

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, 2017

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

(State or other jurisdiction of
incorporation or organization)

58-2301143

(IRS Employer Identification Number)

210 Main Street West

Baudette, Minnesota

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer
(Do not check if smaller reporting company)

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 26, 2017, there were 11,643,039 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended September 30, 2017
TABLE OF CONTENTS

	<u>Page</u>
<u>PART I—FINANCIAL INFORMATION</u>	
Item 1. Financial Statements (unaudited)	
Condensed Consolidated Balance Sheets — As of September 30, 2017 and December 31, 2016	4
Condensed Consolidated Statements of Earnings — For the Three and Nine Months Ended September 30, 2017 and 2016	5
Condensed Consolidated Statements of Cash Flows — For the Nine Months Ended September 30, 2017 and 2016	6
Notes to Condensed Consolidated Financial Statements	7
Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations	26
Item 3. Quantitative and Qualitative Disclosures About Market Risk	42
Item 4. Controls and Procedures	43
<u>PART II—OTHER INFORMATION</u>	
Item 1. Legal Proceedings	43
Item 1A. Risk Factors	43
Item 2. Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities	43
Item 3. Defaults upon Senior Securities	43
Item 4. Mine Safety Disclosures	43
Item 5. Other Information	44
Item 6. Exhibits	44
Signatures	45

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, regulatory environment, 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, 2016, 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.

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

	<i>September 30,</i> <i>2017</i>	<i>December 31,</i> <i>2016</i>
Assets		
Current Assets		
Cash and cash equivalents	\$ 18,031	\$ 27,365
Accounts receivable, net of \$32,463 and \$31,535 of adjustments for chargebacks and other allowances at September 30, 2017 and December 31, 2016, respectively	62,174	45,895
Inventories, net	38,478	26,183
Prepaid income taxes	2,052	-
Prepaid expenses and other current assets	4,847	3,564
Total Current Assets	125,582	103,007
Property and equipment, net	17,387	10,998
Restricted cash	5,004	5,002
Deferred tax asset, net of valuation allowance	30,829	26,227
Intangible assets, net	189,829	175,792
Goodwill	1,838	1,838
Total Assets	\$ 370,469	\$ 322,864
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 5,821	\$ 3,389
Accrued expenses and other	2,741	927
Accrued royalties	11,741	11,956
Accrued compensation and related expenses	2,009	1,631
Current income taxes payable	-	2,398
Accrued government rebates	5,755	5,891
Returned goods reserve	8,317	5,756
Total Current Liabilities	36,384	31,948
Long-term Liabilities		
Long-term royalties	-	625
Borrowings on line of credit	25,000	-
Convertible notes, net of discount and deferred financing costs	126,284	120,643
Total Liabilities	\$ 187,668	\$ 153,216
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common stock, \$0.0001 par value, 33,333,334 shares authorized; 11,648,242 shares issued and 11,643,039 shares outstanding at September 30, 2017; 11,588,701 shares issued and outstanding at December 31, 2016	1	1
Class C special stock, \$0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	-	-
Preferred stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2017 and December 31, 2016, respectively	-	-
Treasury stock, 5,203 shares of common stock, at cost, at September 30, 2017, 0 shares of common stock at December 31, 2016	(259)	-
Additional paid-in capital	177,436	172,563
Retained earnings/(Accumulated deficit)	5,623	(2,916)
Total Stockholders' Equity	182,801	169,648
Total Liabilities and Stockholders' Equity	\$ 370,469	\$ 322,864

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

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

	<i>Three Months Ended September 30,</i>		<i>Nine Months Ended September 30,</i>	
	<i>2017</i>	<i>2016</i>	<i>2017</i>	<i>2016</i>
Net Revenues	\$ 48,164	\$ 38,525	\$ 129,556	\$ 90,417
Operating Expenses:				
Cost of sales (excluding depreciation and amortization)	21,078	16,669	58,586	31,874
Research and development	2,634	1,041	6,419	2,771
Selling, general, and administrative	8,022	6,928	22,695	20,460
Depreciation and amortization	7,099	5,966	20,906	16,531
Total Operating Expenses	38,833	30,604	108,606	71,636
Operating Income	9,331	7,921	20,950	18,781
Other Expense, net				
Interest expense, net	(3,052)	(2,856)	(9,009)	(8,468)
Other income/(expense), net	95	(21)	58	(31)
Income Before Provision for Income Taxes	6,374	5,044	11,999	10,282
Provision for income taxes	(1,654)	(2,501)	(3,446)	(5,268)
Net Income	\$ 4,720	\$ 2,543	\$ 8,553	\$ 5,014
Basic and Diluted Earnings Per Share:				
Basic Earnings Per Share	\$ 0.41	\$ 0.22	\$ 0.74	\$ 0.44
Diluted Earnings Per Share	\$ 0.40	\$ 0.22	\$ 0.73	\$ 0.43
Basic Weighted-Average Shares Outstanding	11,553	11,465	11,542	11,421
Diluted Weighted-Average Shares Outstanding	11,677	11,625	11,666	11,552

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)

	<i>Nine Months Ended September 30,</i>	
	<u>2017</u>	<u>2016</u>
Cash Flows From Operating Activities		
Net income	\$ 8,553	\$ 5,014
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	4,668	4,687
Deferred taxes	(4,602)	(1,084)
Depreciation and amortization	20,906	16,531
Non-cash interest relating to convertible notes and loan cost amortization	5,723	5,421
Changes in operating assets and liabilities:		
Accounts receivable, net	(16,279)	(25,545)
Inventories, net	4,605	(4,016)
Prepaid expenses and other current assets	(1,365)	(623)
Accounts payable	2,078	2,562
Accrued royalties	(840)	6,082
Accrued compensation and related expenses	378	238
Current income taxes, net	(4,450)	198
Accrued government rebates	(136)	1,820
Returned goods reserve	2,561	1,451
Accrued expenses and other	1,814	2,654
	<u>23,614</u>	<u>15,390</u>
Net Cash and Cash Equivalents Provided by Operating Activities		
Cash Flows From Investing Activities		
Acquisition of product rights and other related assets	(50,956)	(144,494)
Acquisition of property and equipment	(6,922)	(3,177)
	<u>(57,878)</u>	<u>(147,671)</u>
Net Cash and Cash Equivalents Used in Investing Activities		
Cash Flows From Financing Activities		
Payment of debt issuance costs	-	(294)
Net borrowings under line of credit agreement	25,000	-
Proceeds from stock option exercises	191	1,362
Excess tax benefit from share-based compensation awards	-	307
Repurchase of common stock under the stock repurchase program	-	(2,500)
Treasury stock purchases for restricted stock vestings and forfeitures	(259)	(122)
	<u>24,932</u>	<u>(1,247)</u>
Net Cash and Cash Equivalents Provided by/(Used in) Financing Activities		
Change in Cash, Cash Equivalents, and Restricted Cash	(9,332)	(133,528)
Cash, cash equivalents, and restricted cash, beginning of period	32,367	154,684
Cash, cash equivalents, and restricted cash, end of period	<u>\$ 23,035</u>	<u>\$ 21,156</u>
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	27,365	154,684
Restricted cash	5,002	-
	<u>32,367</u>	<u>154,684</u>
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	18,031	16,155
Restricted cash	5,004	5,001
	<u>23,035</u>	<u>21,156</u>
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	\$ 2,197	\$ 2,056
Cash paid for income taxes, net	\$ 12,493	\$ 5,847
Supplemental non-cash investing and financing activities:		
Accrued royalties related to asset purchase	\$ -	\$ 3,882
Property and equipment purchased and included in accounts payable	<u>\$ 354</u>	<u>\$ 102</u>

