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, 2019

☐ **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)

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, 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 30, 2019, there were 12,080,121 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

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 Select Market

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended September 30, 2019
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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, products, financial position, operating results, prospects, pipeline or potential markets therefor, 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.

Uncertainties and risks may cause our actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that we may face with respect to importing raw materials, increased competition, acquisitions, contract manufacturing arrangements, delays or failure in obtaining product approvals from the U.S. Food and Drug Administration ("FDA"), general business and economic conditions, market trends, product development, regulatory, and other approvals and marketing.

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, 2018, 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.

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

	September 30, 2019	*December 31, 2018*
Assets		
Current Assets		
Cash and cash equivalents	$ 59,673	$ 43,008
Accounts receivable, net of $47,687 and $47,705 of adjustments for chargebacks and other allowances at September 30, 2019 and December 31, 2018, respectively	70,700	64,842
Inventories, net	46,174	40,503
Prepaid income taxes, net	814	—
Prepaid expenses and other current assets	5,025	4,524
Total Current Assets	182,386	152,877
Property and equipment, net	39,754	38,090
Restricted cash	5,025	5,021
Deferred tax assets, net of deferred tax liabilities and valuation allowance	36,002	27,964
Intangible assets, net	188,372	201,604
Goodwill	3,580	3,580
Other non-current assets	1,656	1,468
Total Assets	$ 456,775	$ 430,604
Liabilities and Stockholders' Equity		
Current Liabilities		
Current component of term loan, net of deferred financing costs	$ 4,154	$ 3,256
Convertible notes, net of discount and deferred financing costs	117,586	112,463
Accounts payable	10,953	8,884
Accrued expenses and other	3,368	1,707
Accrued royalties	5,527	8,456
Accrued compensation and related expenses	3,494	3,524
Current income taxes payable, net	—	5,022
Accrued government rebates	9,184	8,974
Returned goods reserve	15,945	12,552
Deferred revenue	496	711
Total Current Liabilities	170,707	165,549
Non-current Liabilities		
Term loan, net of deferred financing costs and current component	64,873	67,296
Other non-current liabilities	8,065	496
Total Liabilities	$ 243,645	$ 233,341
Commitments and Contingencies (Note 12)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 12,088,915 shares issued and 12,076,604 outstanding at September 30, 2019; 11,862,508 shares issued and 11,851,329 shares outstanding at December 31, 2018	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	—	—
Treasury stock, 12,311 shares of common stock, at cost, at September 30, 2019 and 11,179 shares of common stock, at cost, at December 31, 2018	(723)	(659)
Additional paid-in capital	197,470	186,812
Retained earnings	22,419	11,488
Accumulated other comprehensive loss, net of tax	(6,037)	(379)
Total Stockholders' Equity	213,130	197,263
Total Liabilities and Stockholders' Equity	$ 456,775	$ 430,604

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,*	
	2019	*2018*	*2019*	*2018*
Net Revenues	$ 51,337	$ 50,703	$ 158,581	$ 144,454
Operating Expenses:				
Cost of sales (excluding depreciation and amortization)	15,002	15,605	45,359	52,891
Research and development	4,982	4,667	15,128	11,906
Selling, general, and administrative	14,357	11,769	41,829	30,687
Depreciation and amortization	9,473	8,548	35,048	25,056
Cortrophin pre-launch charges	195	—	195	—
Total Operating Expenses	44,009	40,589	137,559	120,540
Operating Income	7,328	10,114	21,022	23,914
Other Expense, net				
Interest expense, net	(3,336)	(3,768)	(10,096)	(11,132)
Other (expense)/income, net	(33)	20	(117)	(71)
Income Before (Provision)/Benefit for Income Taxes	3,959	6,366	10,809	12,711
(Provision)/benefit for income taxes	(64)	(1,329)	120	(2,647)
Net Income	$ 3,895	$ 5,037	$ 10,929	$ 10,064
Basic and Diluted Earnings Per Share:				
Basic Earnings Per Share	$ 0.32	$ 0.43	$ 0.91	$ 0.85
Diluted Earnings Per Share	$ 0.32	$ 0.42	$ 0.89	$ 0.85
Basic Weighted-Average Shares Outstanding	11,879	11,706	11,826	11,659
Diluted Weighted-Average Shares Outstanding	12,085	11,804	12,060	11,767

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

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

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	2019	*2018*	*2019*	*2018*
Net Income	$ 3,895	$ 5,037	$ 10,929	$ 10,064
Other comprehensive (loss)/income, net of tax:				
Change in fair value of interest rate swap, net of tax	(1,024)	317	(5,658)	533
Total other comprehensive (loss)/income, net of tax	(1,024)	317	(5,658)	533
Total comprehensive income, net of tax	$ 2,871	$ 5,354	$ 5,271	$ 10,597

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, 2019 and 2018
(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 Income/(Loss), Net of Tax	Retained Earnings	Total
Balance, June 30, 2018	$ 1	11,828	$ -	$ 184,531	11	$ (659)	$ 216	$ 1,021	$ 185,110
Stock-based Compensation Expense	-	-	-	1,794	-	-	-	-	1,794
Issuance of Common Shares upon Stock Option and ESPP Exercise	-	30	-	207	-	-	-	-	207
Issuance of Restricted Stock Awards	-	-	-	-	-	-	-	-	-
Change in Fair Value of Interest Rate Swap, Net of Tax	-	-	-	-	-	-	317	-	317
Net Income	-	-	-	-	-	-	-	5,037	5,037
Balance, September 30, 2018	$ 1	11,858	$ -	$ 186,532	11	$ (659)	$ 533	$ 6,058	$ 192,465
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

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Nine Months Ended September 30, 2019 and 2018
(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 Income/(Loss), Net of Tax	(Accumulated Deficit)/ Retained Earnings	Total
Balance, December 31, 2017	$ 1	11,656	$ -	$ 179,020	5	$ (259)	$ -	$ (4,006)	$ 174,756
Stock-based Compensation Expense	-	-	-	4,954	-	-	-	-	4,954
Changes in Treasury Stock Related to Stock-based Compensation Arrangements	-	-	-	-	11	(659)	-	-	(659)
Issuance of Common Shares upon Stock Option and ESPP Exercise	-	137	-	2,558	(5)	259	-	-	2,817
Issuance of Restricted Stock Awards	-	65	-	-	-	-	-	-	-
Change in Fair Value of Interest Rate Swap, Net of Tax	-	-	-	-	-	-	533	-	533
Net Income	-	-	-	-	-	-	-	10,064	10,064
Balance, September 30, 2018	$ 1	11,858	$ -	$ 186,532	11	$ (659)	$ 533	$ 6,058	$ 192,465
Balance, December 31, 2018	$ 1	11,863	$ -	$ 186,812	11	$ (659)	$ (379)	$ 11,488	$ 197,263
Cumulative Effect of Change in Accounting Principle	-	-	-	-	-	-	-	2	2
Stock-based Compensation Expense	-	-	-	6,773	-	-	-	-	6,773
Changes in Treasury Stock Related to Stock-based Compensation Arrangements	-	-	-	-	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

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,	
	2019	*2018*
Cash Flows From Operating Activities		
Net income	$ 10,929	$ 10,064
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	6,773	4,954
Deferred taxes	(6,433)	(2,581)
Depreciation and amortization	35,048	25,056
Acquired product rights and in-process research and development ("IPR&D")	2,653	1,335
Non-cash interest relating to convertible notes and loan cost amortization	5,679	6,392
Changes in operating assets and liabilities:		
Accounts receivable, net	(5,858)	(7,548)
Inventories, net	(5,671)	118
Prepaid expenses and other current assets	(510)	(1,769)
Accounts payable	2,130	2,250
Accrued royalties	(2,929)	(4,709)
Current income taxes, net	(5,836)	1,480
Accrued government rebates	210	1,084
Returned goods reserve	3,393	2,566
Accrued expenses, accrued compensation, and other	1,250	1,150
Net Cash and Cash Equivalents Provided by Operating Activities	40,828	39,842
Cash Flows From Investing Activities		
Acquisition of WellSpring Pharma Services Inc., net of cash acquired	-	(17,067)
Acquisition of product rights, IPR&D, and other related assets	(21,243)	(5,169)
Acquisition of property and equipment, net	(4,932)	(4,736)
Net Cash and Cash Equivalents Used in Investing Activities	(26,175)	(26,972)
Cash Flows From Financing Activities		
Payment of debt issuance costs	-	(153)
Payments on term loan agreement	(1,805)	(1,875)
Proceeds from stock option exercises	4,852	2,817
Treasury stock purchases for restricted stock vestings	(1,031)	(659)
Net Cash and Cash Equivalents Provided by Financing Activities	2,016	130
Change in Cash, Cash Equivalents, and Restricted Cash	16,669	13,000
Cash, cash equivalents, and restricted cash, beginning of period	48,029	36,150
Cash, cash equivalents, and restricted cash, end of period	$ 64,698	$ 49,150
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	43,008	31,144
Restricted cash	5,021	5,006
Cash, cash equivalents, and restricted cash, beginning of period	48,029	36,150
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	59,673	44,136
Restricted cash	5,025	5,014
Cash, cash equivalents, and restricted cash, end of period	64,698	49,150
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 3,627	$ 3,763
Cash paid for income taxes	$ 9,893	$ 3,890
Supplemental non-cash investing and financing activities:		
Property and equipment purchased and included in accounts payable	$ 479	$ 110

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

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, 2018, has been derived from audited financial statements 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, 2018.

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.

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS – continued

Foreign Currency

The Company has a subsidiary located in Canada. The subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar. The results of any non-U.S. dollar transactions are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. Our gain or loss on transactions denominated in foreign currencies was immaterial for the three and nine months ended September 30, 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 doubtful accounts, 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.

Leases

At the inception of a contract we determine if the arrangement is, or contains, a lease. Right-of-use ("ROU") assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term.

