed this position and are actively seeking to resolve the issue. The ultimate outcome of these matters, either individually or in the aggregate, may impact the amount of cash due to us, and may result in the termination of future payments or further claims that royalties received by us in the past be repaid.

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, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open product development services contracts was $3.1 million. We will recognize revenue for these performance obligations as they are satisfied, which is anticipated within the next 18 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, 2020 and 2019 we had three customers that accounted for 10% or more of net revenues. As of September 30, 2020, accounts receivable from these customers totaled 81% of accounts receivable, net.

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

	Three Months Ended		Nine Months Ended	
	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Customer 1	30 %	34 %	31 %	33 %
Customer 2	25 %	24 %	24 %	24 %
Customer 3	19 %	23 %	19 %	24 %

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3. INDEBTEDNESS

Credit Facility

In December 2018, we refinanced our previous $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to $265.2 million. The five-year Credit Facility 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. The Term Loan includes a repayment schedule, pursuant to which $5.9 million of the loan will be paid in quarterly installments during the 12 months ended September 30, 2021. As of September 30, 2020, $5.9 million of the loan is recorded as current borrowings in the unaudited condensed consolidated balance sheets. The DDTL includes a repayment schedule, pursuant to which $7.4 million will be paid in quarterly installments during the 12 months ended September 30, 2021. As of September 30, 2020, $7.4 million of the loan is recorded as current borrowings in the unaudited condensed consolidated balance sheets. In March 2020, we drew $15.0 million under the Revolver, of which $7.5 million has been repaid as of September 30, 2020. As of September 30, 2020, $67.5 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 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.

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 imposes financial covenants consisting of a maximum total leverage ratio, which was, as of September 30, 2020, no greater than 3.50 to 1.00 and a minimum fixed charge coverage ratio, which shall be greater than or equal to 1.25 to 1.00. The primary non-financial covenants under the Credit Facility limit, subject to various exceptions, our ability to incur future indebtedness, to place liens on assets, to pay dividends or make other distributions on our capital stock, to repurchase our capital stock, to conduct acquisitions, to alter our capital structure, and to dispose of assets.

The carrying value of the current and non-current components of the Term Loan and DDTL as of September 30, 2020 and December 31, 2019 are:

	Current	
(in thousands)	**September 30, 2020**	**December 31, 2019**
Current borrowing on debt	$ 13,240	$ 10,412
Deferred financing costs	(455)	(471)
Current debt, net of deferred financing costs	$ 12,785	$ 9,941

	Non-Current	
(in thousands)	**September 30, 2020**	**December 31, 2019**
Non-current borrowing on debt	$ 168,583	$ 177,069
Deferred financing costs	(922)	(1,261)
Non-current debt, net of deferred financing costs and current component	$ 167,661	$ 175,808

The refinancing of the Term Loan was accounted for as a modification of our previous term loan and consequently, the remaining balance of the deferred issuance costs related to the previous term loan are included with the lenders fees associated with the refinance of the Term Loan and amortized as interest expense over the life of the Term Loan using the effective interest method. Fees to third parties associated with the refinance of the Term Loan were

recognized as other (expense)/income, net in the accompanying consolidated statements of operations. The refinancing of the Revolver was accounted for as a modification of our previous revolving credit facility and consequently, the remaining balance of the deferred issuance costs related to the previous revolving credit facility are included with the lenders fees and fees to third parties associated with the refinance of the Revolver and amortized as interest expense on a straight-line basis over the life of the Revolver. All issuance costs allocated to the DDTL were deferred and are being amortized as interest expense on a straight-line basis over the five-year term of the DDTL.

As of September 30, 2020, we had a $66.8 million outstanding balance on the Term Loan, a $115.1 million balance on the DDTL, and a $7.5 million balance on the Revolver. Of the remaining $0.8 million of deferred debt issuance costs allocated to the Revolving Credit Facility, $0.6 million is included in other non-current assets in the unaudited interim condensed consolidated balance sheets and $0.2 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets. Of the remaining $0.4 million of deferred debt issuance costs allocated to the DDTL, $0.1 million is classified as a direct deduction to the current portion of the DDTL in the unaudited condensed consolidated balance sheets and $0.3 million is classified as a direct reduction to the non-current portion of the DDTL in the unaudited condensed consolidated balance sheets. Of the remaining $1.0 million of deferred debt issuance costs allocated to the Term Loan, $0.3 million is classified as a direct deduction to the current portion of the Term Loan in the unaudited condensed consolidated balance sheets and $0.7 million is classified as a direct deduction to the non-current portion of the Term Loan in the unaudited 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
2020	$ 1,805	$ 2,950	$ —
2021	5,414	5,900	—
2022	5,414	8,850	—
2023	54,140	97,350	7,500
Total	$ 66,773	$ 115,050	$ 7,500

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, 2020 and 2019:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2020	September 30, 2019	September 30, 2020	September 30, 2019
Contractual coupon	$ 2,351	$ 1,628	$ 6,450	$ 4,903
Amortization of debt discount	—	1,553	—	4,600
Amortization of finance fees	180	358	542	1,078
Capitalized interest	(18)	(41)	(67)	(152)
	$ 2,513	$ 3,498	$ 6,925	$ 10,429

4. 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. We discontinued hedge accounting for these instruments and are recognizing the net loss in accumulated other comprehensive loss of $13.2 million 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, 2020, the notional amount of the interest rate swap was $181.8 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, 2020, the fair value of the interest rate swap liability was valued at $16.0 million and was recorded in derivatives and other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of September 30, 2020, $13.1 million was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets.

During the three months ended September 30, 2020, the change in the fair value of the interest rate swap of $0.9 million, net of tax, was recorded in accumulated other comprehensive income, net of tax in our unaudited interim condensed consolidated statements of comprehensive (loss)/income. During the nine months ended September 30, 2020, the change in the fair value of the interest rate swap of $8.2 million, net of tax, was recorded in accumulated other comprehensive loss, net of tax in our unaudited interim condensed consolidated statements of comprehensive (loss)/income. Differences between the hedged 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 LIBOR rate. In the three and nine months ended September 30, 2020, $1.2 million and $2.6 million of interest expense was recognized in relation to the interest rate swaps, respectively.

5. 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

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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.

For purposes of determining diluted earnings (loss) per share in 2019, we elected a policy to settle the principal portion of our 3% Convertible Senior Notes (the "Notes"), which matured and were settled in December 2019, in cash. As such, the principal portion of the Notes had no effect on either the numerator or denominator when determining diluted earnings (loss) per share. Any conversion gain was assumed to be settled in shares and was incorporated in diluted earnings per share using the treasury method. The warrants issued in conjunction with the issuance of the Notes were considered to be dilutive if they were in-the-money relative to our average stock price during the period; the bond hedge purchased in conjunction with the issuance of the Notes was always considered to be anti-dilutive.

Earnings (loss) per share for the three and nine months ended September 30, 2020 and 2019 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	
	2020	2019	2020	2019	2020	2019	2020	2019
Net income/(loss)	$ 434	$ 3,895	$ 434	$ 3,895	$ (18,913)	$ 10,929	$ (18,913)	$ 10,929
Net income allocated to restricted stock	(12)	(63)	(13)	(63)	—	(176)	—	(176
Net income/(loss) allocated to common shares	$ 422	$ 3,832	$ 421	$ 3,832	$ (18,913)	$ 10,753	$ (18,913)	$ 10,753
Basic Weighted-Average Shares Outstanding	11,991	11,879	11,991	11,879	11,953	11,826	11,953	11,826
Dilutive effect of stock options and ESPP			12	128			—	106
Dilutive effect of Notes			—	78			—	128
Diluted Weighted-Average Shares Outstanding			12,003	12,085			11,953	12,060
Earnings/(Loss) per share	$ 0.04	$ 0.32	$ 0.04	$ 0.32	$ (1.58)	$ 0.91	$ (1.58)	$ 0.89

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share was 1.1 million and 2.2 million for the three months ended September 30, 2020 and 2019, respectively, and was 1.3 million and 2.9 million for the nine months ended September 30, 2020 and 2019, respectively. Anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the treasury stock method, underlying shares related to out-of-the-money bonds issued as convertible debt (for 2019 only) and out-of-the-money warrants exercisable for common stock.