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

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

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (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 two pharmaceutical manufacturing facilities located in Baudette, Minnesota are capable of producing oral solid dose products, as well as 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, and cash flows. The consolidated balance sheet at December 31, 2016, 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, 2016. Certain prior period information has been reclassified to conform to the current period presentation. Please see *Recently Adopted Accounting Pronouncements*.

Principles of Consolidation

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

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited interim condensed consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, 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, deferred taxes and valuation allowance, 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.

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

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

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In May 2017, the Financial Accounting Standards Board (“FASB”) issued guidance clarifying when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The guidance does not change the accounting for modifications, but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The guidance must be adopted on a prospective basis.

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. 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 will likely change the way we assess the collectability of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

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. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets. We have not yet begun to evaluate the specific impacts of this guidance.

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

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

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. In September 2017, the FASB issued guidance amending and rescinding prior SEC staff announcements and observer comments related to revenue recognition, pursuant to the SEC Staff Announcement at the July 20, 2017 Emerging Issues Task Force meeting. We will adopt this guidance as of January 1, 2018. We are currently undertaking a comprehensive review of our contracts with customers to determine the impact of this standard on our revenue recognition. While we currently expect that the adoption of this guidance will change the way we analyze, document, and disclose revenue recognition under customer contracts, based upon our analysis to date, we do not currently anticipate the adoption of this guidance to have a material effect on our consolidated financial statements. It is important to note that our work on this is ongoing and our final assessment is not yet complete. We have not yet determined the manner in which we will adopt this guidance.

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 earnings, balance sheets, or cash flows.

Recently Adopted Accounting Pronouncements

In January 2017, the FASB issued guidance to simplify the measurement of goodwill. The guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The guidance also eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted for interim or annual goodwill impairment tests performed for testing dates after January 1, 2017. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

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

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

In January 2017, the FASB issued guidance clarifying the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities is not a business, provides a framework to assist entities in evaluating whether both an input and substantive process are present, and narrows the definition of the term output. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The guidance must be adopted on a prospective basis. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In November 2016, the FASB issued guidance to reduce diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The revised guidance requires that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the statement of cash flows. The guidance was effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. If an entity adopted the guidance in an interim period, any adjustments should have been reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017, on a retrospective basis, and all periods have been presented under this guidance. The adoption of this new guidance resulted in the inclusion of our \$5.0 million of restricted cash in the cash and cash equivalents balance in our consolidated statement of cash flows for all reporting periods presented in 2017 and onward.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and cash payments in the statement of cash flows, including those related to debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance, and distributions received from equity method investees. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis and must be applied to all periods presented, but may be applied prospectively if retrospective application would be impracticable. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017, on a retrospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards, consisting of changes in the accounting for excess tax benefits and tax deficiencies, and changes in the accounting for forfeitures associated with share-based awards, among other things. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017. Pursuant to the adoption requirements for excess tax benefits and tax deficiencies, we no longer recognize excess tax benefits or tax deficiencies in Additional Paid in Capital (“APIC”); rather, we recognize them prospectively as a component of our current period provision/(benefit) before income taxes. We did not reverse our current APIC pool, which was \$3.1 million as of December 31, 2016, and we presented the impact of classifying excess tax benefits as an operating activity in the statement of cash flows on a prospective basis. Pursuant to the adoption requirements for forfeitures, we now account for forfeitures as they occur rather than using an estimated forfeiture rate; as a result of the change in accounting, we recorded a \$14 thousand cumulative-effect adjustment increasing our accumulated deficit as of January 1, 2017. The adoption of the remaining amendments did not have a material impact on our consolidated financial statements.

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

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

Revenue is recognized for product sales and contract manufacturing product sales upon passing of risk and title to the customer, when estimates of the selling price and discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured, and we have no further performance obligations. Contract manufacturing arrangements are typically less than two weeks in duration, and therefore the revenue is recognized upon completion of the aforementioned factors rather than using a proportional performance method of revenue recognition. The estimates for discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments reduce gross revenues to net revenues in the accompanying unaudited interim condensed consolidated statements of earnings, and are presented as current liabilities or reductions in accounts receivable in the accompanying unaudited interim condensed consolidated balance sheets (see “Accruals for Chargebacks, Rebates, Returns, and Other Allowances”). Historically, we have not entered into revenue arrangements with multiple elements.

We record revenue related to marketing and distribution agreements with third parties in which we sell products under Abbreviated New Drug Applications (“ANDAs”) or New Drug Applications (“NDAs”) owned or licensed by these third parties. We have assessed and determined that we are the principal for sales under each of these marketing and distribution agreements and recognize the revenue on a gross basis when risk and title are passed to the customer, when estimates of the selling price and discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured, and we have no further performance obligations. Under these agreements, we pay these third parties a specified percentage of the gross profit earned on sales of the products. These profit-sharing percentages are recognized in cost of sales in our consolidated statements of earnings and are accrued in accrued royalties in our consolidated balance sheets until payment has occurred.

Occasionally, we engage in contract services, which include product development services, laboratory services, and royalties on net sales of certain contract manufactured products. For these services, revenue is recognized according to the terms of the agreement with the customer, which sometimes include substantive, measurable risk-based milestones, and when we have a contractual right to receive such payment, the contract price is fixed or determinable, the collection of the resulting receivable is reasonably assured, and we have no further performance obligations under the agreement.

Accruals for Chargebacks, Rebates, Returns, and Other Allowances

Our generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, government rebates, product returns, administrative fees and other rebates, and prompt payment discounts. We accrue for these items at the time of sale and continually monitor and re-evaluate the accruals as additional information becomes available. We adjust the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances. Accruals are relieved upon receipt of payment from the customer or upon issuance of credit to the customer.