We have made certain accounting policy elections whereby we (i) do not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases. Operating lease ROU assets are included in other non-current assets and operating lease liabilities are included in accrued expenses and other and other non-current liabilities in our consolidated balance sheets. As of September 30, 2019, we did not have any finance leases.

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS – continued

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		Nine Months Ended	
Location of Operations	**September 30, 2019**	**September 30, 2018**	**September 30, 2019**	**September 30, 2018**
United States	$ 50,026	$ 48,961	$ 153,088	$ 142,712
Canada	1,311	1,742	5,493	1,742
Total Revenue	$ 51,337	$ 50,703	$ 158,581	$ 144,454

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

(in thousands)	September 30, 2019	December 31, 2018
United States	$ 26,147	$ 24,437
Canada	$ 13,607	13,653
Total property and equipment, net	$ 39,754	$ 38,090

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In November 2018, the Financial Accounting Standards Board ("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 is effective for reporting periods beginning after December 15, 2019, 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.

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 is effective for reporting periods beginning after December 15, 2019, 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.

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS – continued

In June 2016, the FASB issued guidance 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 can now reflect 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. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. We currently expect that the adoption of this guidance may change the way we assess the collectability of our receivables and recoverability of other financial instruments. 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 other 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 October 2018, the FASB issued guidance for accounting for derivatives and hedging. The guidance provides for the inclusion of the Secured Overnight Financing Rate (“SOFR”) Overnight Index swap rate as a benchmark interest rate for hedge accounting purposes. In July 2017, the Financial Conduct Authority in the United Kingdom announced that it would phase out London Interbank Offered Rate (“LIBOR”) as a benchmark by the end of 2021. As a result, the U.S. Federal Reserve identified the SOFR as its preferred alternative reference rate, calculated with a broad set of short-term repurchase agreements backed by treasury securities. Amounts drawn under our five-year senior secured credit facility bear interest rates in relation to LIBOR, and our interest rate swap is designated in LIBOR. The guidance was effective for reporting periods beginning after December 15, 2018. We adopted this guidance as of January 1, 2019 on a prospective basis. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In August 2018, the Securities and Exchange Commission (“SEC”) adopted the final rule amending certain disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The rule was effective on November 5, 2018 and was effective for the quarter that began after the effective date. The adoption of this guidance resulted in the inclusion of the statement of changes stockholder’s equity in our interim financial statement filings.

In June 2018, the FASB issued guidance simplifying the accounting for nonemployee stock-based compensation awards. The guidance aligns the measurement and classification for employee stock-based compensation awards to nonemployee stock-based compensation awards. Under the guidance, nonemployee awards are measured at their grant date fair value. Upon transition, the existing nonemployee awards are measured at fair value as of the adoption date. The guidance was effective for reporting periods beginning after December 15, 2018, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2019. The adoption of this guidance did not have a material impact on our consolidated financial statements.

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS – continued

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. In July 2018, the FASB issued additional guidance, which offers a transition option to entities adopting the new lease standards. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. The guidance was effective for reporting periods beginning after December 15, 2018 and early adoption was permitted. We adopted this guidance on a modified retrospective basis effective January 1, 2019, using the following allowable practical expedients:

- We did not reassess if any expired or existing contracts are or contain leases;
- We did not reassess the classification of any expired or existing leases.

Additionally, we made ongoing accounting policy elections whereby we (i) do not recognize right-of-use assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases.

Upon adoption of the new guidance on January 1, 2019, we recognized a right-of-use asset of approximately $0.5 million, which was reduced by approximately $10 thousand of net prepaid rents at the date of adoption, along with a lease liability of approximately $0.5 million. We also recognized total deferred tax assets of approximately $0.1 million and deferred tax liabilities of approximately $0.1 million related to book-tax basis differences. The net effect of the adoption resulted in a cumulative effect adjustment to retained earnings on January 1, 2019 of approximately $2 thousand.

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.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

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:

Products and Services	**Three Months Ended**		**Nine Months Ended**	
(in thousands)	**September 30, 2019**	**September 30, 2018**	**September 30, 2019**	**September 30, 2018**
Sales of generic pharmaceutical products	$ 31,753	$ 30,287	$ 99,452	$ 83,716
Sales of branded pharmaceutical products	16,605	14,589	48,300	41,714
Sales of contract manufactured products	2,376	2,826	8,499	5,450
Royalties from licensing agreements	268	2,409	594	12,560
Product development services	75	288	806	288
Other[(1)]	260	304	930	726
Total net revenues	$ 51,337	$ 50,703	$ 158,581	$ 144,454

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

The following table depicts revenue recognized during the following periods:

Timing of Revenue Recognition	**Three Months Ended**		**Nine Months Ended**	
(in thousands)	**September 30, 2019**	**September 30, 2018**	**September 30, 2019**	**September 30, 2018**
Performance obligations transferred at a point in time	$ 51,262	$ 50,415	$ 157,775	$ 144,166
Performance obligations transferred over time	75	288	806	288
Total	$ 51,337	$ 50,703	$ 158,581	$ 144,454

In the three and nine months ended September 30, 2019 and 2018, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts. We recognized a decrease of $6.5 million to 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 recognized $6.4 million of net revenue from performance obligations satisfied in prior periods during the nine months ended September 30, 2018, consisting primarily of royalties from licensing agreements and revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. In August 2018, we acquired WellSpring Pharma Services Inc. ("WellSpring") (see Note 3), a contract manufacturing company that also provides technical transfer services to customers, for which services are transferred over time. As a result, we had $0.1 million of contract assets related to revenue recognized based on a percentage of completion but not yet billed at both September 30, 2019 and December 31, 2018 and $0.5 million and $0.7 million of deferred revenue at September 30, 2019 and December 31, 2018, respectively. For the nine months ended September 30, 2019, we recognized $56 thousand of revenue that was included in deferred revenue as of December 31, 2018.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

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, 2018.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the nine months ended September 30, 2019 and 2018, respectively:

	Accruals for Chargebacks, Rebates, Returns, and Other Allowances				
(in thousands)	Chargebacks	Government Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2017	$ 28,230	$ 7,930	$ 8,274	$ 5,226	$ 1,834
Accruals/Adjustments	170,533	8,097	10,942	23,148	6,744
Credits Taken Against Reserve	(156,750)	(7,013)	(8,376)	(21,418)	(6,373)
Balance at September 30, 2018	$ 42,013	$ 9,014	$ 10,840	$ 6,956	$ 2,205
Balance at December 31, 2018	$ 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	$ 38,346	$ 9,184	$ 15,945	$ 7,902	$ 2,257

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consists of agreements in which we manufacture a pharmaceutical product on behalf of 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, 2019, the value of our unsatisfied performance obligations (or backlog) was $6.2 million, which consists of firm orders for contract manufactured products, for which our performance obligations remain unsatisfied and for which the related revenue has yet to be recognized. We anticipate satisfying these performance obligations within six months.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

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.

We receive royalties from a license for patent rights initially owned by Cell Genesys, Inc., which merged with BioSante in 2009. The royalties are the results of sales and milestones related to the Yescarta® product. We recognize revenue for sales-based royalties when the underlying sales occur. We estimate variable consideration related to milestones, which requires significant judgment.

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, 2019, the value of our unsatisfied performance obligations for product development services contracts was $4.3 million. We expect to satisfy these performance obligations in the next 6 to 15 months.

Credit Concentration

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

During the three months ended September 30, 2019, three customers represented 34%, 24%, and 23% of net revenues, respectively. During the nine months ended September 30, 2019, the same three customers represented 33%, 24%, and 24% of net revenues, respectively. As of September 30, 2019, accounts receivable from these customers totaled 84% of accounts receivable, net. During the three months ended September 30, 2018, three customers represented 35%, 23%, and 20% of net revenues, respectively. During the nine months ended September 30, 2018, the same three customers represented 34%, 23%, and 20% of net revenues respectively.

3. BUSINESS COMBINATION

Summary

On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc., acquired all the issued and outstanding equity interests of WellSpring, a Canadian company that performs contract development and manufacturing of pharmaceutical products, for a purchase price of $18.0 million, subject to certain customary adjustments. Pursuant to these customary adjustments, the total purchase consideration was $16.7 million. The consideration was paid entirely from cash on hand. In conjunction with the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Pharmaceuticals Canada Inc. ("ANI Canada").

We acquired WellSpring to provide an additional technical transfer site in order to accelerate the re-commercialization of the previously-approved Abbreviated New Drug Applications ("ANDAs") in our pipeline, to expand our contract manufacturing revenue base, and to increase our manufacturing capabilities to three manufacturing facilities.

Transaction Costs

In conjunction with the acquisition, we incurred approximately $1.1 million in transaction costs, all of which were expensed in 2018.

Purchase Consideration and Net Assets Acquired

The business combination was accounted for using the acquisition method of accounting, with ANI as the accounting acquirer of WellSpring. The acquisition method requires that acquired assets and assumed liabilities be recorded at their fair values as of the acquisition date.

The following presents the final allocation of the purchase price to the assets acquired and liabilities assumed on August 6, 2018:

	(in thousands)
Total Purchase Consideration	$ 16,687
Cash and cash equivalents	220
Accounts receivable	1,311
Inventories	2,197
Prepaid expenses and other current assets	361
Property and equipment	13,935
Deferred tax assets, net	—
Goodwill	1,742
Total assets acquired	19,766
Accounts payable and other current liabilities	2,413
Deferred revenue	666
Total liabilities assumed	3,079
Net assets acquired	$ 16,687

The net assets were recorded at their estimated fair value. In valuing acquired assets and liabilities, fair value estimates were based primarily on future expected cash flows, market rate assumptions for contractual obligations, and appropriate discount rates.

3. BUSINESS COMBINATION – continued

Goodwill is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition, such as the assembled workforce and synergies between the entities. Goodwill established as a result of the acquisition is not tax deductible in any taxing jurisdiction. There was no value ascribed to any separately identifiable intangible assets.