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6. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2020	December 31, 2019
Raw materials	$ 43,010	$ 34,881
Packaging materials	3,144	2,902
Work-in-progress	1,086	361
Finished goods	18,110	16,750
	65,350	54,894
Reserve for excess/obsolete inventories	(6,155)	(6,731)
Inventories, net	$ 59,195	$ 48,163

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 months ended September 30, 2020, we purchased approximately 14% of our inventory from one supplier. As of September 30, 2020, our accounts payable to this supplier was $1.6 million. During the three months ended September 30, 2019, we purchased approximately 10% of our inventory from one supplier. During the nine months ended September 30, 2020, we purchased approximately 12% of our inventory from one supplier. During the nine months ended September 30, 2019, we purchased approximately 13% of our inventory from one supplier.

7. PROPERTY, PLANT, AND EQUIPMENT

Property and equipment consist of the following as of:

(in thousands)	September 30, 2020	December 31, 2019
Land	$ 4,667	$ 4,566
Buildings	11,142	10,275
Machinery, furniture, and equipment	38,257	34,984
Construction in progress	2,671	3,496
	56,737	53,321
Less: accumulated depreciation	(16,293)	(12,770)
Property and equipment, net	$ 40,444	$ 40,551

Depreciation expense was $1.2 million and $1.1 million for the three months ended September 30, 2020 and 2019, respectively. Depreciation expense was $3.5 million and $3.2 million for the nine months ended September 30, 2020 and 2019, respectively. During the three months ended September 30, 2020 and 2019, there was less than $0.1 million of interest capitalized into construction in progress. During the nine months ended September 30, 2020 and 2019, there was $0.1 and $0.2 million of interest capitalized into construction in progress, respectively. Construction in progress consists of multiple projects, primarily related to new equipment to expand our manufacturing capability as our product lines continue to grow.

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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, 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, 2020. No impairment losses were recognized during the three and nine months ended September 30, 2020 and 2019.

Definite-lived Intangible Assets

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

	September 30, 2020		December 31, 2019		Weighted Average Amortization Period
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
Acquired ANDA intangible assets	$ 106,415	$ (39,261)	$ 64,704	$ (30,169)	8.8 years
NDAs and product rights	230,974	(106,201)	230,974	(87,352)	10.0 years
Marketing and distribution rights	17,657	(11,187)	10,923	(8,982)	5.7 years
Non-compete agreement	624	(401)	624	(334)	7.0 years
	$ 355,670	$ (157,050)	$ 307,225	$ (126,837)	

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 and $8.4 million for the three months ended September 30, 2020 and 2019, respectively. Amortization expense was $30.2 million and $31.8 million for the nine months ended September 30, 2020 and 2019, 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, 2020 and 2019 and therefore no impairment loss was recognized in the three and nine months ended September 30, 2020 and 2019.

Expected future amortization expense is as follows:

(in thousands)	
2020	$ 9,664
2021	38,655
2022	35,249
2023	34,501
2024	31,524
2025 and thereafter	49,027
Total	$ 198,620

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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, 2020, 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,	
	2020	2019	2020	2019
Cost of sales	$ 3	$ 4	$ 14	$ 10
Research and development	6	7	25	16
Selling, general, and administrative	23	19	79	64
	$ 32	$ 30	$ 118	$ 90

Stock Incentive Plan

All 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, 2020, 1.1 million shares of our common stock were available for issuance under the 2008 Plan.

On September 8, 2020, we granted 179,643 stock options to Nikhil Lalwani, President and Chief Executive Officer, through an inducement grant outside of our 2008 Plan to induce Mr. Lalwani to accept employment with us (the "Inducement Grant"). The options were granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant date and will be exercisable in four equal annual installments beginning on the first anniversary of the respective grant date. The grant was made pursuant to inducement grants outside of our shareholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Cost of sales	$ 34	$ 26	$ 93	$ 75
Research and development	117	213	450	545
Selling, general, and administrative	2,200	2,201	9,882	6,063
	$ 2,351	$ 2,440	$ 10,425	$ 6,683

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A summary of stock option and restricted stock activity under the 2008 Plan and Inducement Grant during the nine months ended September 30, 2020 and 2019 is presented below:

(in thousands)	Options	Inducement Grants	RSAs
Outstanding at December 31, 2018	759	—	117
Granted	160	—	122
Options Exercised/RSAs Vested	(117)	—	(42) (1)
Forfeited	(24)	—	(3)
Expired	(1)	—	—
Outstanding at September 30, 2019	777	—	194
Outstanding at December 31, 2019	757	—	192
Granted	42	180	305
Options Exercised/RSAs Vested	(8)	—	(128) (2)
Forfeited	(44)	—	(17)
Expired	—	—	—
Outstanding at September 30, 2020	747	180	352

(1) Includes 15 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 $1.0 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

(2) 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.

On January 17, 2020, we entered into employment agreements with our Named Executive Officers (“NEOs”), (i) former President and Chief Executive Officer, Arthur S. Przybyl, (ii) Vice President of Finance and Chief Financial Officer, Stephen P. Carey, (iii) Senior Vice President of Business Development and Specialty Sales, Robert Schrepfer and (iv) Senior Vice President of Operations and Product Development, James G. Marken. As part of the employment agreements, the NEOs’ Non-Statutory Stock Option, Incentive Option and Restricted Stock Grant agreements (“NEO Stock Agreements”) were modified to provide for accelerated vesting of unvested non-statutory stock options and restricted stock awards in the event of a termination for any reason other than "cause" as defined in the employment agreements or by the NEOs for “good reason” as defined in the employment agreements. Additionally, any vested incentive or non-statutory stock options and unvested non-statutory stock options subject to acceleration and held unexercised by the NEOs at the time of such termination at the time will retain their contractual term, which is generally 10 years from grant date. At this time, we did not recognize any incremental stock-based compensation expense associated with these modifications, as no assumptions regarding the assumed probability of these awards' future vests were changed on this modification date.

In May 2020, our former President and Chief Executive Officer, Arthur S. Przybyl, departed the Company. The departure constituted a Termination Without Good Cause as defined in his employment agreement, and he received separation payments and benefits under his employment agreement in respect of a termination without good cause, including those related to his non-statutory stock options and restricted stock awards as discussed above. This action was accounted for as a modification of the underlying awards and the full expense related to the modified awards was recognized in the second quarter 2020. As part of the benefits, 48,448 previously unvested restricted stock awards and 63,305 previously unvested non-statutory stock options vested upon the termination. Additionally, these 63,305 previously unvested non-statutory stock options that vested upon termination and 101,376 previously vested and unexercised non-statutory stock options held by Mr. Przybyl retained their original contractual term. During the

three months ended June 30, 2020, we recognized $3.4 million of stock-based compensation expense associated with this termination and modification of awards.

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, 2020, 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, 2020 and December 31, 2019. 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. If we project taxable losses in any specific taxing jurisdiction, those losses are excluded from the calculation of the worldwide estimated annual effective tax rate and a resulting tax benefit is not recognized. 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. During periods when we incur net losses before income taxes, our annual estimated effective tax rate may be adjusted based on the "loss limitation" requirements applicable to interim tax provisions, resulting in a limited income tax benefit recognized in that period. 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, 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 three months ended September 30, 2019, we recognized an income tax expense of $0.1 million. The income tax expense resulted from applying an estimated annual worldwide effective tax rate of 8.4% to pre-tax consolidated income of $4.0 million reported during the period, reduced by the net effects of certain discrete items occurring in 2019 which impact our income tax provision in the period in which they occur. Discrete items occurring during the three months ended September 30, 2019 include the impact of stock option exercises, disqualifying dispositions of incentive stock options, and return to provision adjustments.

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, reduced by 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.

For the nine months ended September 30, 2019, we recognized an income tax benefit of $0.1 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 16.6% to pre-tax consolidated income of $10.8 million reported during the period, reduced by the net effects of certain discrete items occurring in 2019 which impact our income tax provision in the period in which they occur. Discrete items occurring during the nine months ended September 30, 2019 include the impact of the release of ANI Canada's net valuation allowance, retroactive application of our newly adopted transfer pricing policy to 2018, and the impact of current period awards of stock-based compensation, stock option exercises, disqualifying dispositions of incentive stock options, and return to provision adjustments.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

All our existing leases as of September 30, 2020 are classified as operating leases. As of September 30, 2020, we have thirteen material operating leases for facilities and office equipment with remaining terms expiring from 2021 through 2025 and a weighted average remaining lease term of 1.9 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 nine months ended September 30, 2020 and 2019 consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2020	2019	2020	2019
Operating lease costs	$ 57	$ 57	$ 166	$ 138
Variable lease costs	15	3	44	44
Total lease costs	$ 72	$ 60	$ 210	$ 182

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A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2020	$ 59
2021	172
2022	132
2023	61
2024 and thereafter	31
Total	$ 455
Discount	(25)
Lease liability	430
Current lease liability	(181)
Non-current lease liability	$ 249

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies. The Food and Drug Administration ("FDA"), in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The Drug Enforcement Administration ("DEA") maintains oversight over our products that are controlled substances.