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

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the nine months ended September 30, 2017 and 2016, respectively:

(in thousands)	Accruals for Chargebacks, Rebates, Returns, and Other Allowances				
	Chargebacks	Government Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2015	\$ 11,381	\$ 4,631	\$ 2,648	\$ 1,653	\$ 674
Accruals/Adjustments	74,373	8,013	5,840	8,559	3,743
Credits Taken Against Reserve	(67,449)	(6,193)	(4,389)	(7,225)	(3,023)
Balance at September 30, 2016	\$ 18,305	\$ 6,451	\$ 4,099	\$ 2,987	\$ 1,394
Balance at December 31, 2016	\$ 26,785	\$ 5,891	\$ 5,756	\$ 3,550	\$ 1,554
Accruals/Adjustments	133,849	7,807	8,949	16,840	5,960
Credits Taken Against Reserve	(134,412)	(7,943)	(6,388)	(15,448)	(5,617)
Balance at September 30, 2017	\$ 26,222	\$ 5,755	\$ 8,317	\$ 4,942	\$ 1,897

Credit Concentration

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

During the three months ended September 30, 2017, three customers represented 30%, 30%, and 19% of net revenues, respectively. During the nine months ended September 30, 2017, these same three customers represented 31%, 26%, and 21% of net revenues, respectively. As of September 30, 2017, accounts receivable from these customers totaled 81% of accounts receivable, net. During the three months ended September 30, 2016, three customers represented 31%, 18%, and 17% of net revenues, respectively. During the nine months ended September 30, 2016, these same three customers represented 27%, 21%, and 17% of net revenues, respectively.

3. INDEBTEDNESS

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. The Notes pay 3.0% interest semi-annually in arrears starting on June 1, 2015 and are due December 1, 2019. The initial conversion price was \$69.48 per share. Simultaneous with the issuance of the Notes, we entered into “bond hedge” (or purchased call) and “warrant” (or written call) transactions with an affiliate of one of the offering underwriters in order 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 Notes are convertible at the option of the holder under certain circumstances and upon conversion we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof. As a result of our cash conversion option, we separately accounted for the value of the embedded conversion option as a debt discount (with an offset to APIC) of \$33.6 million. Deferred financing costs are recorded as a reduction of long-term debt in the consolidated balance sheets and are being amortized as additional non-cash interest expense on a straight-line basis over the term of the debt, since this method was not significantly different from the effective interest method.

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

3. INDEBTEDNESS – continued

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

(in thousands)	September 30, 2017	December 31, 2016
Principal amount	\$ 143,750	\$ 143,750
Unamortized debt discount	(15,637)	(20,644)
Deferred financing costs	(1,829)	(2,463)
Net carrying value	<u>\$ 126,284</u>	<u>\$ 120,643</u>

We had accrued interest of \$1.4 million and \$0.4 million related to the Notes recorded in accrued expenses, other in our consolidated balance sheets at September 30, 2017 and December 31, 2016, respectively.

The following table sets forth the components of total interest expense related to the Notes recognized in the accompanying unaudited interim condensed consolidated statements of earnings for the three and nine months ended September 30, 2017 and 2016:

(in thousands)	Three Months Ended		Nine Months Ended	
	September 30, 2017	September 30, 2016	September 30, 2017	September 30, 2016
Contractual coupon	\$ 1,078	\$ 1,078	\$ 3,234	\$ 3,234
Amortization of debt discount	1,692	1,604	5,007	4,748
Amortization of finance fees	211	211	633	633
Capitalized interest	(143)	(58)	(367)	(159)
	<u>\$ 2,838</u>	<u>\$ 2,835</u>	<u>\$ 8,507</u>	<u>\$ 8,456</u>

As of September 30, 2017, the effective interest rate on the Notes was 7.9%, on an annualized basis.

Line of Credit

In May 2016, we entered into a credit arrangement (the “Line of Credit”) with Citizens Bank Capital, a division of Citizens Asset Finance, Inc. (the “Citizens Agreement”). The Citizens Agreement provides for a \$30.0 million asset-based revolving credit loan facility, with availability subject to a borrowing base consisting of eligible accounts receivable and inventory and the satisfaction of conditions precedent specified in the Citizens Agreement. The Citizens Agreement provides for an accordion feature, whereby we may increase the revolving commitment up to an additional \$10.0 million subject to certain terms and conditions. The Citizens Agreement matures on May 12, 2019, at which time all amounts outstanding will be due and payable. Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.25%, 1.50%, or 1.75% per annum, depending upon availability under the Citizens Agreement, or an alternative base rate plus either 0.25%, 0.50%, or 0.75% per annum, depending upon availability under the Citizens Agreement. We incur a commitment fee on undrawn amounts equal to 0.25% per annum.

In February 2017, we drew down \$30.0 million on the Line of Credit. As part of the draw-down, we implemented the accordion feature and increased the Line of Credit to \$40.0 million. In September 2017, we paid down \$5.0 million on the Line of Credit. As of September 30, 2017, we had a \$25.0 million outstanding balance on the Line of Credit. In the second quarter of 2016, we deferred \$0.3 million of debt issuance costs related to the Line of Credit, which are being amortized over the three year life of the Line of Credit. The \$0.2 million net balance of deferred debt issuance costs is included in prepaid expenses and other current assets in the accompanying unaudited interim condensed consolidated balance sheet at September 30, 2017. During the three and nine months ended September 30, 2017, we recorded \$0.2 million and \$0.5 million of interest expense related to the Line of Credit, respectively.

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

4. 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 3), 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 assume that the principal portion of the Notes (Note 3) is settled 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 3) 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.

Earnings per share for the three and nine months ended September 30, 2017 and 2016 are calculated for basic and diluted earnings per share as follows:

(in thousands, except per share amounts)	Basic		Diluted		Basic		Diluted	
	Three Months Ended		Three Months Ended		Nine Months Ended		Nine Months Ended	
	September 30,		September 30,		September 30,		September 30,	
	2017	2016	2017	2016	2017	2016	2017	2016
Net income	\$ 4,720	\$ 2,543	\$ 4,720	\$ 2,543	\$ 8,553	\$ 5,014	\$ 8,553	\$ 5,014
Net income allocated to restricted stock	(35)	(17)	(35)	(17)	(64)	(34)	(64)	(34)
Net income allocated to common shares	<u>\$ 4,685</u>	<u>\$ 2,526</u>	<u>\$ 4,685</u>	<u>\$ 2,526</u>	<u>\$ 8,489</u>	<u>\$ 4,980</u>	<u>\$ 8,489</u>	<u>\$ 4,980</u>
Basic Weighted-Average Shares Outstanding	11,553	11,465	11,553	11,465	11,542	11,421	11,542	11,421
Dilutive effect of stock options and ESPP			124	160			124	131
Diluted Weighted-Average Shares Outstanding			11,677	11,625			11,666	11,552
Earnings Per Share	\$ 0.41	\$ 0.22	\$ 0.40	\$ 0.22	\$ 0.74	\$ 0.44	\$ 0.73	\$ 0.43

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, including the shares underlying the Notes, was 4.8 million and 4.5 million for the three months ended September 30, 2017 and 2016 and was 4.7 million and 4.5 million for the nine months ended September 30, 2017 and 2016, 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, and out-of-the-money warrants exercisable for common stock.