Legacy WellSpring operations generated $1.3 million and $5.5 million of revenue and recorded a net loss of $2.4 million and $3.8 million for the three and nine months ended September 30, 2019, respectively.

Pro Forma Condensed Combined Financial Information (unaudited)

The following unaudited pro forma condensed combined financial information summarizes the results of operations for the periods indicated as if the WellSpring acquisition had been completed as of January 1, 2017.

(in thousands)	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Net revenues	$ 51,384	$ 151,091
Net income	$ 4,456	$ 7,812

4. INDEBTEDNESS

Credit Facility

On December 27, 2018, we refinanced our $125.0 million five-year senior secured credit facility (the "Credit Agreement") with Citizens Bank, N.A. by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to $265.2 million. The Credit Facility will mature in December 2023. The principal new feature of the Credit Facility is a $118.0 million Delayed Draw Term Loan (the "DDTL"), which can only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which will mature in December 2019. The Credit Facility (and specifically the DDTL) has a subjective acceleration clause in case of a material adverse event. As a result, the remaining 3% Convertible Senior Notes are classified as current in the accompanying unaudited interim condensed consolidated balance sheets. The Credit Facility also extended the maturity of the remaining $72.2 million secured term loan balance (the "Term Loan") to December 2023. In addition, the Credit Facility increased the previous $50.0 million line of credit (the "Revolver") to $75.0 million. Also on December 27, 2018, we entered into an interest rate swap arrangement to manage our exposure to changes in LIBOR-based interest rates underlying our refinanced Term Loan (Note 5). The Term Loan includes a repayment schedule, pursuant to which $4.5 million of the loan will be paid in quarterly installments during the 12 months ended September 30, 2020. As a result, $4.5 million of the loan is recorded in current component of term loan, net of deferred financing in the accompanying unaudited interim condensed consolidated balance sheets. Amounts drawn on the Term Loan and, if drawn upon, the DDTL, 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. We incur a commitment fee on the Revolver at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. We also incur a delayed draw ticking fee on the DDTL at a rate per annum that varies within a range of 0.25% to 0.50%.

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 initially shall be no greater than 3.75 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 outside the normal course of business.

The carrying value of the current and non-current components of the Term Loan as of September 30, 2019 and December 31, 2018 are:

	Current	
(in thousands)	September 30, 2019	December 31, 2018
Current borrowing on secured term loan	$ 4,512	$ 3,609
Deferred financing costs	(358)	(353)
Current component of term loan, net of deferred financing costs	$ 4,154	$ 3,256

	Non-current	
(in thousands)	September 30, 2019	December 31, 2018
Non-current borrowing on secured term loan	$ 65,871	$ 68,578
Deferred financing costs	(998)	(1,282)
Term loan, net of deferred financing costs and current component	$ 64,873	$ 67,296

4. INDEBTEDNESS – continued

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 paid to third parties associated with the refinance of the Term Loan were recognized as other (expense)/income, net in the accompanying unaudited interim condensed 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 will be amortized as interest expense on a straight-line basis over the five-year term of the DDTL.

As of September 30, 2019, we had a $70.4 million balance on the Term Loan. As of September 30, 2019, we had not drawn on the Revolver or DDTL. Of the $1.1 million of deferred debt issuance costs allocated to the Revolver, $0.8 million is included in other non-current assets in the accompanying unaudited interim condensed consolidated balance sheets and $0.3 million is included in prepaid expenses and other current assets in the accompanying unaudited interim condensed consolidated balance sheets. Of the $0.5 million of deferred debt issuance costs allocated to the DDTL, $0.4 million is included in other non-current assets in the accompanying unaudited interim condensed consolidated balance sheets and $0.1 million is included in prepaid expenses and other current assets in the accompanying unaudited interim condensed consolidated balance sheets. Of the $1.4 million of deferred debt issuance costs allocated to the Term Loan, $0.4 million is classified as a direct deduction to the current portion of the Term Loan and is included in current component of term loan, net of deferred financing costs in the accompanying unaudited interim condensed consolidated balance sheets and $1.0 million is classified as a direct deduction to the non-current portion of the Term Loan and is included in term loan, net of deferred financing costs and current component in the accompanying unaudited interim condensed consolidated balance sheets.

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

(in thousands)		
2019 (remainder of the year)	$	1,805
2020		3,609
2021		5,414
2022		5,414
2023		54,141
Total	$	70,383

4. INDEBTEDNESS – continued

Convertible Senior Notes

In December 2014, we issued $143.8 million of our Convertible Senior Notes due 2019 (the "Notes") in a registered public offering. After deducting the underwriting discounts and commissions and other expenses (including the net cost of the bond hedge and warrant, discussed below), the net proceeds from the offering were approximately $122.6 million. The Notes pay 3.0% interest semi-annually in arrears on June 1 and December 1 of each year, starting on June 1, 2015, and are due December 1, 2019. In December 2018, we entered into separate, privately negotiated agreements with certain holders of our Notes and repurchased $25.0 million of our outstanding Notes. We accounted for the repurchase as an extinguishment of the portion of the Notes and recognized a loss on extinguishment of $0.5 million, which was recorded in other (expense)/income, net in the accompanying unaudited interim condensed consolidated statements of operations. At the same time, we unwound a corresponding portion of the bond hedge and warrant, which are described in further detail below. As a result of unwinding this portion of the bond hedge and warrant, we received a net amount of $0.4 million. The repurchase of the Notes and the unwinding of the bond hedge and warrant resulted in a $1.7 million net reduction to additional paid-in capital ("APIC") in the accompanying unaudited interim condensed consolidated balance sheets. The remaining Notes are convertible into 1,709,002 shares of common stock, based on an initial conversion price of $69.48 per share.

The Notes are convertible at the option of the holder (i) during any calendar quarter beginning after March 31, 2015, if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day, (ii) during the five business days after any five consecutive trading day period in which the trading price per $1,000 principal amount of the Notes for each trading day of such period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; and (iii) on or after June 1, 2019 until the second scheduled trading day immediately preceding the maturity date.

Upon conversion by the holders, we have elected to settle such conversion in a combination of shares of our common stock and cash. As a result of our conversion election, we separately accounted for the value of the embedded conversion option as a debt discount (with an offset to APIC) of $33.6 million. The value of the embedded conversion option was determined based on the estimated fair value of the debt without the conversion feature, which was determined using market comparables to estimate the fair value of similar non-convertible debt (Note 13); the debt discount is being amortized as additional non-cash interest expense using the effective interest method over the term of the Notes.

4. INDEBTEDNESS – continued

Offering costs of $5.5 million were allocated to the debt and equity components in proportion to the allocation of proceeds to the components, as deferred financing costs and equity issuance costs, respectively. The deferred financing costs of $4.2 million are being amortized as additional non-cash interest expense using the straight-line method over the term of the debt, since this method was not significantly different from the effective interest method. We have classified the deferred financing costs as a direct deduction to the net carrying value of our Notes. The $1.3 million portion allocated to equity issuance costs was charged to APIC.

A portion of the offering proceeds was used to simultaneously enter into "bond hedge" (or purchased call) and "warrant" (or written call) transactions with an affiliate of one of the offering underwriters (collectively, the "Call Option Overlay"). We entered into the Call Option Overlay to synthetically raise the initial conversion price of the Notes to $96.21 per share and reduce the potential common stock dilution that may arise from the conversion of the Notes. The exercise price of the bond hedge is $69.48 per share and the exercise price of the warrant is $96.21 per share of our common stock. Because the bond hedge and warrant are both indexed to our common stock and otherwise would be classified as equity, we recorded both elements as equity, resulting in a net reduction to APIC of $15.6 million. After the repurchase of $25.0 million of our outstanding Notes and the unwinding of the corresponding portion of the bond hedge and warrant, our remaining bond hedge had an underlying 1,709,002 common shares as of September 30, 2019 and the remaining warrant had an underlying 1,709,002 common shares as of September 30, 2019.

The carrying value of the Notes is as follows as of:

(in thousands)	September 30, 2019	December 31, 2018
Principal amount	$ 118,750	$ 118,750
Unamortized debt discount	(1,048)	(5,648)
Deferred financing costs	(116)	(639)
Net carrying value	$ 117,586	$ 112,463

We had accrued interest of $1.2 million and $0.3 million related to the Notes recorded in accrued expenses, other in our consolidated balance sheets at September 30, 2019 and December 31, 2018, respectively.

The following table sets forth the components of total interest expense related to the Notes and Term Loan recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three and nine months ended September 30, 2019 and 2018:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2019	September 30, 2018	September 30, 2019	September 30, 2018
Contractual coupon	$ 1,628	$ 1,835	$ 4,903	$ 5,393
Amortization of debt discount	1,553	1,783	4,600	5,280
Amortization of finance fees	358	370	1,078	1,111
Capitalized interest	(41)	(174)	(152)	(552)
	$ 3,498	$ 3,814	$ 10,429	$ 11,232

5. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

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

When we enter into a hedge arrangement and intend to apply hedge accounting, we formally document the hedge relationship and designate the instrument for financial reporting purposes as a fair value hedge, a cash flow hedge, or a net investment hedge. When we determine that a derivative financial instrument qualifies as a cash flow hedge and is effective, the changes in fair value of the instrument are recorded in accumulated other comprehensive loss, net of tax in our consolidated balance sheets and will be reclassified to earnings when the hedged item affects earnings.

In April 2018, we entered into an interest rate swap arrangement, 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 previous term loan. The interest rate swap hedged the variable cash flows associated with the borrowings under our previous term loan, effectively providing a fixed rate of interest throughout the life of the previous term loan.