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, 2020 and 2019, net revenues for these products totaled $4.3 million and $4.7 million, respectively. During the nine months ended September 30, 2020 and 2019, net revenues for these products totaled $12.4 million and $15.5 million, respectively.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. We believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval.

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 these unapproved products for the three months ended September 30, 2020 and 2019 were $0.7 million and $0.5 million, respectively.

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Our contract manufacturing revenues for these unapproved products for the nine months ended September 30, 2020 and 2019 were $2.3 million and $2.0 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, such as opioids. Our policies have been subject to such exclusions which place further potential risk of financial loss on us.

Commercial Litigation – Arbor Pharmaceuticals, LLC

In November of 2017, we were served with a complaint filed by Arbor Pharmaceuticals, LLC, in the United States District Court, District of Minnesota. The complaint alleges 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 seeks a trial by jury and monetary damages (inclusive of actual and consequential damages, treble damages, disgorgement of ANI profit, and legal fees) of an unspecified amount. Discovery in this action closed on March 31, 2019. Trial has been postponed due to COVID-19 and is currently expected to be re-scheduled sometime in 2021. We continue to defend this lawsuit vigorously.

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. We dispute any liability in this matter and intend to vigorously defend ourselves in the litigation.

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, as well as the impact of the prior settlements on this claim, is currently being evaluated by the Company, its insurers, and its legal counsel.

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 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. The Company has been named in other 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. The Company has been served with complaints in three of those cases: Cooper v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81130-RLR, Lineberry v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81079-RLR, and Lovette v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81040-RLR. 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 three 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. We dispute any liability in these MDL matters and intend to vigorously defend ourselves in the litigation.

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.

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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, 2020.

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, 2020 and December 31, 2019. We also determined that the changes in such fair value were immaterial in the three and nine months ended September 30, 2020 and 2019.

In April 2020, we terminated two interest rate swaps used to manage interest rate exposure on underlying interest payments for our Term Loan and DDTL and entered into one new interest rate swap agreement to manage our total exposure under these borrowings (Note 4). 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 4, the fair value of the interest rate swap was a $16.0 million liability at September 30, 2020.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of September 30, 2020 and December 31, 2019, by level within the fair value hierarchy:

(in thousands) Description	Fair Value at September 30, 2020	Level 1	Level 2	Level 3
Liabilities				
Interest rate swaps	$ 15,971	$ —	$ 15,971	$ —

Description	Fair Value at December 31, 2019	Level 1	Level 2	Level 3
Liabilities				
Interest rate swaps	$ 6,215	$ —	$ 6,215	$ —

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.

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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. During the three months ended September 30, 2020, we recognized a $0.1 million impairment of a fixed asset. No other fair value impairment was recognized in the three and nine months ended September 30, 2020 and 2019.

Acquired Non-Financial Assets Measured at Fair Value

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 will be 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 September 30, 2020 and therefore no impairment loss was recognized for the nine months ended September 30, 2020.

In May 2020, we entered into an agreement with a private company to purchase an ANDA and API for one currently marketed generic drug product and certain API for $0.2 million using cash on hand. We also incurred and paid $7 thousand 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. The API inventory was recognized at fair value. The ANDA will be 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 September 30, 2020 and therefore no impairment loss was recognized for the nine months ended September 30, 2020.

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. The product portfolio included ten commercial products, three approved products with launches pending, four filed products and four in-development products as well as a license to commercialize two approved products. Payments were made using cash on hand. 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 will be 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 have significant remaining work required in order to be commercialized and the products do 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 are 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, 2020 and therefore no impairment loss was recognized for the nine months ended September 30, 2020.

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In June 2019, we acquired from Coeptis Pharmaceuticals, Inc. seven development stage generic products, as well as API and reference-listed drug inventory related to certain of the products for a payment of $2.3 million. The entire payment, and $24 thousand of transaction costs directly related to the acquisition, was recorded as research and development expense because the potential generic products have significant remaining work required in order to commercialize the products and do not have an alternative future use. In addition, we could make up to $12.0 million in payments for certain development and commercial milestones. These milestones were determined to be contingent liabilities and will be accrued when they are both estimable and probable.

In April 2019, we entered into an agreement with PII and BAS, under which a previously-commercialized product would be developed and marketed. Per the agreement, we paid PII a series of licensing fees in conjunction with the achievement of certain development and commercial milestones. In the fourth quarter of 2019, the product was launched, triggering a $0.5 million payment due to PII. The payment was capitalized as an intangible asset and is being amortized in full over its useful life of 10 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 and therefore no impairment loss was recognized for the nine months ended September 30, 2020.

In March 2019, we entered into an agreement with Teva Pharmaceutical Industries Ltd. to purchase a basket of ANDAs for 35 previously-marketed generic drug products for $2.5 million in cash. We made the $2.5 million cash payment using cash on hand and capitalized $10 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $2.5 million of ANDAs were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible assets, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 15%. The ANDAs are being amortized in full over their 10 year useful lives 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, 2020 and therefore no impairment loss was recognized for the nine months ended September 30, 2020.

In January 2019, we entered into an amendment to asset purchase agreements with Teva related to three purchases of baskets of ANDAs. Under the terms of the Asset Purchase Agreement Amendment, all royalty obligations of the Company owed to Teva with respect to products associated with ten ANDAs under the original asset purchase agreements ceased being effective as of December 31, 2018. As consideration for the termination of such future royalty obligations, we paid Teva a sum of $16.0 million in cash. Upon payment of $16.0 million, the purchase price of each basket of ANDAs was increased to reflect the subsequent payment as if that payment had been made on the initial acquisition date. As a result, in addition to increasing the carrying value of the acquired ANDA intangible assets by $9.2 million, we recognized cumulative amortization expense of $6.8 million. The payment was allocated to the three ANDA baskets based on the relative fair value of the ANDA baskets, which were determined using Level 3 unobservable inputs. In order to determine the fair value of the acquired ANDA intangible assets, we used the present value of the estimated cash flows related to the ANDAs, using a discount rate of 12%. The additional carrying value is being amortized over the remaining useful lives of the three ANDA baskets 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, 2020 and therefore no impairment loss was recognized for the nine months ended September 30, 2020.

In April 2018, we entered into an agreement with Impax Laboratories, Inc. (now Amneal) to purchase the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that had not yet been commercialized at the time of the acquisition, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that was pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash. At the same time, we entered into a supply agreement with Amneal under which we may elect to purchase the finished goods for one of the products for up to 17 months beginning October 1, 2019, under certain conditions. If we elected to purchase the finished goods from Amneal for this period, we could have been required to pay a milestone payment of up to $10.0 million upon launch, depending on the number of competitors selling the

product at the time of launch. The payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. The launch of one of the acquired products had the potential to trigger a milestone payment of $25.0 million to Teva, depending on the number of competitors selling the product at the time of launch. We launched this product in 2019 and the payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. Additionally, depending on the number of competitors selling the product one year after the launch date, we could have been required to pay a second milestone of $15.0 million to Teva. The one-year anniversary of the launch occurred during the nine months ended September 30, 2020 and the payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. We made the $2.3 million cash payment using cash on hand and capitalized $0.1 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $1.0 million acquired ANDA intangible assets were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the acquired ANDA intangible assets, we used the present value of the estimated cash flows related to the approved ANDAs, using discount rates of 10% to 15%. The acquired ANDAs are being amortized in full over their 10 year useful lives and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. The $58 thousand of manufacturing equipment used to manufacture one of the products was recorded at its relative fair value, based on the estimated net book value of the equipment purchased. The equipment is being amortized in full over its five year useful life 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, 2020 and therefore no impairment loss was recognized for the nine months ended September 30, 2020. The $1.3 million of in-process research and development related to products with significant further work required in order to commercialize the products, and for which there is no alternative future use. The in-process research and development was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 75%, reflective of the higher risk associated with these products. As the transaction was accounted for as an asset purchase, the $1.3 million of in-process research and development was immediately recognized as research and development expense.