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

5. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2017	December 31, 2016
Raw materials	\$ 17,807	\$ 14,138
Packaging materials	1,362	930
Work-in-progress	915	477
Finished goods ⁽¹⁾	18,865	10,812
	<u>38,949</u>	<u>26,357</u>
Reserve for excess/obsolete inventories	(471)	(174)
Inventories, net	<u>\$ 38,478</u>	<u>\$ 26,183</u>

⁽¹⁾ Includes finished goods acquired in asset purchases (Note 12).

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 ongoing product manufacturing. During the three months ended September 30, 2017, we purchased approximately 40% of our inventory from two suppliers. As of September 30, 2017, the amounts payable to these suppliers was \$1.8 million. During the nine months ended September 30, 2017, we purchased approximately 24% of our inventory (exclusive of inventory acquired in asset purchases (Note 12)) from two suppliers. As of September 30, 2017, the amounts payable to these suppliers was \$0.8 million. During the three months ended September 30, 2016, we purchased approximately 28% of our inventory from one supplier. During the nine months ended September 30, 2016, we purchased approximately 23% of our inventory, exclusive of inventory acquired in an asset purchase, from one supplier.

6. PROPERTY, PLANT, AND EQUIPMENT

Property, plant, and equipment consist of the following as of:

(in thousands)	September 30, 2017	December 31, 2016
Land	\$ 160	\$ 160
Buildings	3,781	3,756
Machinery, furniture, and equipment	11,687	8,176
Construction in progress	8,033	4,293
	<u>23,661</u>	<u>16,385</u>
Less: accumulated depreciation	(6,274)	(5,387)
Property, Plant, and Equipment, net	<u>\$ 17,387</u>	<u>\$ 10,998</u>

Depreciation expense was \$0.3 million and \$0.2 million for the three months ended September 30, 2017 and 2016, respectively. Depreciation expense was \$0.9 million and \$0.7 million for the nine months ended September 30, 2017 and 2016, respectively. During the three months ended September 30, 2017 and 2016, there was \$0.1 million and \$58 thousand of interest capitalized into construction in progress, respectively. During the nine months ended September 30, 2017 and 2016, there was \$0.4 million and \$0.2 million of interest capitalized into construction in progress, respectively. Construction in progress consists of multiple projects, primarily related to new equipment to expand our manufacturing capability as our product lines continue to grow.

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

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. (“BioSante”), we recorded goodwill of \$1.8 million in our one reporting unit. In the first quarter of 2017, effective as of January 1, 2017, we adopted new accounting guidance with respect to goodwill. As a result, our accounting policy related to the measurement of goodwill has changed.

Goodwill Accounting Policy

Goodwill represents the excess of the total purchase consideration over the fair value of acquired assets and assumed liabilities, using the purchase method of accounting. Goodwill is not amortized, but is subject to periodic review for impairment. 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.

Before employing detailed impairment testing methodologies, we first evaluate the likelihood of impairment by considering qualitative factors relevant to our reporting unit. When performing the qualitative assessment, we evaluate events and circumstances that would affect the significant inputs used to determine the fair value of the goodwill. Events and circumstances evaluated include: macroeconomic conditions that could affect us, industry and market considerations for the generic pharmaceutical industry that could affect us, cost factors that could affect our performance, our financial performance (including share price), and consideration of any company-specific events that could negatively affect us, our business, or the fair value of our business. If we determine that it is more likely than not that goodwill is impaired, we will then apply detailed testing methodologies. Otherwise, we will conclude that no impairment has occurred.

Detailed impairment testing involves comparing the fair value of our one reporting unit to its carrying value, including goodwill. Fair value reflects the price a market participant would be willing to pay in a potential sale of ANI. If the fair value exceeds carrying value, then it is concluded that no goodwill impairment has occurred. If the carrying value of the reporting unit exceeds its fair value, an impairment loss will be recorded, measured as the difference between the excess of the carrying value of the reporting unit over its fair value, not to exceed the total amount of goodwill allocated to that reporting unit.

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 nine months ended September 30, 2017. No impairment losses were recognized during the three or nine months ended September 30, 2017 or 2016.

Definite-lived Intangible Assets

Acquisition of New Drug Applications and Product Rights

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark, and certain finished goods inventory for Inderal XL for \$20.2 million in cash. We made the \$20.2 million cash payment using cash on hand. We accounted for this transaction as an asset purchase. We also capitalized \$40 thousand of costs directly related to the transaction. The \$15.1 million product rights intangible asset acquired in the asset purchase is being amortized in full over its estimated useful life of 10 years. Please see Note 12 for further details regarding the transaction.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for \$30.6 million in cash. We made the \$30.6 million cash payment using \$30.0 million of funds from our Line of Credit (Note 3) and \$0.6 million of cash on hand. We accounted for this transaction as an asset purchase. We also capitalized \$0.1 million of costs directly related to the transaction. The \$19.0 million product rights intangible asset acquired in the asset purchase is being amortized in full over its estimated useful life of 10 years. Please see Note 12 for further details regarding the transaction.

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

7. GOODWILL AND INTANGIBLE ASSETS – continued

In April 2016, we purchased the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods from Cranford Pharmaceuticals, LLC for \$60.0 million in cash up front and milestone payments based on future gross profits from sales of products under the NDA. We made the \$60.0 million upfront cash payment using cash on hand, capitalized \$0.3 million of costs directly related to the transaction, and recognized \$3.9 million of minimum milestone payments for a total purchase price of \$64.2 million. We accounted for this transaction as an asset purchase and the resultant \$52.4 million NDA asset is being amortized in full over its estimated useful life of 10 years. The resultant \$0.6 million non-compete agreement associated with the transaction is being amortized in full over its estimated useful life of seven years.

In September 2015, we entered into an agreement to purchase the NDAs for Cortrophin gel and Cortrophin-Zinc from Merck Sharp & Dohme B.V. for \$75.0 million in cash and a percentage of future net sales. The transaction closed in January 2016, and we made the \$75.0 million cash payment using cash on hand. In addition, we capitalized \$0.3 million of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The \$75.3 million NDA assets are being amortized in full over their estimated useful lives of 10 years.

Marketing and Distribution Rights

In January 2016, we purchased from H2-Pharma, LLC the rights to market, sell, and distribute the authorized generic of Lipofen® and a generic hydrocortisone rectal cream product, along with the rights to an early-stage development project, for total consideration of \$10.0 million. The consideration consisted of a cash payment of \$8.8 million and the assumption of \$1.2 million in existing royalties owed on the acquired rights. We capitalized \$42 thousand of costs directly related to the purchase. We accounted for this transaction as an asset purchase. No value was ascribed to the early-stage development project because the development was still at the preliminary stage, with no expenses incurred or research performed to date. The \$10.0 million marketing and distribution rights assets are being amortized in full over their average estimated useful lives of approximately four years.