In December 2018, we refinanced our previous Credit Agreement and, as part of that refinancing, extended the maturity of our $72.2 million secured term loan balance to December 2023. At the same time, we terminated the original interest rate swap and entered into a new interest rate swap arrangement, which is also 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. We accounted for the close-out of the original interest rate swap as a termination of the interest rate swap and wrote the interest rate swap liability and accumulated other comprehensive loss balance off as of the date of termination. As there were no excluded components, there was no net impact to the consolidated statement of operations. The interest rate swap hedges the variable cash flows associated with the borrowings under our Term Loan (Note 4), effectively providing a fixed rate of interest throughout the life of our Term Loan.

The interest rate swap arrangement with Citizens Bank, N.A became effective on December 27, 2018, with a maturity date of December 27, 2023. The notional amount of the swap agreement at inception was $72.2 million and will decrease in line with our Term Loan. As of September 30, 2019, the notional amount of the interest rate swap was $70.4 million. The interest rate swap has a weighted average fixed rate of 2.60% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of September 30, 2019, the fair value of the interest rate swap liability was valued at $3.0 million and was recorded in other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of September 30, 2019, $2.4 million, the fair value of the interest rate swap net of tax, was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets. During the three and nine months ended September 30, 2019, changes in the fair value of the interest rate swap of $0.3 million and $2.0 million, net of tax, were recorded in accumulated other comprehensive loss, net of tax in our unaudited interim condensed consolidated statements of comprehensive income, respectively. 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 based on the LIBOR rate. During the three and nine months ended September 30, 2019, $63 thousand and $0.1 million of interest expense was recognized in relation to the interest rate swap, respectively.

5. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY – continued

In February 2019, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our DDTL. The notional amount of the interest rate swap is $118.0 million and will have a cash and interest impact beginning in December 2019. The interest rate swap provides an effective fixed rate of 2.47% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of September 30, 2019, the fair value of the interest rate swap liability was valued at $4.7 million and was recorded in other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of September 30, 2019, $3.7 million, the fair value of the interest rate swap net of tax, was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets. During the three and nine months ended September 30, 2019, changes in the fair value of the interest rate swap of $0.7 million and $3.7 million, net of tax, were recorded in accumulated other comprehensive loss, net of tax in our unaudited interim condensed consolidated statements of comprehensive income, respectively. Differences between the hedged LIBOR rate and the fixed rate will be recorded as interest expense in the same period that the related interest is recorded for the DDTL based on the LIBOR rate. During the three and nine months ended September 30, 2019, we did not record interest expense in relation to the February 2019 interest rate swap.

6. EARNINGS PER SHARE

Basic earnings per share is computed by dividing net income 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 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, stock purchase warrants, and any conversion gain on our Notes (Note 4), 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 per share excludes from the numerator net income attributable to the unvested restricted shares, and excludes the impact of those shares from the denominator.

For purposes of determining diluted earnings per share, we have elected a policy to settle the principal portion of the Notes (Note 4) in cash. As such, the principal portion of the Notes has no effect on either the numerator or denominator when determining diluted earnings per share. Any conversion gain is assumed to be settled in shares and is incorporated in diluted earnings per share using the treasury method. The warrants issued in conjunction with the issuance of the Notes (Note 4) are considered to be dilutive when they are in-the-money relative to our average stock price during the period; the bond hedge purchased in conjunction with the issuance of the Notes is always considered to be anti-dilutive.

6. EARNINGS PER SHARE – continued

Earnings per share for the three and nine months ended September 30, 2019 and 2018 are calculated for basic and diluted earnings per share as follows:

	Basic		Diluted		Basic		Diluted	
	Three Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	2019	2018	2019	2018	2019	2018	2019	2018
Net income	$ 3,895	$ 5,037	$ 3,895	$ 5,037	$ 10,929	$ 10,064	$ 10,929	$ 10,064
Net income allocated to restricted stock	(56)	(51)	(56)	(51)	(169)	(101)	(169)	(101)
Net income allocated to common shares	$ 3,832	$ 4,986	$ 3,832	$ 4,986	$ 10,753	$ 9,963	$ 10,753	$ 9,963
Basic Weighted-Average Shares Outstanding	11,879	11,706	11,879	11,706	11,826	11,659	11,826	11,659
Dilutive effect of stock options and ESPP			128	98			106	108
Dilutive effect of Notes			78	-			128	-
Diluted Weighted-Average Shares Outstanding			12,085	11,804			12,060	11,767
Earnings Per Share	$ 0.32	$ 0.43	$ 0.32	$ 0.42	$ 0.91	$ 0.85	$ 0.89	$ 0.85

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share was 2.2 million and 4.8 million for the three months ended September 30, 2019 and 2018 and was 2.9 million and 4.7 million for the nine months ended September 30, 2019 and 2018, 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 when applicable, and out-of-the-money warrants exercisable for common stock.

7. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2019	December 31, 2018
Raw materials	$ 33,058	$ 27,671
Packaging materials	2,958	2,563
Work-in-progress	741	1,210
Finished goods	11,379	10,620
	48,136	42,064
Reserve for excess/obsolete inventories	(1,962)	(1,561)
Inventories, net	$ 46,174	$ 40,503

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, 2019, we purchased approximately 10% of our inventory from one supplier. As of September 30, 2019, our amount payable to this supplier was immaterial. During the three months ended September 30, 2018, we purchased approximately 36% of our inventory from one supplier. During the nine months ended September 30, 2019, we purchased approximately 13% of our inventory from one supplier. As of September 30, 2019, our amount payable to this supplier was immaterial. During the nine months ended September 30, 2018, we purchased approximately 25% of our inventory from two suppliers.

8. PROPERTY, PLANT, AND EQUIPMENT

Property and equipment consist of the following as of:

(in thousands)	September 30, 2019	December 31, 2018
Land	$ 4,566	$ 4,558
Buildings	10,161	10,079
Machinery, furniture, and equipment	33,156	26,814
Construction in progress	3,491	5,040
	51,374	46,491
Less: accumulated depreciation	(11,620)	(8,401)
Property and equipment, net	$ 39,754	$ 38,090

Depreciation expense was $1.1 million and $0.6 million for the three months ended September 30, 2019 and 2018, respectively. Depreciation expense was $3.2 million and $1.3 million for the nine months ended September 30, 2019 and 2018, respectively. During the three months ended September 30, 2019 and 2018, there was $41 thousand and $0.2 million of interest capitalized into construction in progress, respectively. During the nine months ended September 30, 2019 and 2018, there was $0.2 million and $0.6 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.

9. 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, 2019. No impairment losses were recognized during the three and nine months ended September 30, 2019 or 2018.

Definite-lived Intangible Assets

Acquisition of Abbreviated New Drug Applications

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. The transaction closed in March 2019 and we made the $2.5 million payment using cash on hand. We also capitalized $10 thousand of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $2.5 million of ANDAs are being amortized in full over their estimated useful lives of 10 years. Please see Note 13 for further details regarding the transaction.

9. GOODWILL AND INTANGIBLE ASSETS – continued

In January 2019, we entered into an amendment to three asset purchase agreements (the "Asset Purchase Agreement Amendment") with Teva Pharmaceuticals USA, Inc. ("Teva"). 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 using cash on hand. Upon the payment of $16.0 million, the purchase price of each basket of ANDAs was increased as if the payment had been made on the initial acquisition date. As a result, we recognized cumulative amortization expense of $6.8 million upon recording the transaction. Please see Note 13 for further details regarding the transaction.

In April 2018, we entered into an agreement with Impax Laboratories, Inc. (now Amneal Pharmaceuticals, Inc., or "Amneal") to purchase the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have not yet been commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash up front. The transaction closed in May 2018 and we made the $2.3 million payment using cash on hand. We also capitalized $0.1 million of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $1.0 million acquired ANDA intangible assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 13 for further details regarding the transaction.

In April 2018, we entered into an agreement with IDT Australia, Limited to purchase the ANDAs for 23 previously-marketed generic drug products and API for four of the acquired products for $2.7 million in cash and a royalty on net profits from sales of one of the products. The transaction closed in April 2018 and we made the $2.7 million payment using cash on hand. We also capitalized $18 thousand of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $2.5 million acquired ANDA intangible assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 13 for further details regarding the transaction.

Marketing and Distribution Rights

In March 2018, we entered into an agreement with Appco Pharma, LLC ("Appco"), in which a potential generic product, Ranitidine, was to be developed and marketed. Per the agreement, we paid Appco a series of licensing fees in conjunction with certain development milestones. Ranitidine was launched in the third quarter of 2019, resulting in the final milestone payment of $80 thousand. The $80 thousand milestone payment was capitalized as an intangible asset and will be amortized in full over its estimated useful life of eight years. Please see Note 13 for further details regarding the transaction. In September 2019, the Food and Drug Administration ("FDA") issued a public statement that some ranitidine medicines contain a nitrosamine impurity called N-nitrosdimethylamine ("NDMA") at low levels. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests and the cause of the presence of this impurity in the ranitidine products is not yet fully understood at this time. While the ranitidine produced for us has not been specifically recalled, we have voluntarily suspended sale of this product as we follow the investigation. The FDA does not have scientific evidence to recommend whether individuals should continue or stop taking ranitidine medicines at this time. The agency is conducting further tests to determine the risk to consumers. We will continue to evaluate the facts and circumstances around our Ranitidine product to determine if the carrying value of the intangible asset has been impacted.

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

	September 30, 2019		December 31, 2018		Weighted Average
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	Amortization Period
Acquired ANDA intangible assets	$ 64,704	$ (28,553)	$ 46,194	$ (17,093)	10.0 years
NDAs and product rights	230,974	(81,070)	230,974	(62,222)	10.0 years
Marketing and distribution rights	10,503	(8,498)	10,423	(7,051)	4.7 years
Non-compete agreement	624	(312)	624	(245)	7.0 years
	$ 306,805	$ (118,433)	$ 288,215	$ (86,611)	

9. GOODWILL AND INTANGIBLE ASSETS – continued

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 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 $8.4 million and $7.9 million for the three months ended September 30, 2019 and 2018, respectively. Amortization expense was $31.8 million and $23.7 million for the nine months ended September 30, 2019 and 2018, respectively.