13. CORTROPHIN 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 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 have been 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. Under U.S. GAAP, we cannot capitalize these pre-launch purchases of materials as inventory prior to FDA approval, and accordingly, they are charged to expense in the period in which they are incurred. We expect these pre-launch purchases of material to increase significantly in the future as we build raw materials, API and finished goods for the expected launch of this product. During the three and nine months ended September 30, 2020, we incurred related charges for the purchase of materials of less than $0.1 million and $8.3 million, respectively. During the three months ended September 30, 2019, we incurred related charges for the purchase of materials of $0.2 million. Due to the inherent uncertainty of the timing of FDA approval for this product, we cannot reasonably predict whether these materials will ultimately be eligible for use in commercial finished goods inventory. In the future, we also expect to incur other charges directly related to the Cortrophin pre-

launch commercialization efforts, including, but not limited to, sales and marketing and consulting expenses, which will vary in frequency and impact on our results of operations.

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 Form 10-Q quarterly report, 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, 2019 (the "2019 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 2019 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 2019 Annual Report.

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. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), 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.

Our strategy is to use our assets to develop, acquire, manufacture, and market branded and generic specialty prescription pharmaceuticals. By executing this strategy, we believe we will be able to continue to grow our business, expand and diversify our product portfolio, and create long-term value for our investors.

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

Product Launches

In June 2020, we launched Mexiletine Hydrochloride Capsules USP, 150mg, 200mg, and 250mg. Mexiletine Hydrochloride Capsules are indicated for the treatment of documented ventricular arrhythmias, such as sustained ventricular tachycardia, that, in the judgment of the physician, are life-threatening.

In April 2020, we launched Omega-3-Acid Ethyl Esters Capsules, 1 gram. Omega-3-Acid Ethyl Esters Capsules are indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (greater than or equal to 500mg per dL) hypertriglyceridemia.

In April 2020, we launched Polyethylene Glycol 3350, 17g/Packet (PEG-3350). Polyethylene Glycol 3350 is indicated for the treatment of occasional constipation.

In February 2020, we launched Sulfamethoxazole and Trimethoprim Oral Suspension USP 200 mg/40 mg per 5 mL. Sulfamethoxazole and Trimethoprim Oral Suspension is indicated in the treatment and prevention of various infections proven or strongly suspected to be caused by susceptible bacteria which include urinary tract infections, acute otitis media, bronchitis, shigellosis, Pneumocystis jiroveci pneumonia, and traveler's diarrhea.

In January 2020, we launched Tolterodine Extended-Release Capsules, 2mg and 4 mg. Tolterodine Tartrate Extended-Release Capsules are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

In January 2020, we launched Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg. Paliperidone Extended-Release Tablets is an atypical antipsychotic agent indicated for the treatment of schizophrenia, the treatment of schizoaffective disorder as monotherapy, and as an adjunct to mood stabilizers and/or antidepressants.

Cortrophin Gel Re-commercialization Update

In April 2020, the Food and Drug Administration ("FDA") issued a Refusal to File ("RTF") letter for our Supplemental New Drug Application ("sNDA") for Cortrophin Gel. Since this time, our efforts have been focused on the preparation of a complete and timely resubmission of the sNDA. We immediately retained a prominent regulatory consulting firm to support our efforts and augment the capabilities of our internal Cortrophin development team. In addition, we restructured the composition of the internal team. We have performed a comprehensive review of the original sNDA filing and prepared an internal gap assessment. The resultant remediation activities are currently in-progress and we currently anticipate re-submitting the sNDA no later than the first quarter of 2021.

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. Under U.S. GAAP, we cannot capitalize these pre-launch purchases of materials as inventory prior to FDA approval, and accordingly, they are charged to expense in the period in which they are incurred. We expect these pre-launch purchases of material to increase significantly in the future as we build raw materials, API and finished goods for the expected launch of this product.

Management Transition

On May 10, 2020, our former President and Chief Executive Officer, Arthur S. Przybyl, departed the Company. Our Board of Directors retained an executive search firm to lead the search for a new President and Chief Executive Officer. In August 2020, we announced that Nikhil Lalwani was named our President and Chief Executive Officer and his employment was effective September 8, 2020, at which time he also joined our Board of Directors.

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 June 30, 2020, per IQVIA/IMS data, total market generic and brand prescriptions in the United States declined when compared to each of the previous calendar quarters during the trailing 12 months. The decline was in part attributable to the COVID-19 pandemic, including but not limited to negative impacts from "shelter-in-place" and quarantine orders in certain states, restrictions on travel, the prohibition of elective medical procedures, and the related downstream impact of the global economic activity during this period. The decline in prescriptions due to the COVID-19 pandemic negatively impacted our generic and brand net revenues during the three months ended June 30, 2020 when compared to the three months ended March 31, 2020 and June 30, 2019. During the three months ended September 30, 2020, IQVIA/IMS data indicates both brand and generic total market prescription volume increased when compared to the three month period ended June 30, 2020, in part due to the easing of COVID-19 related restrictions. However, total market prescription volume did not increase to pre-pandemic levels during this period. We have not experienced a significant impact to our manufacturing operations, however have seen minor disruptions to our supply chain from the COVID-19 pandemic during 2020. Our manufacturing facilities in Baudette, MN 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 have on our future financial condition, results of operations and cash flows due to numerous uncertainties. These uncertainties include the scope, severity and 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. The outbreak of COVID-19 in many countries, including the United States and Canada, has had a significant adverse impact on global economic activity and has contributed to significant volatility and negative pressure in financial markets. As a result, the COVID-19 pandemic is negatively impacting almost every industry, either directly or indirectly. 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.

GENERAL

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

(in thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Net revenues	$ 52,979	$ 51,337	$ 151,223	$ 158,581
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	20,118	15,002	62,617	45,359
Research and development	2,939	4,982	12,318	15,128
Selling, general, and administrative	15,725	14,357	50,621	41,829
Depreciation and amortization	11,358	9,473	33,739	35,048
Cortrophin pre-launch charges	37	195	8,275	195
Operating income/(loss)	2,802	7,328	(16,347)	21,022
Interest expense, net	(2,510)	(3,336)	(6,898)	(10,096)
Other expense, net	(229)	(33)	(335)	(117)
Income/(loss) before benefit/(provision) for income taxes	63	3,959	(23,580)	10,809
Benefit/(provision) for income taxes	371	(64)	4,667	120
Net income/(loss)	$ 434	$ 3,895	$ (18,913)	$ 10,929

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, 2020	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2020	Nine Months Ended September 30, 2019
Net revenues	100.0 %	100.0 %	100.0 %	100.0 %
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	38.0 %	29.2 %	41.4 %	28.6 %
Research and development	5.5 %	9.7 %	8.1 %	9.5 %
Selling, general, and administrative	29.7 %	28.0 %	33.5 %	26.4 %
Depreciation and amortization	21.4 %	18.5 %	22.3 %	22.1 %
Cortrophin pre-launch charges	0.1 %	0.4 %	5.5 %	0.1 %
Operating income/(loss)	5.3 %	14.2 %	(10.8)%	13.3 %
Interest expense, net	(4.7)%	(6.4)%	(4.6)%	(6.4)%
Other expense, net	(0.4)%	(0.1)%	(0.2)%	(0.1)%
Income/(loss) before benefit/(provision) for income taxes	0.2 %	7.7 %	(15.6)%	6.8 %
Benefit/(provision) for income taxes	0.7 %	(0.1)%	3.1 %	0.1 %
Net income/(loss)	0.9 %	7.6 %	(12.5)%	6.9 %

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019

Net Revenues

(in thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019	Change	% Change
Generic pharmaceutical products	$ 37,712	$ 31,753	$ 5,959	18.8 %
Branded pharmaceutical products	12,411	16,605	(4,194)	(25.3)%
Contract manufacturing	2,152	2,376	(224)	(9.4)%
Royalty and other	704	603	101	16.7 %
Total net revenues	$ 52,979	$ 51,337	$ 1,642	3.2 %

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.

Net revenues for the three months ended September 30, 2020 were $53.0 million compared to $51.3 million for the same period in 2019, an increase of $1.6 million, or 3.2%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $37.7 million during the three months ended September 30, 2020, an increase of 18.8% compared to $31.8 million for the same period in 2019. The primary reasons for the increase were the January 2020 launch of Miglustat, Penicillamine, and Paliperidone, all products acquired from Amerigen Pharmaceuticals, Ltd. ("Amerigen"). The increases were tempered by declines in revenues of Ezetimibe Simvastatin, Vancomycin Capsules, and Methazolamide.