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

(in thousands)	September 30, 2017		December 31, 2016		Weighted Average Amortization Period
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
Acquired ANDA intangible assets	\$ 42,076	\$ (11,541)	\$ 42,076	\$ (8,390)	10.0 years
NDAs and product rights	184,306	(31,975)	150,250	(17,081)	10.0 years
Marketing and distribution rights	11,042	(4,569)	11,042	(2,662)	4.7 years
Non-compete agreement	624	(134)	624	(67)	7.0 years
	<u>\$ 238,048</u>	<u>\$ (48,219)</u>	<u>\$ 203,992</u>	<u>\$ (28,200)</u>	

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 the Inderal XL and InnoPran XL asset purchases, because we anticipate that the acquired assets will provide a greater economic benefit in the earlier years, we are amortizing 80% of the value of the intangible assets over the first five years of useful lives of the assets and amortizing the remaining 20% of the value of the intangible assets over the second five years of useful lives of the assets. Amortization expense was \$6.8 million and \$5.7 million for the three months ended September 30, 2017 and 2016, respectively. Amortization expense was \$20.0 million and \$15.8 million for the nine months ended September 30, 2017 and 2016, respectively.

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

7. GOODWILL AND INTANGIBLE ASSETS – continued

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, 2017 and 2016 and therefore no impairment loss was recognized in the three and nine months ended September 30, 2017 or 2016.

Expected future amortization expense is as follows:

(in thousands)	
2017 (remainder of the year)	\$ 6,707
2018	26,825
2019	26,825
2020	26,343
2021	24,898
2022 and thereafter	78,231
Total	<u>\$ 189,829</u>

8. STOCK-BASED COMPENSATION

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of September 30, 2017, 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. In the three and nine months ended September 30, 2017, we recognized \$1 thousand and \$5 thousand of stock-based compensation expense related to the ESPP in cost of sales and \$11 thousand and \$50 thousand of stock-based compensation expense related to the ESPP in selling, general, and administrative expense in our accompanying unaudited interim condensed consolidated statements of earnings, respectively. In the three and nine months ended September 30, 2016, we recognized \$1 thousand of stock-based compensation expense related to the ESPP in cost of sales and \$11 thousand of stock-based compensation expense related to the ESPP in selling, general, and administrative expense in our accompanying unaudited interim condensed consolidated statements of earnings, respectively.

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Fifth Amended and Restated 2008 Stock Incentive Plan (the “2008 Plan”), which was approved by shareholders at the May 17, 2017 annual meeting. The approved 2008 Plan provided for an increase of 0.8 million shares available to the plan. As of September 30, 2017, we have 0.8 million shares of common stock available 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 earnings:

(in thousands)	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	<u>2017</u>	<u>2016</u>	<u>2017</u>	<u>2016</u>
Cost of sales	\$ 19	\$ 23	\$ 68	\$ 37
Research and development	173	25	485	74
Selling, general, and administrative	1,270	1,305	4,059	4,564
	<u>\$ 1,462</u>	<u>\$ 1,353</u>	<u>\$ 4,612</u>	<u>\$ 4,675</u>

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

8. STOCK-BASED COMPENSATION – continued

A summary of stock option and restricted stock activity under the 2008 Plan during the nine months ended September 30, 2017 and 2016 is presented below:

(in thousands)	Options	RSAs
Outstanding December 31, 2015	474	63
Granted	293	42
Options Exercised/RSAs Vested	(120)	(15)
Forfeited	(59)	(12)
Outstanding September 30, 2016	<u>588</u>	<u>78</u>
Outstanding December 31, 2016	578	63
Granted	192	50
Options Exercised/RSAs Vested	(7)	(27) ⁽¹⁾
Forfeited	(3)	-
Outstanding September 30, 2017	<u>760</u>	<u>86</u>

⁽¹⁾ Includes five 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 \$259 thousand total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

9. STOCKHOLDER'S EQUITY

Stock Repurchase Program

In October 2015, our Board of Directors authorized a program to repurchase up to \$25.0 million of our outstanding common stock through December 31, 2016. The authorization allowed for repurchases to be conducted through open market or privately negotiated transactions. Shares acquired under the stock repurchase program were returned to the status of authorized but unissued shares of common stock.

In January 2016, we purchased 65 thousand shares under the stock repurchase program for \$2.5 million. This program terminated on December 31, 2016.

10. INCOME TAXES

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

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. The utilization of our NOL carryforwards will be limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code. As of both September 30, 2017 and December 31, 2016, we had provided a valuation allowance against certain state net operating loss ("NOL") carryforwards of \$0.3 million.

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

10. INCOME TAXES – continued

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, as well as guidance on derecognition, classification, interest and penalties, and financial statement reporting disclosures. 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, 2017 and December 31, 2016. We are subject to taxation in various 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 expected for the entire year. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and estimated permanent differences, and excludes certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discrete items result in variances to the effective tax rate from period to period. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. 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 material discrete items occur.

The effective tax rate for the three months ended September 30, 2017 was 25.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017. Our effective tax rate for the three months ended September 30, 2017 was impacted primarily by the Domestic Production Activities Deduction, as well as the 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.

The effective tax rate for the three months ended September 30, 2016 was 49.6% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2016. The effective tax rate for the period was primarily driven by permanent differences related to our former international tax structure surrounding our Cortrophin NDAs, which resulted in significant non-deductible amortization and interest expense in 2016.

The effective tax rate for the nine months ended September 30, 2017 was 28.7% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017. Our effective tax rate for the nine months ended September 30, 2017 was impacted primarily by the Domestic Production Activities Deduction, as well as the 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.

The effective tax rate for the nine months ended September 30, 2016 was 51.2% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2016. The effective tax rate for the period was primarily driven by permanent differences related to our former international tax structure surrounding our Cortrophin NDAs, which resulted in significant non-deductible amortization and interest expense in 2016.

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

11. COMMITMENTS AND CONTINGENCIES

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.

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, 2017 and 2016, net revenues for these products totaled \$7.9 million and \$8.6 million, respectively. During the nine months ended September 30, 2017 and 2016, net revenues for these products totaled \$20.9 million and \$26.6 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, 2017 and 2016 were \$0.6 million and \$0.3 million, respectively. Our contract manufacturing revenues for these unapproved products for the nine months ended September 30, 2017 and 2016 were \$1.5 million and \$1.1 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, 2017 and 2016 were less than 1% of total revenues.

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

11. COMMITMENTS AND CONTINGENCIES – continued

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.

Federal Investigation

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.

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, including California, New Jersey, and Pennsylvania, 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. In August 2012, we were dismissed with prejudice from all New Jersey cases. In August 2016, we settled the outstanding California cases. We consider our exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide that we manufactured prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) our market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once we received a request for change of labeling from the FDA, we submitted our proposed changes within 30 days, and such changes were subsequently approved by the FDA.

At the present time, we are unable to assess the likely outcome of the cases in the remaining states. Our insurance company has assumed the defense of this matter and paid all losses in settlement of the California cases. We cannot provide assurances that the outcome of these matters 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.