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, 2019 and 2018 and therefore no impairment loss was recognized in the three and nine months ended September 30, 2019 and 2018.

Expected future amortization expense is as follows:

(in thousands)	
2019 (remainder of the year)	$ 8,405
2020	33,135
2021	31,694
2022	28,289
2023	27,541
2024 and thereafter	59,308
Total	$ 188,372

10. 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, 2019, we have 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2019	2018	2019	2018
Cost of sales	$ 4	$ 2	$ 10	$ 6
Research and development	7	5	16	8
Selling, general, and administrative	19	15	64	43
	$ 30	$ 22	$ 90	$ 57

10. STOCK-BASED COMPENSATION – continued

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, 2019, 0.3 million shares of our common stock remained available for issuance under the 2008 Plan.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2019	2018	2019	2018
Cost of sales	$ 26	$ 24	$ 75	$ 66
Research and development	213	184	545	564
Selling, general, and administrative	2,201	1,564	6,063	4,266
	$ 2,440	$ 1,772	$ 6,683	$ 4,896

A summary of stock option and restricted stock activity under the 2008 Plan during the nine months ended September 30, 2019 and 2018 is presented below:

(in thousands)	Options	RSAs
Outstanding December 31, 2017	767	86
Granted	156	65
Options Exercised/RSAs Vested	(140)	(33)[1]
Forfeited	(22)	-
Outstanding September 30, 2018	761	118
Outstanding December 31, 2018	759	117
Granted	160	122
Options Exercised/RSAs Vested	(117)	(42)[2]
Forfeited	(24)	(3)
Expired	(1)	-
Outstanding September 30, 2019	777	194

[1] Includes 11 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 $659 thousand total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

[2] 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.

11. 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.

During the three months ended June 30, 2019, we adopted an intercompany transfer pricing policy that uses the "comparable profits method" for pricing intercompany services between ANI Pharmaceuticals, Inc. and ANI Canada. For U.S. and Canadian tax purposes, the policy was adopted in conjunction with the acquisition date of August 6, 2018. The impact on the prior periods was not material.

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. We have provided a valuation allowance against certain of our state net operating loss ("NOL") carryforwards that are not expected to be used during the carryforward periods. As of December 31, 2018, we had provided a valuation allowance against ANI Canada's net deferred tax assets of $1.9 million. As a result of the newly adopted transfer pricing policy, our assessment of the amount of ANI Canada's deferred tax assets that are more likely than not to be realized changed. As a result, during the three months ended June 30, 2019, we released a net valuation allowance of $1.9 million related to ANI Canada.

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, 2019 and December 31, 2018. 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. 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.

11. INCOME TAXES – continued

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 $3.9 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.

The estimated consolidated effective tax rate for the three months ended September 30, 2018, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit could be recognized, was 20.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in the third quarter. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

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 $10.9 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.

The estimated consolidated effective tax rate for the nine months ended September 30, 2018, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit could be recognized, was 20.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

12. COMMITMENTS AND CONTINGENCIES

Operating Leases

All our existing leases as of September 30, 2019 are classified as operating leases. As of September 30, 2019, we have eleven material operating leases for facilities and office equipment with remaining terms expiring from 2021 through 2024 and a weighted average remaining lease term of 2.6 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 4.02% and 8.95%.

Rent expense for the nine months ended September 30, 2019 consisted of the following:

(in thousands)	
Operating lease costs	$ 138
Variable lease costs	44
Total lease costs	$ 182

A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2019 (remainder of the year)	$ 48
2020	195
2021	133
2022	97
2023	40
2024 and thereafter	3
Total	$ 516
Discount	(33)
Lease liability	483
Current lease liability	(177)
Non-current lease liability	$ 306

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies. The 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.

12. COMMITMENTS AND CONTINGENCIES – continued

Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone ("EEMT") and Opium Tincture, are marketed without approved NDAs or ANDAs. During the three months ended September 30, 2019 and 2018, net revenues for these products totaled $4.7 million and $6.2 million, respectively. During the nine months ended September 30, 2019 and 2018, net revenues for these products totaled $15.5 million and $18.3 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, 2019 and 2018 were $0.5 million and $0.6 million, respectively. Our contract manufacturing revenues for these unapproved products for the nine months ended September 30, 2019 and 2018 were $2.0 million and $1.6 million, respectively.

We receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract 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 royalties on the net sales of these unapproved products for the three and nine months ended September 30, 2019 and 2018 were less than 1% of total revenues.

Louisiana Medicaid Lawsuit

On September 11, 2013, the Attorney General of the State of Louisiana filed a lawsuit in Louisiana state court against numerous pharmaceutical companies, including us, under various state laws, alleging that each defendant caused the state's Medicaid agency to provide reimbursement for drug products that allegedly were not approved by the FDA and therefore allegedly not reimbursable under the federal Medicaid program. The lawsuit relates to three cough and cold prescription products manufactured and sold by our former Gulfport, Mississippi operation, which was sold in September 2010. Through its lawsuit, the state seeks unspecified damages, statutory fines, penalties, attorneys' fees, and costs. While we cannot predict the outcome of the lawsuit at this time, we could be subject to material damages, penalties, and fines. We intend to vigorously defend against all claims in the lawsuit.

12. COMMITMENTS AND CONTINGENCIES – continued

Civil Action

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, and seeks injunctive relief and damages. Discovery in this action closed on March 31, 2019. A trial date has not been scheduled. We continue to defend this action vigorously.

Other Commitments and Contingencies

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. At the end of 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.

At the present time, we are unable to assess the likely outcome of the case. Our insurance company had assumed the defense of the legacy claims and paid all losses in settlement of the California cases. We cannot provide assurances that the outcome of this new matter will not have an adverse effect on our business, financial condition, and operating results. Furthermore, like all pharmaceutical manufacturers, we may be exposed to other product liability claims in the future, which 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.

Our ANDA for Erythromycin Ethylsuccinate ("EES") was originally approved by the FDA on November 27th, 1978. We purchased the EES ANDA from Teva on July 10, 2015. In August 2016, we filed with the FDA to reintroduce this product under a Changes Being Effected in 30 Days submission (a "CBE-30 submission"). Under a CBE-30 submission, certain defined changes to an ANDA can be made if the FDA does not object in writing within 30 days. The FDA's regulations, guidance documents, and our historic actions support the filing of a CBE-30 for the types of changes that we proposed for our EES ANDA. We received no formal written letter from the FDA within 30 days of the CBE-30 submission date, and as such, launched the product in accordance with FDA regulations on September 27, 2016. On December 16, 2016, and nearly four months after our CBE-30 submission, the FDA sent us a formal written notice that a Prior Approval Supplement ("PAS") was required for this ANDA. Under a PAS, proposed changes to an ANDA cannot be implemented without prior review and approval by the FDA. Because we did not receive this notice in the timeframe prescribed by the FDA's regulations, we reserved our legal right to an internal Agency appeal. We believe that our supplemental ANDA is valid, and as such continued to market the product. In addition, we filed a PAS which was approved by the FDA on November 2, 2018 with no FDA objection to our prior actions.

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. The Company has been cooperating and intends to continue cooperating with the investigation. However, no assurance can be given as to the timing or outcome of the investigation.

13. FAIR VALUE DISCLOSURES

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, borrowings under lines of credit, and other current liabilities) approximate their carrying values because of their short-term nature. While our Notes are recorded on our accompanying unaudited interim condensed consolidated balance sheets at their net carrying value of $117.6 million as of September 30, 2019, the Notes are being traded on the bond market and their fair value is $125.9 million, based on their closing price on September 30, 2019, a Level 1 input.

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, 2019 and December 31, 2018. We also determined that the changes in such fair value were immaterial in the three and nine months ended September 30, 2019 and 2018.

In December 2018, we refinanced our previous Credit Agreement and, as part of that refinancing, extended the maturity of our $72.2 million secured term loan balance to December 2023. At the same time, we closed out the original interest rate swap and entered into a new interest rate swap arrangement (Note 5) to manage our exposure to the variable interest rate on our Term Loan (Note 4). The notional amount of our interest rate swap was set to match the balance of our Term Loan. The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 5, the fair value of the interest rate swap was a $3.0 million liability at September 30, 2019.

In February 2019, we entered into an interest rate swap arrangement (Note 5), with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our DDTL (Note 4). The fair value of our interest rate swap was 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 included inputs of readily observable market data, a Level 2 input. As described in detail in Note 5, the fair value of the interest rate swap was a $4.7 million liability at September 30, 2019.

13. FAIR VALUE DISCLOSURES – continued

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of September 30, 2019 and December 31, 2018, by level within the fair value hierarchy:

(in thousands)

Description	Fair Value at September 30, 2019	Level 1	Level 2	Level 3
Liabilities				
Interest rate swap	$ 7,757	$ -	$ 7,757	$ -
CVRs	$ -	$ -	$ -	$ -

Description	Fair Value at December 31, 2018	Level 1	Level 2	Level 3
Liabilities				
Interest rate swap	$ 496	$ -	$ 496	$ -
CVRs	$ -	$ -	$ -	$ -

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

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

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

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

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

We measure our long-lived assets, including property, plant, and equipment, ROU assets, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three and nine months ended September 30, 2019 and 2018. Please see Note 3 for discussion of assets and liabilities acquired in the acquisition of WellSpring.

13. FAIR VALUE DISCLOSURES – continued

Acquired Non-Financial Assets Measured at Fair Value

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 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 (Note 9). 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 will be 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, 2019 and therefore no impairment loss was recognized for the nine months ended September 30, 2019.

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 (Note 9). 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 will be 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, 2019 and therefore no impairment loss was recognized for the nine months ended September 30, 2019.