- Net revenues for branded pharmaceutical products were $12.4 million during the three months ended September 30, 2020, a decrease of 25.3% compared to $16.6 million for the same period in 2019. The primary reasons for the decrease were lower unit sales of Inderal XL and InnoPran XL and a decline in revenues of Atacand.

- Contract manufacturing revenues were $2.2 million during the three months ended September 30, 2020, a decrease of 9.4% compared to $2.4 million for the same period in 2019, due to a decreased volume of orders from contract manufacturing customers in the period.

- Royalty and other revenues were $0.7 million during the three months ended September 30, 2020, an increase of $0.1 million from $0.6 million for the same period in 2019, primarily due to an increase in product development revenues earned by ANI Canada and an increase in royalty revenues.

Cost of Sales (Excluding Depreciation and Amortization)

	Three Months Ended September 30,			
(in thousands)	2020	2019	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 20,118	$ 15,002	$ 5,116	34.1 %

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, 2020, cost of sales increased to $20.1 million from $15.0 million for the same period in 2019, an increase of $5.1 million, or 34.1%, primarily as a result of increased volumes related to a shift in product mix toward generic products and increased sales of products subject to profit-sharing arrangements. Cost of sales as a percentage of net revenues increased to 38.0% during the three months ended September 30, 2020, from 29.2% during same period in 2019, primarily as a result of a shift in product mix to an increase volume of generic products, which have lower average selling prices, and increased sales of products subject to profit-sharing arrangements during the current quarter.

During the three months ended September 30, 2020, we purchased approximately 14% of our inventory from one supplier. As of September 30, 2020, our amount payable to this supplier was $1.6 million. During the three months ended September 30, 2019, we purchased 10% of our inventory from one supplier.

Other Operating Expenses

(in thousands)	Three Months Ended September 30, 2020	2019	Change	% Change
Research and development	$ 2,939	$ 4,982	$ (2,043)	(41.0)%
Selling, general, and administrative	15,725	14,357	1,368	9.5 %
Depreciation and amortization	11,358	9,473	1,885	19.9 %
Cortrophin pre-launch charges	37	195	(158)	(81.0)%
Total other operating expenses	$ 30,059	$ 29,007	$ 1,052	3.6 %

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, 2020, other operating expenses increased to $30.1 million from $29.0 million for the same period in 2019, an increase of $1.1 million, or 3.6%, primarily as a result of the following factors:

- Research and development expenses decreased from $5.0 million to $2.9 million, a decrease of 41.0%, primarily due to a decrease in expense related to the Cortrophin re-commercialization project. We currently anticipate that Cortrophin-related expenses in the fourth quarter of 2020 will be moderately higher than those of the third quarter, as we continue to focus on our supplemental New Drug Application ("sNDA") resubmission efforts.

- Selling, general, and administrative expenses increased from $14.4 million to $15.7 million, an increase of 9.5%, primarily due to increased pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, and increased legal, insurance and other professional fees.

- Depreciation and amortization increased from $9.5 million to $11.4 million, an increase of 19.9%, primarily due to the amortization of the Abbreviated New Drug Applications ("ANDAs") and marketing and distribution rights acquired in January 2020 from Amerigen and the ANDA acquired in July 2020.

- As described in Note 13, *Cortrophin Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we recognized Cortrophin pre-launch charges of less than $0.1 million in the three months ended September 30, 2020. We recognized Cortrophin pre-launch charges of $0.2 million in the three months ended September 30, 2019.

Other Expense, net

(in thousands)	Three Months Ended September 30, 2020	2019	Change	% Change
Interest expense, net	$ (2,510)	$ (3,336)	$ 826	(24.8)%
Other expense, net	(229)	(33)	(196)	593.9 %
Total other expense, net	$ (2,739)	$ (3,369)	$ 630	(18.7)%

For the three months ended September 30, 2020, we recognized other expense of $2.7 million versus other expense of $3.4 million for the same period in 2019, a decrease of $0.6 million. Interest expense, net for the three months ended September 30, 2020 consists primarily of interest expense on borrowings under our secured term loan ("Term Loan"), delayed draw term loan ("DDTL"), and line of credit ("Revolver"). Interest expense, net for the three months ended September 30, 2019 consists primarily of interest expense on our convertible debt, including amortization of related debt discount, and interest expense on borrowings under our Term Loan. For the three months ended September 30, 2020 and 2019, there was $18 thousand and $41 thousand of interest capitalized into construction in progress, respectively.

Benefit/(Provision) for Income Taxes

(in thousands)	Three Months Ended September 30, 2020	2019	Change	% Change
Benefit/(provision) for income taxes	$ 371	$ (64)	$ (435)	679.7 %

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 interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate expected for the entire year plus the effects of certain discrete items occurring in the quarter. 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. During periods when we incur net losses before income taxes, our annual estimated effective tax rate may be adjusted based on the "loss limitation" requirements applicable to interim tax provisions, resulting in a limited income tax benefit recognized in that 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. 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.

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 three months ended September 30, 2019, we recognized an income tax expense of $0.1 million. The income tax expense resulted from applying an estimated annual worldwide effective tax rate of 8.4% to pre-tax consolidated income of $4.0 million reported during the period, reduced by the net effects of certain discrete items occurring in 2019 which impact our income tax provision in the period in which they occur. Discrete items occurring during the three months ended September 30, 2019 include the impact of stock option exercises, disqualifying dispositions of incentive stock options, and return to provision adjustments.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2020 AND 2019

(in thousands)	Nine Months Ended September 30, 2020	2019	Change	% Change
Generic pharmaceutical products	$ 108,607	$ 99,452	$ 9,155	9.2 %
Branded pharmaceutical products	32,201	48,300	(16,099)	(33.3)%
Contract manufacturing	7,026	8,499	(1,473)	(17.3)%
Royalty and other income	3,389	2,330	1,059	45.5 %
Total net revenues	$ 151,223	$ 158,581	$ (7,358)	(4.6)%

Net revenues for the nine months ended September 30, 2020 were $151.2 million compared to $158.6 million for the same period in 2019, a decrease of $7.4 million, or 4.6%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $108.6 million during the nine months ended September 30, 2020, an increase of 9.2% compared to $99.5 million for the same period in 2019. The primary reasons for the increase are the January 2020 launch of Miglustat, Paliperidone, Penicillamine, Mixed

Amphetamine Salts, Bexarotene and other products acquired from Amerigen, and the September 2019 launch of Vancomycin Oral Solution. These increases were tempered by decreases in revenues of Ezetimibe Simvastatin, Erythromycin Ethylsuccinate ("EES"), Vancomycin Capsules, Esterified Estrogen with Methyltestosterone ("EEMT"), and Nilutamide. During the nine months ended September 30, 2020, and primarily during the second quarter ended June 30, 2020, the overall generic pharmaceutical product market and our generic revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from "shelter-in-place" orders and the prohibition of elective medical procedures. These actions resulted in a decline in generic prescriptions during the nine months ended September 30, 2020, primarily during the second quarter ended June 30, 2020, when compared to the nine months ended September 30, 2019.

- Net revenues for branded pharmaceutical products were $32.2 million during the nine months ended September 30, 2020, a decrease of 33.3% compared to $48.3 million for the same period in 2019. The primary reasons for the decrease were lower unit sales of Inderal LA, Inderal XL and InnoPran XL, as well as a decrease in sales of Arimidex and Atacand. These decreases were tempered by an increase in sales of Atacand HCT and Vancocin. During the nine months ended September 30, 2020, and primarily during the second quarter ended June 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 "shelter-in-place" orders and the prohibition of elective medical procedures. These actions resulted in a decline in brand prescriptions during the nine months ended September 30, 2020, primarily during the second quarter ended June 30, 2020, when compared to the nine months ended September 30, 2019.

- Contract manufacturing revenues were $7.0 million during the nine months ended September 30, 2020, a decrease of 17.3% compared to $8.5 million for the same period in 2019, due to a decreased volume of orders from contract manufacturing customers in the period.

- Royalty and other were $3.4 million during the nine months ended September 30, 2020, an increase of $1.1 million from $2.3 million for the same period in 2019, primarily due to an increase in product development revenues earned by ANI Canada and an increase in royalty revenues.