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

11. COMMITMENTS AND CONTINGENCIES – continued

We launched Erythromycin Ethylsuccinate (“EES”) on September 27, 2016 under a previously approved ANDA. 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 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 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 believe that our supplemental ANDA is valid, and as such continue to market the product. In addition, we filed a PAS which was accepted by the FDA and was originally assigned action date of June 2017. This date was later revised to October 2017 due to the election by the FDA to perform a Pre-Approval Inspection (“PAI”) of our Baudette manufacturing facilities. The FDA conducted its PAI between May 15, 2017 and May 18, 2017. On July 31, 2017, we received an Establishment Inspection Report from the FDA documenting that no objectionable conditions resulted from the inspection and that no FDA-483 or verbal observations were issued. On September 21, 2017, we received a Major CR Letter (Complete Response Letter). We are currently in the process of responding to the letter. We continue to reserve all of our legal options in this matter.

12. FAIR VALUE DISCLOSURES

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The fair value of borrowings on our line of credit also approximate their carrying value. While our Notes are recorded on our accompanying unaudited interim condensed consolidated balance sheets at their net carrying value of \$126.3 million as of September 30, 2017, the Notes are being traded on the bond market and their full fair value is \$155.3 million, based on their closing price on September 30, 2017, 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, and the changes in such fair value, was immaterial as of September 30, 2017 and December 31, 2016. We also determined that the changes in such fair value were immaterial as of September 30, 2017 and December 31, 2016.

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

12. FAIR VALUE DISCLOSURES – continued

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, 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 nine months ended September 30, 2017 and 2016.

Acquired Non-Financial Assets Measured at Fair Value

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark, and certain finished goods inventory for Inderal XL for \$20.2 million in cash (Note 7). We made the \$20.2 million cash payment using cash on hand and capitalized \$40 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The \$15.1 million product rights intangible asset was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible asset, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over its 10 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, 2017 and therefore no impairment loss was recognized for the nine months ended September 30, 2017. We also recorded \$5.0 million of finished goods inventory. The fair value of the finished goods inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for \$30.6 million in cash (Note 7). We made the \$30.6 million cash payment using \$30.0 million of funds from our Line of Credit (Note 3) and \$0.6 million of cash on hand. We also capitalized \$0.1 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The \$19.0 million product rights intangible asset was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible asset, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over its 10 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, 2017 and therefore no impairment loss was recognized for the nine months ended September 30, 2017. We also recorded \$11.6 million of finished goods inventory. The fair value of the finished goods inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin.

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

12. FAIR VALUE DISCLOSURES – continued

In April 2016, we purchased the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods from Cranford Pharmaceuticals, LLC for \$60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA (Note 7). In addition, at closing, we transferred \$5.0 million to an escrow account as security for future milestone payments. This escrow account balance is not expected to be released in less than one year and is included in restricted cash in our accompanying consolidated balance sheet as of December 31, 2016. We made the \$60.0 million upfront cash payment using cash on hand, capitalized \$0.3 million of costs directly related to the transaction, and recognized \$3.9 million of minimum milestone payments for a total purchase price of \$64.2 million. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. We recorded \$10.9 million of finished goods inventory. The fair value of the finished goods was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin. We recorded the \$3.9 million of minimum milestone payments as accrued royalties. In order to determine the fair value of the NDA, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 12%. The \$52.4 million NDA is being amortized in full over its 10 year useful life. We recorded \$0.6 million for the non-compete agreement associated with the transaction. In order to determine the fair value of the non-compete agreement, we used the probability-weighted lost cash flows method, using a discount rate of 10%. The non-compete agreement is being amortized in full over its seven year useful life. The intangible assets will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified in the nine months ended September 30, 2017 and therefore no impairment loss was recognized for the nine months ended September 30, 2017.

In January 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs for two previously marketed generic drug products for \$75.0 million in cash and a percentage of future net sales from product sales (Note 7). In addition, we capitalized \$0.3 million in legal costs directly related to the transaction. We accounted for this transaction as an asset purchase. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the NDAs, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The NDAs are being amortized in full over their 10 year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the nine months ended September 30, 2017 and therefore no impairment loss was recognized for the nine months ended September 30, 2017.

13. SUBSEQUENT EVENT

On November 2, 2017, we entered into Change in Control Severance Agreements (the “Severance Agreements”) with each of our current Named Executive Officers (each an NEO, and collectively the “NEOs”). Each of the Severance Agreements designates the payments to be received if an NEO’s employment is terminated under certain conditions following a change in control. Please see *Other Information* in Part II, Item 5 of this Form 10-Q quarterly report.

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, 2016.

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (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. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota, which are capable of producing oral solid dose products, as well as 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, 2017, our products include both branded and generic pharmaceuticals, specifically:

Generic Products	Branded Products
Diphenoxylate Hydrochloride and Atropine Sulfate	Cortenema
Erythromycin Ethylsuccinate	Inderal LA
Esterified Estrogen with Methyltestosterone	Inderal XL
Etodolac	InnoPran XL
Fenofibrate	Lithobid
Flecainide	Reglan
Fluvoxamine	Vancocin
Hydrocortisone Enema	
Hydrocortisone Rectal Cream (1% and 2.5%)	
Indapamide	
Lithium Carbonate ER	
Mesalamine Enema	
Methazolamide	
Metoclopramide Syrup	
Nilutamide	
Nimodipine	
Opium Tincture	
Oxycodone Capsules	
Oxycodone Oral Solution (5mg/5mL and 100mg/5mL)	
Pindolol	
Propafenone	
Propranolol ER	
Vancomycin	

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 product 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 maximize the capacity and 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 the existing and expected competition. We seek to develop products for which we can obtain a 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

Acquisitions

In February 2017, we acquired from Cranford Pharmaceuticals, LLC the distribution license, trademark and certain finished goods inventory for Inderal® XL for \$20.2 million in cash. Inderal XL is a beta adrenergic blocker indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

In February 2017, we acquired from Holmdel Pharmaceuticals, LP the New Drug Application (“NDA”), trademark, and certain finished goods inventory for InnoPran XL®, including a license to an Orange Book listed patent, for \$30.6 million in cash. InnoPran XL is a beta adrenergic blocker indicated for the treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Cortrophin Gel Re-commercialization Update

In the third quarter of 2017, we executed a long-term commercial supply agreement with our Cortrophin gel fill/finish contract manufacturer, specializing in aseptic parenteral manufacturing using mobile isolator technology. We plan to initiate manufacturing Cortrophin gel development batches in the fourth quarter of 2017, using the active pharmaceutical ingredient (“API”) from our recently manufactured intermediate scale batches. Combined with our current relationships with raw material suppliers for porcine pituitary glands and purified corticotropin powder (the API), we have secured our Cortrophin gel supply chain.