13. FAIR VALUE DISCLOSURES – continued

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 have not yet been commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash (Note 9). 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 do elect to purchase the finished goods from Amneal for this period, we may be 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. This milestone payment was determined to be contingent consideration and will be recognized when the contingency is 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 recently launched this product and the payment was not triggered. As a result, no payment was owed, and this contingent liability has been resolved. However, depending on the number of competitors selling the product one year after the launch date, we could be required to pay a second milestone of $15.0 million to Teva. This milestone was determined to be a contingent liability and will be recognized when it is both estimable and probable. Because we do not believe this milestone is probable, we did not record a contingent liability for the milestone. 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 will be 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 will be amortized in full over its 5-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, 2019 and therefore no impairment loss was recognized for the nine months ended September 30, 2019. 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. FAIR VALUE DISCLOSURES – continued

In April 2018, we entered into an agreement with IDT Australia, Limited to purchase the ANDAs for 23 previously-marketed generic drug products and API for four of the acquired products for $2.7 million in cash and a single-digit royalty on net profits from sales of one of the products (Note 9). We made the $2.7 million cash payment using cash on hand and capitalized $18 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $2.5 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 product rights intangible assets, we used the present value of the estimated cash flows related to the product rights, using discount rates of 10% to 15%. The acquired ANDA intangible assets will be 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, 2019 and therefore no impairment loss was recognized for the nine months ended September 30, 2019. We also recorded $0.2 million of raw materials inventory, measured at fair value. The fair value of the raw materials inventory was determined based on the estimated replacement cost.

In March 2018, we entered into an agreement with Appco, in which a potential generic product, Ranitidine, was to be developed and marketed. Per the agreement, we paid Appco a series of licensing fees in conjunction with certain development milestones. Ranitidine was launched in the third quarter of 2019, resulting in the final milestone payment of $80 thousand. The $80 thousand milestone payment was capitalized as an intangible asset and will be amortized in full over its estimated useful life of eight years. In September 2019, the FDA issued a public statement that some ranitidine medicines contain a nitrosamine impurity referred to as NDMA at low levels. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests and the cause of the presence of this impurity in the ranitidine products is not yet fully understood at this time. While the ranitidine produced for us has not been specifically recalled, we have voluntarily suspended sale of this product as we follow the investigation. The FDA does not have scientific evidence to recommend whether individuals should continue or stop taking ranitidine medicines at this time. The agency is conducting further tests to determine the risk to consumers. We will continue to evaluate the facts and circumstances around our Ranitidine product to determine if the carrying value of the intangible asset has been impacted.

14. 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 three months ended September 30, 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 three months ended September 30, 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 months ended September 30, 2019, we incurred related charges for the purchase of materials of $0.2 million. 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. 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 Annual Report on Form 10-K for the year ended December 31, 2018.

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.

As of September 30, 2019, our products include both branded and generic pharmaceuticals, specifically:

Generic Products	Branded Products
Candesartan Hydrochlorothiazide	Arimidex
Cholestyramine	Atacand
Desipramine Hydrochloride	Atacand HCT
Diphenoxylate Hydrochloride and Atropine Sulfate	Casodex
Erythromycin Ethylsuccinate	Cortenema
Erythromycin Ethylsuccinate for Oral Suspension	Inderal LA
Esterified Estrogen with Methyltestosterone	Inderal XL
Etodolac	InnoPran XL
Ezetimibe-Simvastatin	Lithobid
Felbamate	Reglan
Fenofibrate	Vancocin
Flecainide	
Fluvoxamine	
Hydrocortisone Enema	
Hydrocortisone Rectal Cream (1% and 2.5%)	
Indapamide	
Lithium Carbonate ER	
Mesalamine Enema	
Methazolamide	
Methylphenidate Hydrochloride (18mg and 27mg)	
Metoclopramide Syrup	
Morphine Sulfate Oral Solution	
Nilutamide	
Nimodipine	
Opium Tincture	
Oxycodone Hydrochloride Capsules	
Oxycodone Hydrochloride Oral Solution (5 mg/5 mL)	
Oxycodone Hydrochloride Oral Solution (100 mg/5 mL)	
Pindolol	
Propafenone	
Propranolol ER	
Ranitidine	
Terbutaline Sulfate	
Vancomycin	
Vancomycin Hydrochloride for Oral Solution	

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 September 2019, we launched Vancomycin Hydrochloride for Oral Solution, which is a prescription medication administered orally for treatment of enterocolitis caused by staphylococcus aureus, including methicillin-resistant strains, and antibiotic-associated pseudomembranous colitis caused by clostridium difficile.

In October 2019, we launched Aspirin and Extended Release Dipyridamole capsules, which are indicated to reduce the risk of stroke in patients who have had transient ischemia of the brain or completed ischemic stroke due to thrombosis.

Cortrophin Gel Re-commercialization Update

We continue to successfully progress our Cortrophin re-commercialization program. Significant accomplishments since the August 7, 2019 quarterly report on Form 10-Q include:

- The completion of a fourth commercial scale batch of Corticotropin API. This batch was analytically consistent with previously manufactured batches and met all specifications. We have completed manufacturing for three registration stability batches and expect to complete API process validation in early fourth quarter of 2019.
- The successful completion of viral clearance studies.
- The completion of a third commercial scale batch of Cortrophin Gel. This batch was analytically consistent with previously manufactured batches and met all specifications. We have completed manufacturing for three registration stability batches and expect to complete drug product process validation in fourth quarter of 2019 using commercial scale API.
- Receipt of clinical data on Cortrophin Gel (80 units/mL) from a study that evaluated the blood-level cortisol response in a 20-person healthy volunteer population. The results indicate that our Cortrophin Gel (80 units/mL) is effective for its intended use. The data demonstrates that our modernized drug product has a cortisol response profile consistent with that observed in historical scientific literature that evaluated the drug product manufactured in the 1960s. No adverse safety events were reported and minor events were as expected.

We remain on track to file a supplemental NDA in March of 2020.

GENERAL

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

(in thousands)	Three Months Ended September 30, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Net revenues	$ 51,337	$ 50,703	$ 158,581	$ 144,454
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	15,002	15,605	45,359	52,891
Research and development	4,982	4,667	15,128	11,906
Selling, general, and administrative	14,357	11,769	41,829	30,687
Depreciation and amortization	9,473	8,548	35,048	25,056
Cortrophin pre-launch charges	195	-	195	-
Operating income	7,328	10,114	21,022	23,914
Interest expense, net	(3,336)	(3,768)	(10,096)	(11,132)
Other (expense)/income, net	(33)	20	(117)	(71)
Income before (provision)/benefit for income taxes	3,959	6,366	10,809	12,711
(Provision)/benefit for income taxes	(64)	(1,329)	120	(2,647)
Net income	$ 3,895	$ 5,037	$ 10,929	$ 10,064

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, 2019	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2019	Nine Months Ended September 30, 2018
Net revenues	100.0%	100.0%	100.0%	100.0%
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	29.2%	30.8%	28.6%	36.6%
Research and development	9.7%	9.2%	9.5%	8.2%
Selling, general, and administrative	28.0%	23.2%	26.4%	21.3%
Depreciation and amortization	18.5%	16.9%	22.1%	17.3%
Cortrophin pre-launch charges	0.4%	-%	0.1%	-%
Operating income	14.2%	19.9%	13.3%	16.6%
Interest expense, net	(6.4)%	(7.4)%	(6.4)%	(7.8)%
Other (expense)/income, net	(0.1)%	-%	(0.1)%	-%
Income before (provision)/benefit for income taxes	7.7%	12.5%	6.8%	8.8%
(Provision)/benefit for income taxes	(0.1)%	(2.6)%	0.1%	(1.8)%
Net income	7.6%	9.9%	6.9%	7.0%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018

Net Revenues

(in thousands)	Three Months Ended September 30, 2019	2018	Change	% Change
Generic pharmaceutical products	$ 31,753	$ 30,287	$ 1,466	4.8%
Branded pharmaceutical products	16,605	14,589	2,016	13.8%
Contract manufacturing	2,376	2,826	(450)	(15.9)%
Royalty and other	603	3,001	(2,398)	(79.9)%
Total net revenues	$ 51,337	$ 50,703	$ 634	1.3%

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, 2019 were $51.3 million compared to $50.7 million for the same period in 2018, an increase of $0.6 million, or 1.3%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $31.8 million during the three months ended September 30, 2019, an increase of 4.8% compared to $30.3 million for the same period in 2018. The primary reason for the increase was the launch of Vancomycin Oral Solution, Candesartan, and other products launched in 2018 and 2019, as well as increased unit sales of Vancomycin tablets. These increases were tempered by decreases in sales of Esterified Estrogen with Methyltestosterone (“EEMT”), Diphenoxylate Hydrochloride and Atropine Sulfate, and Fenofibrate.

  As described in Note 12, *Commitments and Contingencies,* in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market EEMT and Opium Tincture without Food and Drug Administration (“FDA”) approved NDAs. The FDA's policy with respect to the continued marketing of unapproved products appears 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 marketing of 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 with potential safety risks or that lack evidence of effectiveness. While 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, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the three months ended September 30, 2019 and 2018 were $4.7 million and $6.2 million, respectively.

- Net revenues for branded pharmaceutical products were $16.6 million during the three months ended September 30, 2019, an increase of 13.8% compared to $14.6 million for the same period in 2018. The primary reason for the increase was sales of Atacand and Atacand HCT, which were launched under our label in October 2018 and previously included in Royalty and other, as well as increased sales of Inderal LA and Vancocin. These increases were tempered by a decrease in sales of Arimidex and InnoPran XL.

- Contract manufacturing revenues were $2.4 million during the three months ended September 30, 2019, a decrease of 15.9% compared to $2.8 million for the same period in 2018, due to the timing and volume of orders from contract manufacturing customers in the period. As described in Note 12, *Commitments and Contingencies,* in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the three months ended September 30, 2019 and 2018 were $0.5 million and $0.6 million, respectively.