Cost of Sales (Excluding Depreciation and Amortization)

	Nine Months Ended September 30,			
(in thousands)	2020	2019	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 62,617	$ 45,359	$ 17,258	38.0 %

For the nine months ended September 30, 2020, cost of sales increased to $62.6 million from $45.4 million for the same period in 2019, an increase of $17.3 million or 38.0%, primarily as a result of increased volumes related to a shift in product mix toward generic products, $4.2 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the period, increased sales of products subject to profit-sharing arrangements, and inventory reserve charges of $3.9 million related to excess inventory on hand, expired product and discontinued projects, partially offset by the non-recurrence of the January 2019 royalty buy out from the Asset Purchase Agreement Amendment with Teva Pharmaceuticals USA, Inc. Cost of sales, exclusive of the $4.2 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 39% during the nine months ended September 30, 2020, from 28.6% during same period in 2019, primarily as a result of a shift in product mix to an increased volume of generic products, which have lower average selling prices, increased sales of products subject to profit-sharing arrangements, and inventory reserve charges related to excess inventory on hand, expired product and discontinued projects.

During the nine months ended September 30, 2020, we purchased 12% of our inventory from one supplier. During the nine months ended September 30, 2019, we purchased 13% of our inventory from one supplier.

Other Operating Expenses

(in thousands)	Nine Months Ended September 30, 2020	2019	Change	% Change
Research and development	$ 12,318	$ 15,128	$ (2,810)	(18.6)%
Selling, general, and administrative	50,621	41,829	8,792	21.0 %
Depreciation and amortization	33,739	35,048	(1,309)	(3.7)%
Cortrophin pre-launch charges	8,275	195	8,080	NM [1]
Total other operating expenses	$ 104,953	$ 92,200	$ 12,753	13.8 %

[1] Not Meaningful

For the nine months ended September 30, 2020, other operating expenses increased to $105.0 million from $92.2 million for the same period in 2019, an increase of $12.8 million, or 13.8%, primarily as a result of the following factors:

- Research and development expenses decreased from $15.1 million to $12.3 million, a decrease of 18.6%, primarily due to the non-recurrence of the $2.3 million of expense related to in-process research and development acquired from Coeptis during the nine months ended September 30, 2019 and a decrease in expense related to the Cortrophin re-commercialization project and the Methylphenidate project. These decreases were tempered by the $3.8 million in-process research and development expense from the Amerigen acquisition in January 2020.

- Selling, general, and administrative expenses increased from $41.8 million to $50.6 million, an increase of 21.0%, primarily due to $6.5 million of termination benefit expenses related to the departure of our former President and CEO, comprised of $3.4 million of stock-based compensation expense and $3.1 million of expense for salary continuation, bonus, and fringe benefits, and increased quality assurance expenses. We also incurred $0.8 million in recruitment and related legal charges associated with our CEO search.

- Depreciation and amortization decreased from $35.0 million to $33.7 million, a decrease of 3.7%, primarily due to the non-recurrence of amortization expense recorded in relation to the January 2019 royalty buy out, partially offset by the amortization of the ANDAs and marketing and distribution rights acquired in January 2020 from Amerigen and amortization of the ANDA acquired in July 2020.

- As described in Note 13, *Cortrophin Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we recognized Cortrophin pre-launch charges of $8.3 million in the nine months ended September 30, 2020. We recognized Cortrophin pre-launch charges of $0.2 million in the nine months ended September 30, 2019. We currently expect to incur total expense related to this activity of approximately $11.0-$15.0 million for 2020.

Other Expense, net

(in thousands)	Nine Months Ended September 30, 2020	2019	Change	% Change
Interest expense, net	$ (6,898)	$ (10,096)	$ 3,198	(31.7)%
Other expense, net	(335)	(117)	(218)	186.3 %
Total other expense, net	$ (7,233)	$ (10,213)	$ 2,980	(29.2)%

For the nine months ended September 30, 2020, we recognized other expense of $7.2 million versus other expense of $10.2 million for the same period in 2019, a decrease of $3.0 million. Interest expense, net for 2020 consists primarily of interest expense on our Term Loan, DDTL, and Revolver. Interest expense, net for 2019 consists primarily of interest

expense on our convertible debt, including amortization of related debt discount, and interest expense on borrowings under our Term Loan. For the nine months ended September 30, 2020 and 2019, there was $0.1 million of interest capitalized into construction in progress.

Benefit for Income Taxes

(in thousands)	Nine Months Ended September 30, 2020	2019	Change	% Change
Benefit for income taxes	$ 4,667	$ 120	$ (4,547)	NM (1)

(1) Not Meaningful

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate expected for the entire year plus the effects of certain discrete items occurring in the quarter. 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. 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.

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, reduced by 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.

For the nine months ended September 30, 2019, we recognized an income tax benefit of $0.1 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 16.6% to pre-tax consolidated income of $10.8 million reported during the period, reduced by the net effects of certain discrete items occurring in 2019 which impact our income tax provision in the period in which they occur. Discrete items occurring during the nine months ended September 30, 2019 include the impact of the release of ANI Canada’s net valuation allowance, retroactive application of our newly adopted transfer pricing policy to 2018, and the impact of current period awards of stock-based compensation, stock option exercises, disqualifying dispositions of incentive stock options, and return to provision adjustments.

LIQUIDITY AND CAPITAL RESOURCES

The following table highlights selected liquidity and working capital information from our balance sheets:

(in thousands)	September 30, 2020	December 31, 2019
Cash and cash equivalents	$ 17,900	$ 62,332
Accounts receivable, net	83,745	72,129
Inventories, net	59,195	48,163
Prepaid income taxes	1,621	1,076
Prepaid expenses and other current assets	3,358	3,995
Total current assets	$ 165,819	$ 187,695
Current debt, net of deferred financing costs	$ 12,785	$ 9,941
Accounts payable	13,460	14,606
Accrued expenses and other	2,534	2,362
Accrued royalties	6,088	5,084
Accrued compensation and related expenses	5,993	3,736
Accrued government rebates	11,678	8,901
Returned goods reserve	23,250	16,595
Deferred revenue	112	451
Total current liabilities	$ 75,900	$ 61,676

On September 30, 2020, we had $17.9 million in unrestricted cash and cash equivalents. On December 31, 2019, we had $62.3 million in unrestricted cash and cash equivalents. We generated $21.0 million of cash from operations in the nine months ended September 30, 2020. In January 2020, we acquired the U.S. portfolio of 23 generic products and certain commercial and development inventory and materials from Amerigen Pharmaceuticals, Ltd., for which we have used $57.4 million in cash and could make future payments of up to $25.0 million in contingent profit share payments over the next four years. The contingent payments are earned if annual gross profit exceeds a minimum threshold and are earned on a subset of the acquired products. At the time of the acquisition, the acquired portfolio included ten commercial products, three approved products with launches pending, four filed products, and four in-development products as well as a license to commercialize two approved products. The transaction was funded from cash on hand and $15.0 million of borrowings from our Revolver, of which $7.5 million was repaid in the second quarter. In July 2020, we acquired an ANDA and certain inventories from a private company for total consideration of $4.4 million. The transaction was funded from cash on hand.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue and corresponding collections from customers, and our revolving line of credit facility, under which $67.5 million remains available for borrowing as of September 30, 2020, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months. During the period of uncertainty and volatility related to the COVID-19 outbreak, we will continue to closely monitor our liquidity.

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)	2020	2019
Operating Activities	$ 20,976	$ 40,828
Investing Activities	$ (66,203)	$ (26,175)
Financing Activities	$ 769	$ 2,016

Net Cash Provided by Operations

Net cash provided by operating activities was $21.0 million for the nine months ended September 30, 2020, compared to $40.8 million provided by operating activities during the same period in 2019, a decrease of $19.9 million. The decrease was due to changes in working capital and the net loss during the nine months ended September 30, 2020, including payments made for Cortrophin pre-launch materials and increases to trade accounts receivable.

Net Cash Used in Investing Activities

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 used in investing activities for the nine months ended September 30, 2019 was $26.2 million, principally due to the June 2019 acquisition of in-process research and development related to seven development-stage products for $2.3 million, the March 2019 asset acquisition of ANDAs for $2.5 million, the January 2019 Asset Purchase Agreement Amendment for $16.0 million, a July 2019 contractual license payment for $0.3 million, and $4.9 million of capital expenditures during the period.