We have continued to advance the manufacture of corticotropin API, manufacturing our first intermediate scale batch of API. This intermediate scale batch of corticotropin API was five times larger than our initial small-scale API batch and resulted in proportional increases in both yield and potency. We initiated manufacturing a second intermediate scale batch in the third quarter and expect to complete manufacturing of intermediate scale API batches two and three by the end of this year. We expect to be able to demonstrate lot-to-lot consistency as we continue to build our comprehensive characterization package. We plan to initiate commercial scale API manufacturing in early 2018.

We have continued to modernize the corticotropin characterization package by developing and implementing new and current analytical technologies that were not part of the original Cortrophin gel NDA. These molecular biology techniques have been developed to analyze both corticotropin as well as other related peptides. We have also developed a variety of methods to characterize in-process samples after completion of critical stages of corticotropin API manufacturing. These methods are being used to better control the API manufacturing process and identify its critical process parameters. These methods are being utilized throughout the API manufacturing process as a means of establishing lot-to-lot consistency and process control and demonstrating comparability to historically manufactured commercial lots of API.

We intend to request a meeting with the Food and Drug Administration (“FDA”) in the fourth quarter of 2017 to present our Regulatory Filing Plan.

Vancocin Oral Solution Update

We are currently advancing a commercialization effort for Vancocin oral solution. Following completion of ongoing formulation and manufacturing optimization, we intend to file a prior approval supplement (“PAS”) in the second half of 2018. This product will be manufactured at our site in Baudette, Minnesota. The launch of this product will fulfill a currently unmet patient need for an FDA approved liquid oral dosage form of the vancomycin molecule.



GENERAL

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net revenues	\$ 48,164	\$ 38,525	\$ 129,556	\$ 90,417
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	21,078	16,669	58,586	31,874
Research and development	2,634	1,041	6,419	2,771
Selling, general, and administrative	8,022	6,928	22,695	20,460
Depreciation and amortization	7,099	5,966	20,906	16,531
Operating income	9,331	7,921	20,950	18,781
Interest expense, net	(3,052)	(2,856)	(9,009)	(8,468)
Other income/(expense), net	95	(21)	58	(31)
Income before provision for income taxes	6,374	5,044	11,999	10,282
Provision for income taxes	(1,654)	(2,501)	(3,446)	(5,268)
Net income	\$ 4,720	\$ 2,543	\$ 8,553	\$ 5,014

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2017	2016	2017	2016
Net revenues	100.0%	100.0%	100.0%	100.0%
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	43.8%	43.2%	45.2%	35.2%
Research and development	5.5%	2.7%	5.0%	3.1%
Selling, general, and administrative	16.7%	18.0%	17.5%	22.6%
Depreciation and amortization	14.7%	15.5%	16.1%	18.3%
Operating income	19.3%	20.6%	16.2%	20.8%
Interest expense, net	(6.3)%	(7.4)%	(7.0)%	(9.4)%
Other income/(expense), net	0.2%	(0.1)%	-%	-%
Income before provision for income taxes	13.2%	13.1%	9.2%	11.4%
Provision for income taxes	(3.4)%	(6.4)%	(2.7)%	(5.8)%
Net income	9.8%	6.7%	6.5%	5.6%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016

Net Revenues

(in thousands)	Three Months Ended September 30,		Change	% Change
	2017	2016		
Generic pharmaceutical products	\$ 30,546	\$ 30,191	\$ 355	1.2%
Branded pharmaceutical products	15,688	6,834	8,854	129.6%
Contract manufacturing	1,829	1,427	402	28.2%
Contract services and other income	101	73	28	38.4%
Total net revenues	<u>\$ 48,164</u>	<u>\$ 38,525</u>	<u>\$ 9,639</u>	<u>25.0%</u>

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, 2017 were \$48.2 million compared to \$38.5 million for the same period in 2016, an increase of \$9.6 million, or 25.0%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$30.5 million during the three months ended September 30, 2017, an increase of 1.2% compared to \$30.2 million for the same period in 2016. The primary reason for the increase was sales of Erythromycin Ethylsuccinate, which was launched in the third quarter of 2016 and Diphenoxylate Hydrochloride and Atropine Sulfate Tablets, which was launched in the second quarter of 2017. These increases were partially offset by decreased unit sales of Propranolol ER.

As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market Esterified Estrogen with Methyltestosterone (“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 three months ended September 30, 2017 and 2016 were \$7.9 million and \$8.6 million, respectively.

- Net revenues for branded pharmaceutical products were \$15.7 million during the three months ended September 30, 2017, an increase of 129.6% compared to \$6.8 million for the same period in 2016. The primary reason for the increase was sales of Inderal XL and InnoPran XL, both of which were launched in first quarter of 2017, as well as increased sales of Inderal LA and other branded products. These increases were partially offset by decreased unit sales for Vancocin. We experience periodic larger orders for our Vancocin product that relate to clinical trials. We had no such orders in either the three months ended September 30, 2017 or 2016. We cannot be sure that such purchases will occur in future periods.

- Contract manufacturing revenues were \$1.8 million during the three months ended September 30, 2017, an increase of 28.2% compared to \$1.4 million for the same period in 2016, due to timing of orders from contract manufacturing customers in the period. As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, 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, 2017 and 2016 were \$0.6 million and \$0.3 million, respectively.
- Contract services and other income were \$0.1 million during the three months ended September 30, 2017, an increase of 38.4% from \$73 thousand for the same period in 2016.

As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the 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 royalties on the net sales of these unapproved products were less than 1% of total revenues for the three months ended September 30, 2017 and 2016.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended September 30,		Change	% Change
	2017	2016		
Cost of sales (excl. depreciation and amortization)	\$ 21,078	\$ 16,669	\$ 4,409	26.5%

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 earnings.

For the three months ended September 30, 2017, cost of sales increased to \$21.1 million from \$16.7 million for the same period in 2016, an increase of \$4.4 million or 26.5%, primarily as a result of increased sales of products subject to profit-sharing arrangements, as well as increased volumes and the impact on cost of sales of the excess of fair value over cost for Inderal XL and InnoPran XL inventory acquired during the first three months of 2017 through asset acquisition transactions and subsequently sold during the period. Cost of sales as a percentage of net revenues increased to 43.8% during the three months ended September 30, 2017, from 43.2% during same period in 2016, primarily as a result of the \$2.8 million net impact on cost of sales (5.7% as a percent of net revenues) of the excess of fair value over cost for Inderal XL and InnoPran XL inventory sold during the period. This trend will continue until such time that the inventory acquired as components of the Inderal XL and InnoPran XL asset purchases is consumed. In the third quarter of 2016, cost of sales included \$1.1 million (2.9% as a percent of net revenue) related to the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period. The increase in cost of sales as a percentage of net revenues was partially offset by a change in product mix toward higher margin branded products.