- Royalty and other were $0.6 million during the three months ended September 30, 2019, a decrease of $2.4 million from $3.0 million for the same period in 2018, due primarily to the launch of Atacand and Atacand HCT under our own label in October 2018. The net sales from those products are now included in the net sales of branded pharmaceutical products. Royalty and other also includes the impact of product development and laboratory services revenue from our ANI Canada subsidiary.

Cost of Sales (Excluding Depreciation and Amortization)

	Three Months Ended September 30,			
(in thousands)	2019	2018	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 15,002	$ 15,605	$ (603)	(3.9)%

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, 2019, cost of sales decreased to $15.0 million from $15.6 million for the same period in 2018, a decrease of $0.6 million or 3.9%, due primarily to lower royalty expense resulting from the January 2019 royalty buy out and lower sales of products subject to profit-sharing arrangements. Cost of sales as a percentage of net revenues decreased to 29.2% during the three months ended September 30, 2019, from 30.8% during same period in 2018, primarily due to lower sales of products subject to profit-sharing arrangements.

We source the raw materials for our products, including APIs 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. Changes in API suppliers usually must be approved by the FDA, which can take 18 months or longer. As a result, we are dependent upon our current vendors to reliably supply the API required for on-going product manufacturing. In addition, certain of our API for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections.

During the three months ended September 30, 2019, we purchased approximately 10% of our inventory from one supplier. As of September 30, 2019, our amount payable to this supplier was immaterial. In the three months ended September 30, 2018, we purchased 36% of our inventory (exclusive of inventory acquired in the acquisition of WellSpring as described in Note 3, *Business Combinations*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report) from one supplier.

In order to manufacture Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride capsules, we must submit a request to the Drug Enforcement Administration ("DEA") for a quota to purchase the amount of morphine sulfate, opium, and oxycodone hydrochloride needed to manufacture the respective products. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are dependent upon the DEA to annually approve a sufficient quota of API to support the continued manufacture of Morphine Sulfate oral solution, Opium Tincture, Oxycodone Hydrochloride oral solution (5 mg/5 mL), Oxycodone Hydrochloride oral solution (100 mg/5 mL), and Oxycodone Hydrochloride capsules.

Other Operating Expenses

	Three Months Ended September 30,			
(in thousands)	2019	2018	Change	% Change
Research and development	$ 4,982	$ 4,667	$ 315	6.7%
Selling, general, and administrative	14,357	11,769	2,588	22.0%
Depreciation and amortization	9,473	8,548	925	10.8%
Cortrophin pre-launch charges	195	-	195	NM(1)
Total other operating expenses	$ 29,007	$ 24,984	$ 4,023	16.1%

(1) Not Meaningful

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, 2019, other operating expenses increased to $29.0 million from $25.0 million for the same period in 2018, an increase of $4.0 million, or 16.1%, primarily as a result of the following factors:

- Research and development expenses increased from $4.7 million to $5.0 million, an increase of 6.7%, due to timing of work on development projects, primarily the Cortrophin gel re-commercialization project, partially offset by a decrease in expense related to the Methylphenidate project. We anticipate that research and development costs will continue to be greater in 2019 than in 2018, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Cortrophin product.

- Selling, general, and administrative expenses increased from $11.8 million to $14.4 million, an increase of 22.0%, driven by cost related to our ANI Canada subsidiary, increased U.S. based headcount and increased pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, increased stock compensation expense, higher legal fees, and increased sales and marketing related costs. We anticipate that selling, general, and administrative expenses will continue to be greater in 2019 than in 2018 as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $8.5 million to $9.5 million, an increase of 10.8%, primarily due to amortization of the ANDAs acquired in March 2019 and the amortization of the additional value of the ANDA baskets resulting from the January 2019 royalty buy out. We anticipate that depreciation and amortization expense will continue to be greater in 2019 than in 2018.

- As described in Note 14, *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 $0.2 million in the three months ended September 30, 2019. No Cortrophin pre-launch charges were recognized in the three months ended September 30, 2018.

Other Expense, net

(in thousands)	Three Months Ended September 30, 2019	2018	Change	% Change
Interest expense, net	$ (3,336)	$ (3,768)	$ 432	(11.5)%
Other (expense)/income, net	(33)	20	(53)	(265.0)%
Total other expense, net	$ (3,369)	$ (3,748)	$ 379	(10.1)%

For the three months ended September 30, 2019, we recognized other expense of $3.4 million versus other expense of $3.7 million for the same period in 2018, a decrease of $0.4 million. Interest expense, net for 2019 and 2018 consists primarily of interest expense on our convertible debt and interest expense on borrowings under our secured term loan ("Term Loan"). For the three months ended September 30, 2019 and 2018, there was $41 thousand and $0.2 million of interest capitalized into construction in progress, respectively.

Provision for Income Taxes

(in thousands)	Three Months Ended September 30, 2019	2018	Change	% Change
Provision for income taxes	$ (64)	$ (1,329)	$ 1,265	(95.2)%

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

For 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 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 $3.9 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.

The estimated consolidated effective tax rate for the three months ended September 30, 2018, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit could be recognized, was 20.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in the third quarter. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2019 AND 2018

Net Revenues

	Nine Months Ended September 30,			
(in thousands)	2019	2018	Change	% Change
Generic pharmaceutical products	$ 99,452	$ 83,716	$ 15,736	18.8%
Branded pharmaceutical products	48,300	41,714	6,586	15.8%
Contract manufacturing	8,499	5,450	3,049	55.9%
Royalty and other	2,330	13,574	(11,244)	(82.8)%
Total net revenues	$ 158,581	$ 144,454	$ 14,127	9.8%

Net revenues for the nine months ended September 30, 2019 were $158.6 million compared to $144.5 million for the same period in 2018, an increase of $14.1 million, or 9.8%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $99.5 million during the nine months ended September 30, 2019, an increase of 18.8% compared to $83.7 million for the same period in 2018. The primary reason for the increase was the launch of Vancomycin Oral Solution, Ezetimibe-Simvastatin, Candesartan, our Erythromycin Ethylsuccinate family of products, and other products launched in 2018 and 2019, as well as increased unit sales of Vancomycin tablets. These increases were tempered by decreases in sales of EEMT, Diphenoxylate Hydrochloride and Atropine Sulfate, and Fenofibrate.

  As described in Note 12, *Commitments and Contingencies,* in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market EEMT and Opium Tincture without FDA approved NDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled “Marketed New Drugs without Approved NDAs or Abbreviated New Drug Applications ANDAs.” Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of 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 with potential safety risks or that lack evidence of effectiveness. While 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, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the nine months ended September 30, 2019 and 2018 were $15.5 million and $18.3 million, respectively.

- Net revenues for branded pharmaceutical products were $48.3 million during the nine months ended September 30, 2019, an increase of 15.8% compared to $41.7 million for the same period in 2018. The primary reason for the increase was sales of Arimidex and Casodex, which were launched under our label in July 2018 and sales of Atacand and Atacand HCT, which were launched under our label in October 2018. These increases were tempered by lower unit sales of InnoPran XL, Lithobid, and Vancocin.

- Contract manufacturing revenues were $8.5 million during the nine months ended September 30, 2019, an increase of 55.9% compared to $5.5 million for the same period in 2018, due primarily to contract manufacturing revenue in our ANI Canada subsidiary. As described in Note 12, *Commitments and Contingencies,* in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the nine months ended September 30, 2019 and 2018 were $2.0 million and $1.6 million, respectively.

- Royalty and other were $2.3 million during the nine months ended September 30, 2019, a decrease of $11.2 million from $13.6 million for the same period in 2018, due primarily to the launch of Atacand, Atacand HCT, Arimidex, and Casodex under our own label in 2018. During the nine months ended September 30, 2019, we recognized $0.5 million of royalty revenue related to a true-up from our former partner for sales of the authorized generic for Vancocin. Royalty and other also includes the impact of product development and laboratory services revenue from our ANI Canada subsidiary.

Cost of Sales (Excluding Depreciation and Amortization)

	Nine Months Ended September 30,			
(in thousands)	2019	2018	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 45,359	$ 52,891	$ (7,532)	(14.2)%

For the nine months ended September 30, 2019, cost of sales decreased to $45.4 million from $52.9 million for the same period in 2018, a decrease of $7.5 million or 14.2%. The nine months ended September 30, 2018 included $5.6 million of costs of sales related to the excess of fair value over cost on Inderal XL and InnoPran XL inventory and write-off of remaining inventory acquired as part of the acquisition when we re-launched the products under our own label. In addition, cost of sales for the nine months ended September 30, 2019 included lower sales of products subject to profit-sharing arrangements, as well as the impact of the January 2019 royalty buy out from the Asset Purchase Agreement Amendment with Teva. Cost of sales as a percentage of net revenues decreased to 28.6% during the nine months ended September 30, 2019, from 36.6% during same period in 2018, primarily due to the non-recurrence of $5.6 million net impact on cost of sales (12.1% as a percent of net revenues) of the excess of fair value over cost for Inderal XL and InnoPran XL inventory sold and written off during the period, as well as lower royalty expense recognized in the period.

During the nine months ended September 30, 2019, we purchased 13% of our inventory from one supplier. As of September 30, 2019, our amount payable to this supplier was immaterial. During the nine months ended September 30, 2018, we purchased 25% of our inventory (exclusive of inventory acquired in the acquisition of WellSpring as described in Note 3, *Business Combinations*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report) from two suppliers.