Net Cash Provided by Financing Activities

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. Net cash provided by financing activities was $2.0 million for the nine months ended September 30, 2019, principally due to $4.9 million of proceeds from stock option exercises, partially offset by $1.8 million of payments on the Term Loan and $1.0 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 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, 2019. 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 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, 2019.

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 Form 10-Q quarterly report and is incorporated herein by reference.

OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2020, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

CONTRACTUAL OBLIGATIONS

As of September 30, 2020, 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 December 2018, we refinanced our previous $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to $265.2 million. The five-year Credit Facility 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. In March 2020, we drew $15.0 million under the Revolver, of which $7.5 million was repaid during the nine months ended September 30, 2020. As of September 30, 2020, $67.5 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 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, 2020, we had a $181.8 million outstanding balance on the Credit Facility.

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 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, 2020 by approximately $1 thousand.

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, 2020.

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, 2020. 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, 2020 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 Form 10-Q quarterly report, 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 in our 2019 Annual Report under the heading "Part I — Item 1A. Risk Factors." 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 known to us after the filing of our 2019 Annual Report 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.

The novel coronavirus ("COVID-19") pandemic has resulted in significant financial market volatility, and its impact on the global economy and our operations remains uncertain. A continuation or worsening of the pandemic could have a material adverse impact on our business, results of operations and financial condition and on the market price of our common stock.

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States and Canada, imposed unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. As outbreaks continue to occur in various parts of the United States, significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations and on the global economy as a whole.

Demand for the products we sell was negatively impacted by COVID-19 during 2020, which could continue depending on the duration and severity of the COVID-19 pandemic, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and/or extensions of time for restrictions that been imposed to date, and numerous other uncertainties.

As outbreaks occur, government-mandated "shelter-in-place" or similar orders or restrictions could be reinstituted or tightened, which could result in fewer patients visiting physicians for conditions treated by our products, as well as fewer

elective surgeries and fewer visits to pharmacies to have prescriptions filled. As a result, we could see a negative impact in future product sales.

It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to pre-pandemic levels. The COVID-19 pandemic has resulted in periods of significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

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

(a) Not applicable

(b) Not applicable

(c) Not applicable

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

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
10.1	Employment Agreement between Nikhil Lalwani and ANI Pharmaceuticals, Inc., dated July 24, 2020 (incorporated by reference to Exhibit 10.1 of ANI Pharamaceuticals, Inc. Current Report on Form 8-K filed on August 3, 2020).
10.2	Inducement Stock Option Award Agreement, effective as of September 8, 2020, between ANI Pharmaceuticals, Inc. and Nikhil Lalwani.
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, 2020 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 5, 2020

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

Date: November 5, 2020

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

INDUCEMENT STOCK OPTION AWARD AGREEMENT
(Non-Plan Inducement Award)

THIS INDUCEMENT STOCK OPTION AWARD AGREEMENT (this "Agreement") is entered into and effective as of this 8th day of September, 2020 (the "Date of Grant"), by and between ANI Pharmaceuticals, Inc. (the "Company") and Nikhil Lalwani (the "Optionee").

A. The Company desires to grant the Optionee a non-statutory stock option to purchase shares of common stock of the Company as an inducement material to the Optionee entering into employment with the Company.
B. This stock option is not being granted pursuant to the terms of the ANI Pharmaceuticals, Inc. Sixth Amended and Restated 2008 Stock Incentive Plan (the "Plan"), but shall be subject to the terms of the Plan as if granted thereunder and such terms shall be deemed incorporated herein by reference and made a part of this inducement grant, except to the extent otherwise provided for under that certain employment agreement by and between the Company and Optionee dated July 24, 2020 (the "Employment Agreement"), as in effect on the date the Employment Agreement was originally executed, notwithstanding any amendments thereto. Unless otherwise defined herein or in the Employment Agreement, the terms defined in the Plan shall have the same meanings in this Agreement.

Accordingly, the parties agree as follows:

1. Grant of Option.

   The Company hereby grants to the Optionee the right, privilege, and option (the "Option") to purchase 179,643 shares (the "Option Shares") of the Company's common stock, $0.0001 par value (the "Common Stock"). The Option is not intended to be an "incentive stock option," as that term is used in Section 422 of the Internal Revenue Code of 1986, as amended (the "Code"). The Company will register the Option Shares underlying the Option concurrently with the next registration of shares under the Plan but in no event later than the date any portion of the Option becomes exercisable.

2. Option Exercise Price.

   The per share price to be paid by Optionee in the event of an exercise of the Option will be $29.00, which represents 100% of the Fair Market Value of a share of Common Stock on the Date of Grant, as determined in accordance with the Plan.

3. Duration of Option and Time of Exercise.

13.1 Initial Period of Exercisability. The Option will become exercisable with respect to the Option Shares in installments. The following table sets forth the initial dates of exercisability of each installment and the number of Option Shares as to which this Option will become exercisable on such dates:

Exercisability	Available for Exercise
September 8, 2021	44,910
September 8, 2022	44,911
September 8, 2023	44,911
September 8, 2024	44,911

The foregoing rights to exercise this Option will be cumulative with respect to the Option Shares becoming exercisable on each such date. In no event will this Option be exercisable after, and this Option will become void and expire as to all unexercised Option Shares at 5:00 p.m. Central time on September 7, 2030 (the "Time of Termination").

13.2 Termination of Employment or Other Service

(a) Termination by Company Without Good Cause or by Optionee for Good Reason. In the event the Optionee is terminated by the Company "Without Good Cause" or the Optionee resigns for "Good Reason" (in each case, as defined in the Employment Agreement, and each, a "Qualifying Termination Event"), then notwithstanding any other provision contained in this Agreement or the Plan, the vesting of the Option shall be accelerated to the extent determined by the applicable provisions of the Employment Agreement, subject to the Optionee's compliance with the conditions required by the Employment Agreement including, but not limited to the execution of a release of claims specified in the Employment Agreement. This Option will remain exercisable, to the extent exercisable after taking into accounting such acceleration, for a period of eighteen months after such termination (but in no event after the Time of Termination).

(b) Termination Due to Change in Control Conditions. In the event Change in Control Conditions (as defined in the Employment Agreement) have occurred, then notwithstanding any other provision contained in this Agreement or the Plan, the vesting of the Option shall be accelerated to the extent determined by the applicable provisions of the Employment Agreement, subject to the Optionee's compliance with the conditions required by the Employment Agreement including, but not limited to the execution of a release of claims specified in the Employment Agreement. This Option will remain exercisable, to the extent exercisable after taking into accounting such acceleration, until the Time of Termination.

(c) Termination Due to Death, Disability or Retirement. In the event the Optionee's employment or other service with the Company and all Subsidiaries is terminated by reason of death, Disability or Retirement, this Option will remain exercisable, to the extent exercisable as of the date of such termination, for a period of one year after such termination (but in no event after the Time of Termination).

(d) Termination for Reasons Other Than Due to Death, Disability, Retirement, a Qualifying Termination or Change in Control Conditions. In the event that the Optionee's employment or other service with the Company and all Subsidiaries is terminated for any reason other than due to death, Disability, Retirement, a Qualifying Termination or Change in Control Conditions, all rights of the Optionee under the Plan, the Employment Agreement or this Agreement will immediately terminate without notice of any kind, and this Option will no longer be exercisable; provided, however, that if such termination is due to any reason other than termination by the Company or any Subsidiary for Good Cause (as defined in the Employment Agreement), this Option will remain exercisable to the extent exercisable as of such termination for a period of three months after such termination (but in no event after the Time of Termination).

(e) Breach of Employment, Consulting, Confidentiality or Non-Compete Agreements. Notwithstanding anything in this Agreement to the contrary and in addition to the rights of the Committee as set forth in Section 12.4 of the Plan, in the event that the Optionee materially breaches the terms of any employment, consulting, confidentiality or non-compete agreement entered into with the Company or any Subsidiary (including an employment, consulting, confidentiality or non-compete agreement made in connection with the grant of the Option), whether such breach occurs before or after termination of the Optionee's employment or other service with the Company or any Subsidiary, the Committee in its sole discretion may require the Optionee to surrender shares of Common Stock received, and to disgorge any profits

(however defined by the Committee), made or realized by the Optionee in connection with this Option or any shares issued upon the exercise or vesting of this Option.

13.3 Change in Control. For the avoidance of doubt, the provisions of the Plan related to acceleration in the event of a Change in Control (as defined in the Plan) shall not apply. Notwithstanding the foregoing, the Committee, in its sole discretion, retains the right to accelerate all or a portion of the Option in the event of a Change in Control.

4. Manner of Option Exercise.

14.1 Notice. This Option may be exercised by the Optionee in whole or in part from time to time, subject to the conditions contained in the Plan, the Employment Agreement and in this Agreement, by delivery, in person, by facsimile or electronic transmission or through the mail, to the Company at its principal executive office in Baudette, Minnesota, of a written notice of exercise. Such notice must be in a form satisfactory to the Committee, must identify the Option, must specify the number of Option Shares with respect to which the Option is being exercised, and must be signed by the person or persons so exercising the Option. Such notice must be accompanied by payment in full of the total purchase price of the Option Shares purchased. In the event that the Option is being exercised, as provided by the Plan and Section 3.2 above, by any person or persons other than the Optionee, the notice must be accompanied by appropriate proof of right of such person or persons to exercise the Option. As soon as practicable after the effective exercise of the Option, the Optionee will be recorded on the stock transfer books of the Company as the owner of the Option Shares purchased, and the Company will deliver to the Optionee certificated or uncertificated ("book entry") shares. In the event that the Option is being exercised, as provided by resolutions of the Committee and Section 4.2 below, by tender of a Broker Exercise Notice, the Company will deliver such shares directly to the Optionee's broker or dealer or their nominee.

4.2 Payment.

(a) At the time of exercise of this Option, the Optionee must pay the total purchase price of the Option Shares to be purchased entirely in cash (including check, bank draft or money order); provided, however, that the Committee, in its sole discretion and upon terms and conditions established by the Committee, may allow such payments to be made, in whole or in part, by (i) tender of a Broker Exercise Notice; (ii) by tender, or attestation as to ownership, of Previously Acquired Shares that are acceptable to the Committee; (iii) by a "net exercise" of the Option (as described below); or (iv) by a combination of such methods.

(b) In the event the Optionee is permitted to pay the total purchase price of this Option in whole or in part with Previously Acquired Shares, the value of such shares will be equal to their Fair Market Value on the date of exercise of this Option.

(c) In the case of a "net exercise" of an Option, the Company will not require a payment of the exercise price of the Option from the Optionee but will reduce the number of shares of Common Stock issued upon the exercise by the largest number of whole shares that has a Fair Market Value on the exercise date that does not exceed the aggregate exercise price for the shares exercised under this method.

(d) Shares of Common Stock will no longer be issuable under this Option (and this Option will therefore not thereafter be exercisable) following the exercise of such Option to the extent of (i) shares used to pay the exercise price of an Option under the "net exercise," (ii) shares actually delivered to the Optionee as a result of such exercise and (iii) any shares withheld for purposes of tax withholding.

5. Rights of Optionee; Transferability.

5.1 Employment or Service. Nothing in this Agreement will interfere with or limit in any way the right of the Company or any Subsidiary to terminate the employment or service of the Optionee at any time, nor confer upon the Optionee any right to continue in the employ of or provide services to the Company or any Subsidiary at any particular position or rate of pay or for any particular period of time.

5.2 Rights as a Stockholder. The Optionee will have no rights as a stockholder of the Company unless and until all conditions to the effective exercise of this Option (including, without limitation, the conditions set forth in Sections 4 and 6 of this Agreement) have been satisfied and the Optionee has become the holder of record of such shares. No adjustment will be made for dividends or distributions with respect to this Option as to which there is a record date preceding the date the Optionee becomes the holder of record of such shares, except as may otherwise be provided in the Plan or determined by the Committee in its sole discretion.

5.3 Restrictions on Transfer. Except pursuant to testamentary will or the laws of descent and distribution or as otherwise expressly permitted by the Plan, no right or interest of the Optionee in this Option prior to exercise may be assigned or transferred, or subjected to any lien, during the lifetime of the Optionee, either voluntarily or involuntarily, directly or indirectly, by operation of law or otherwise. The Optionee will, however, be entitled to designate a beneficiary to receive this Option upon such Optionee's death, and, in the event of the Optionee's death, exercise of this Option (to the extent permitted pursuant to Section 3.2(a) of this Agreement) may be made by the Optionee's legal representatives, heirs and legatees.

6. Withholding Taxes.

The Company is entitled to (a) withhold and deduct from future wages of the Optionee (or from other amounts that may be due and owing to the Optionee from the Company or a Subsidiary), or make other arrangements for the collection of, all amounts the Company reasonably determines are necessary to satisfy any and all federal, foreign, state and local withholding and employment-related tax requirements attributable to the Option, including, without limitation, the grant, exercise or vesting of, this Option or a disqualifying disposition of any Option Shares; (b) withhold cash paid or payable or shares of Common Stock from the shares issued or otherwise issuable to the Optionee in connection with this Option; or (c) require the Optionee promptly to remit the amount of such withholding to the Company before taking any action, including issuing any shares of Common Stock, with respect to this Option. Shares of Common Stock issued or otherwise issuable to the Optionee in connection with this Option that gives rise to the tax withholding obligation that are withheld for purposes of satisfying the Optionee's withholding or employment-related tax obligation will be valued at their Fair Market Value on the Tax Date.

7. Adjustments.

In the event of any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, divestiture or extraordinary dividend (including a spin-off), or any other similar change in the corporate structure or shares of the Company, the Committee (or, if the Company is not the surviving corporation in any such transaction, the board of directors of the surviving corporation), in order to prevent dilution or enlargement of the rights of the Optionee, will make appropriate adjustment (which determination will be conclusive) as to the number and kind of securities or other property (including cash) subject to, and the exercise price of, this Option.

8. Plan Terms Incorporated by Reference.

The Option Shares granted and issued pursuant to this Agreement have not been granted and issued under the Plan; however, the terms of the Plan are incorporated by reference in this Agreement except to the extent otherwise provided in the Employment Agreement, and the Optionee, by execution of this Agreement, acknowledges having received a copy of the Plan. The provisions of this Agreement will be interpreted as to be consistent with the Plan and Employment Agreement, as applicable, and any ambiguities in this Agreement will be interpreted by reference to the Plan and Employment Agreement, as applicable. In the event that any provision of this Agreement is inconsistent with the terms of the Plan or Employment Agreement, as applicable, the terms of the Plan or Employment Agreement, as applicable will prevail.

9. Miscellaneous.

9.1 Binding Effect. This Agreement will be binding upon the heirs, executors, administrators and successors of the parties to this Agreement.

9.2 Governing Law. This Agreement and all rights and obligations under this Agreement will be construed in accordance with the Plan and the Employment Agreement, as applicable, and governed by the laws of the State of Delaware, without regard to conflicts of laws provisions. Any legal proceeding related to this Agreement will be brought in an appropriate Delaware court, and the parties to this Agreement consent to the exclusive jurisdiction of the court for this purpose.

9.3 Entire Agreement. This Agreement, the Employment Agreement and the Plan set forth the entire agreement and understanding of the parties to this Agreement with respect to the grant and exercise of this Option and the administration of the Plan and supersede all prior agreements, arrangements, plans and understandings relating to the grant and exercise of this Option and the administration of the Plan.

9.4 Amendment and Waiver. Other than as provided in the Plan and the Employment Agreement, as applicable, this Agreement may be amended, waived, modified or canceled only by a written instrument executed by the parties to this Agreement or, in the case of a waiver, by the party waiving compliance.

9.5 Construction. Wherever possible, each provision of this Agreement will be interpreted so that it is valid under the applicable law. If any provision of this Agreement is to any extent invalid under the applicable law, that provision will still be effective to the extent it remains valid. The remainder of this Agreement also will continue to be valid, and the entire Agreement will continue to be valid in other jurisdictions.

9.6 Counterparts. For convenience of the parties hereto, this Agreement may be executed in any number of counterparts, each such counterpart to be deemed an original instrument, and all such counterparts together to constitute the same agreement.

[Remainder of page intentionally left blank]

The parties to this Agreement have executed this Agreement effective the day and year first above written.

ANI PHARMACEUTICALS, INC.

ANI PHARMACEUTICALS, INC.

By /s/ Stephen P. Carey

Stephen P. Carey
Its Vice President, Finance and Chief Financial Officer

By execution of this Agreement, the Optionee acknowledges having received a copy of the Plan.

OPTIONEE

/s/ Nikhil Lalwani

(Signature)

Nikhil Lalwani

(Name and Address)

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 5, 2020

/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 5, 2020

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended September 30, 2020 (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 5, 2020

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

Dated: November 5, 2020

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