Other Operating Expenses

(in thousands)	Nine Months Ended September 30, 2019	2018	Change	% Change
Research and development	$ 15,128	$ 11,906	$ 3,222	27.1%
Selling, general, and administrative	41,829	30,687	11,142	36.3%
Depreciation and amortization	35,048	25,056	9,992	39.9%
Cortophin pre-launch charges	195	-	195	NM(1)
Total other operating expenses	$ 92,200	$ 67,649	$ 24,551	36.3%

(1) Not Meaningful

For the nine months ended September 30, 2019, other operating expenses increased to $92.2 million from $67.6 million for the same period in 2018, an increase of $24.6 million, or 36.3%, primarily as a result of the following factors:

- Research and development expenses increased from $11.9 million to $15.1 million, an increase of 27.1%, due to $2.3 million of expense related to in-process research and development acquired in the acquisition from Coeptis, as well as work on development projects, primarily the Cortrophin gel re-commercialization project and work on the ANDAs acquired in the asset purchase agreement with Impax Laboratories, Inc. (now Amneal), partially offset by the non-recurrence of $1.3 million of expense related to in-process research and development acquired in the asset purchase with Impax Laboratories, Inc. in the second quarter of 2018. We anticipate that research and development costs will continue to be greater in 2019 than in 2018, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Cortrophin product.

- Selling, general, and administrative expenses increased from $30.7 million to $41.8 million, an increase of 36.3%, driven by cost related to our ANI Canada subsidiary, increased U.S. based headcount and increased pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, increased stock compensation expense, higher Generic Drug User Fee Amendments ("GDUFA") and Prescription Drug User Fee Act ("PDUFA") user fees paid to the U.S. FDA, higher legal fees, and increased sales and marketing related costs. We anticipate that selling, general, and administrative expenses will continue to be greater in 2019 than in 2018 as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $25.1 million to $35.0 million, an increase of 39.9%, primarily due to the $6.8 million cumulative amortization expense recorded in relation to the January 2019 royalty buy out as well as the amortization of the ANDAs acquired in April 2018, May 2018, and March 2019. We anticipate that depreciation and amortization expense will continue to be greater in 2019 than in 2018.

- As described in Note 14, *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 $0.2 million in the nine months ended September 30, 2019. No Cortrophin pre-launch charges were recognized in the nine months ended September 30, 2018.

Other Expense, net

(in thousands)	Nine Months Ended September 30, 2019	2018	Change	% Change
Interest expense, net	$ (10,096)	$ (11,132)	$ 1,036	(9.3)%
Other expense, net	(117)	(71)	(46)	64.8%
Total other expense, net	$ (10,213)	$ (11,203)	$ 990	(8.8)%

For the nine months ended September 30, 2019, we recognized other expense of $10.2 million versus other expense of $11.2 million for the same period in 2018, a decrease of $1.0 million. Interest expense, net for 2019 and 2018 consists primarily of interest expense on our convertible debt and interest expense on borrowings under our Term Loan. For the nine months ended September 30, 2019 and 2018, there was $0.2 million and $0.6 million of interest capitalized into construction in progress, respectively.

Provision for Income Taxes

(in thousands)	Nine Months Ended September 30, 2019	2018	Change	% Change
Benefit/(provision) for income taxes	$ 120	$ (2,647)	$ 2,767	(104.5)%

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, 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 $10.9 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.

The estimated consolidated effective tax rate for the nine months ended September 30, 2018, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit could be recognized, was 20.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	September 30, 2019	December 31, 2018
Cash and cash equivalents	$ 59,673	$ 43,008
Accounts receivable, net	70,700	64,842
Inventories, net	46,174	40,503
Prepaid income taxes, net	814	-
Prepaid expenses and other current assets	5,025	4,524
Total current assets	$ 182,386	$ 152,877
Current component of term loan, net of deferred financing costs	$ 4,154	$ 3,256
Convertible notes, net of discount and deferred financing costs	117,586	112,463
Accounts payable	10,953	8,884
Accrued expenses and other	3,368	1,707
Accrued royalties	5,527	8,456
Accrued compensation and related expenses	3,494	3,524
Current income taxes payable, net	-	5,022
Accrued government rebates	9,184	8,974
Returned goods reserve	15,945	12,552
Deferred revenue	496	711
Total current liabilities	$ 170,707	$ 165,549

At September 30, 2019, we had $59.7 million in unrestricted cash and cash equivalents. At December 31, 2018, we had $43.0 million in unrestricted cash and cash equivalents. We generated $40.8 million of cash from operations in the nine months ended September 30, 2019. In June 2019, we acquired from Coeptis Pharmaceuticals, Inc. seven development stage generic products, as well as active pharmaceutical ingredient API and reference-listed drug inventory related to certain of the products for a payment of $2.3 million. In addition, we could make up to $12.0 million in payments for certain development and commercial milestones. We made the $2.3 million payment using cash on hand. In March 2019, we purchased from Teva Pharmaceutical Industries Ltd. a basket of ANDAs for 35 previously-marketed generic drug products for $2.5 million in cash. We made the $2.5 million payment using cash on hand. In January 2019, we entered into the Asset Purchase Agreement Amendment, under which all royalty obligations 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 $16.0 million using cash on hand.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue, delayed draw term loan, and our revolving line of credit facility will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months.

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

	Nine Months Ended September 30,	
(in thousands)	2019	2018
Operating Activities	$ 40,828	$ 39,842
Investing Activities	$ (26,175)	$ (26,972)
Financing Activities	$ 2,016	$ 130

Net Cash Provided by Operations

Net cash provided by operating activities was $40.8 million for the nine months ended September 30, 2019, compared to $39.8 million during the same period in 2018, an increase of $1.0 million. This increase was principally due to an increase in net sales and resulting net income tempered by increases in working capital needs.

Net Cash Used in Investing Activities

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 used in investing activities for the nine months ended September 30, 2018 was $27.0 million, principally due to the preliminary payment of $17.1 million of consideration, net of cash acquired, to acquire WellSpring, the April and May 2018 asset acquisitions of ANDAs for $5.2 million, and $4.7 million of capital expenditures during the period.

Net Cash Provided by Financing Activities

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 vestings. Net cash provided by financing activities was $0.1 million for the nine months ended September 30, 2018, principally due to $2.8 million of proceeds from stock option exercises, partially offset by $1.9 million of payments on the Term Loan, $0.7 million treasury stock purchased in relation to restricted stock vestings, and $0.2 million of debt issuance fees paid in relation to the Term Loan.

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, 2018. 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, 2018.

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.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2019 and December 31, 2018, 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.

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.

As of September 30, 2019, our largest debt obligation was related to our Convertible Senior Notes due 2019 (the "Notes"). In order to reduce the potential equity dilution that would result upon conversion of the Notes issued, we entered into note hedge transactions with a financial institution affiliated with one of the underwriters of the Notes offering. The note hedge transactions are expected generally, but not guaranteed, to reduce the potential dilution to our common stock and/or offset the cash payments we are required to make in excess of the principal amount upon any conversion of the Notes, in the event that the market price per share of our common stock, as measured under the terms of the Convertible Note Hedge Transactions, is greater than the conversion price of the Notes, which is initially approximately $69.48. In addition, in order to partially offset the cost of the note hedge transactions, we issued warrants to the hedge counterparty to purchase shares of our common stock at a strike price of $96.21. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock exceeds the strike price of the warrants. In addition, non-performance by the counterparties under the hedge transactions would potentially expose us to dilution of our common stock to the extent our stock price exceeds the conversion price.

Interest accrues at a fixed rate of 3.0% on the outstanding principal amount of the Notes and is paid semi-annually every December 1st and June 1st until the Notes mature on December 1, 2019. Since the interest rate is fixed, we have no interest-rate market risk related to the Notes. However, if our stock price increases, the fair value of our Notes, and their likelihood of being converted, will change accordingly. As a result, we face equity risk in relation to our Notes.

On December 27, 2018, we refinanced our $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 principal new feature of the Credit Facility is a $118.0 million Delayed Draw Term Loan (the "DDTL"), which can only be drawn on in order to pay down the Company's remaining 3.0% Convertible Senior Notes, which will mature in December 2019. The Credit Facility also extended the maturity of the $72.2 million secured term loan balance (the "Term Loan") to December 2023. In addition, the Credit Facility increased the previous $50.0 million line of credit (the "Revolver") to $75.0 million. Amounts drawn 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. We incur a commitment fee on the Revolver at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. We also incur a delayed draw ticking fee on the DDTL at a rate per annum that varies within a range of 0.25% to 0.50%. As of September 30, 2019, we had a $70.4 million outstanding balance on the Term Loan. As of September 30, 2019, we had not drawn on the Revolver or DDTL.

On December 27, 2018, we entered into an interest rate swap to manage our exposure to the variable interest rate on our refinanced secured Term Loan. The interest rate swap hedges the variable cash flows associated with the secured Term Loan borrowings under the secured Term Loan, effectively providing a fixed rate of interest throughout the life of the secured Term Loan. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

On February 7, 2019, we entered into an interest rate swap to manage our exposure to the variable interest rate on our DDTL. The interest rate swap hedges the variable cash flows associated with borrowings under the DDTL, effectively providing a fixed rate of interest throughout the life of the DDTL. As a result of the interest rate swap, our exposure to interest rate volatility will be 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, 2019 by approximately $33 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, 2019.

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, 2019. 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, 2019 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except as noted below.

On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. ("ANI Canada"), acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc. in an all cash transaction. In conjunction with the transaction, we have integrated ANI Canada's operations into our system of internal control over financial reporting for the quarter ended September 30, 2019.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 12, *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 most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2018 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. There have been no material changes to those risk factors since their disclosure in our most recent Annual Report on Form 10-K.

Item 2. Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities

None.

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
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
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	
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase 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 6, 2019

By: /s/ Arthur S. Przybyl
Arthur S. Przybyl
President and Chief Executive Officer
(principal executive officer)

Date: November 6, 2019

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

Exhibit 31.1

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

I, Arthur S. Przybyl, 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 6, 2019

/s/ Arthur S. Przybyl
Arthur S. Przybyl
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 6, 2019

/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, 2019 (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 6, 2019

/s/ Arthur S. Przybyl
Arthur S. Przybyl
President and Chief Executive Officer
(principal executive officer)

Dated: November 6, 2019

/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.