We source the raw materials for our products from both domestic and international suppliers, which we carefully select. Generally, we qualify only a single source of API for use in each product due to the cost and time required to validate and qualify a second source of supply. Any change in one of our API suppliers must usually be approved through a PAS by the FDA. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare, but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we select suppliers with great care, based on various factors including quality, reliability of supply, and long-term financial stability. Certain of the APIs for our drug products, including those that are marketed without approved NDAs or ANDAs, such as EEMT, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections.

During the three months ended September 30, 2017, we purchased 40% of our inventory from two suppliers. As of September 30, 2017, the amounts payable to these suppliers was \$1.8 million. In the three months ended September 30, 2016, we purchased approximately 28% of our inventory from one supplier.

In order to manufacture Opium Tincture, Oxycodone capsules, and Oxycodone oral solution, we must receive approval from the Drug Enforcement Agency ("DEA") for a quota to purchase the amount of opium and oxycodone 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 our continued manufacture of Opium Tincture, Oxycodone capsules, and Oxycodone oral solution.

Other Operating Expenses

(in thousands)	Three Months Ended September 30,		Change	% Change
	2017	2016		
Research and development	\$ 2,634	\$ 1,041	\$ 1,593	153.0%
Selling, general, and administrative	8,022	6,928	1,094	15.8%
Depreciation and amortization	7,099	5,966	1,133	19.0%
Total other operating expenses	\$ 17,755	\$ 13,935	\$ 3,820	27.4%

Other operating expenses consist of research and development costs, selling, general, and administrative expenses, and depreciation and amortization.

For the three months ended September 30, 2017, other operating expenses increased to \$17.8 million from \$13.9 million for the same period in 2016, an increase of \$3.8 million, or 27.4%, primarily as a result of the following factors:

- Research and development expenses increased from \$1.0 million to \$2.6 million, an increase of 153.0%, due to timing of work on development projects, primarily the Cortrophin gel re-commercialization project. Current projects also include work on the ANDAs purchased in 2014 and 2015. We anticipate that research and development costs will continue to be greater in 2017 than in 2016, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Cortrophin products.
- Selling, general, and administrative expenses increased from \$6.9 million to \$8.0 million, an increase of 15.8%, primarily due to increases in personnel and related costs. We anticipate that selling, general, and administrative expenses will be greater in 2017 than in 2016 as we support anticipated additional revenue growth.
- Depreciation and amortization increased from \$6.0 million to \$7.1 million, an increase of 19.0%, due primarily to the amortization of the distribution license and trademark for Inderal XL, which were acquired in February 2017 and the amortization of the product rights for InnoPran XL, which were acquired in February 2017. We anticipate that depreciation and amortization expense will continue to be greater in 2017 than in 2016 as a result of our first quarter 2017 asset purchases.

Other Expense, net

(in thousands)	Three Months Ended September 30,		Change	% Change
	2017	2016		
Interest expense, net	\$ (3,052)	\$ (2,856)	\$ (196)	6.9%
Other income/(expense), net	95	(21)	116	(552.4)%
Total other expense, net	\$ (2,957)	\$ (2,877)	\$ (80)	2.8%

For the three months ended September 30, 2017, we recognized other expense, net of \$3.0 million versus other expense, net of \$2.9 million for the same period in 2016, an increase of \$0.1 million. Interest expense, net for both periods consists primarily of interest expense on our convertible debt and, to a lesser extent, interest expense on borrowings under our line of credit. For the three months ended September 30, 2017 and 2016, there was \$0.1 million and \$58 thousand of interest capitalized into construction in progress, respectively.

Provision for Income Taxes

(in thousands)	Three Months Ended September 30,		Change	% Change
	2017	2016		
Provision for income taxes	\$ (1,654)	\$ (2,501)	\$ 847	(33.9)%

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 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.

For the three months ended September 30, 2017, we recognized income tax expense of \$1.7 million, versus \$2.5 million for the same period in 2016, a decrease of \$0.8 million. The effective tax rate for the three months ended September 30, 2017 was 25.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017. Our effective tax rate for the three months ended September 30, 2017 was impacted primarily by the Domestic Production Activities Deduction, as well as the 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.

The effective tax rate for the three months ended September 30, 2016 was 49.6% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2016. The effective tax rate for the period was primarily driven by permanent differences related to our former international tax structure surrounding our Cortrophin NDAs, which resulted in significant non-deductible amortization and interest expense in 2016.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2017 AND 2016

Net Revenues

(in thousands)	Nine Months Ended September 30,		Change	% Change
	2017	2016		
Generic pharmaceutical products	\$ 88,608	\$ 65,905	\$ 22,703	34.4%
Branded pharmaceutical products	35,398	19,919	15,479	77.7%
Contract manufacturing	5,151	3,977	1,174	29.5%
Contract services and other income	399	616	(217)	(35.2)%
Total net revenues	\$ 129,556	\$ 90,417	\$ 39,139	43.3%

Net revenues for the nine months ended September 30, 2017 were \$129.6 million compared to \$90.4 million for the same period in 2016, an increase of \$39.1 million, or 43.3%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$88.6 million during the nine months ended September 30, 2017, an increase of 34.4% compared to \$65.9 million for the same period in 2016. The primary reason for the increase was sales of Nilotamide and Erythromycin Ethylsuccinate, both of which were launched in the third quarter of 2016, as well as sales of Fenofibrate and other products launched in the second quarter of 2016. These increases were tempered by volume decreases in EEMT sales.

As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, 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, 2017 and 2016 were \$20.9 million and \$26.6 million, respectively.

- Net revenues for branded pharmaceutical products were \$35.4 million during the nine months ended September 30, 2017, an increase of 77.7% compared to \$19.9 million for the same period in 2016. The primary reason for the increase was sales of Inderal XL and InnoPran XL, both of which were launched in first quarter of 2017, as well as sales of Inderal LA, which was launched in the second quarter of 2016. These increases were partially offset by decreased unit sales for Vancocin. We experience periodic larger orders for our Vancocin product that relate to clinical trials. Such orders constituted \$2.4 million of our branded pharmaceutical product revenue for the nine months ended September 30, 2016. We had no such orders in the nine months ended September 30, 2017, and we cannot be sure that such purchases will occur in future periods.

- Contract manufacturing revenues were \$5.2 million during the nine months ended September 30, 2017, an increase of 29.5% compared to \$4.0 million for the same period in 2016, due to timing of orders from contract manufacturing customers in the period. As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, 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, 2017 and 2016 were \$1.5 million and \$1.1 million, respectively.
- Contract services and other income were \$0.4 million during the nine months ended September 30, 2017, a decrease of 35.2% from \$0.6 million for the same period in 2016, primarily because sales of Fenofibrate in the ANI label have replaced the royalties previously received on the product. We launched Fenofibrate under our own label in the second quarter of 2016.

As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the 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 royalties on the net sales of these unapproved products were less than 1% of total revenues for the nine months ended September 30, 2017 and 2016.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Nine Months Ended September 30,		Change	% Change
	2017	2016		
Cost of sales (excl. depreciation and amortization)	\$ 58,586	\$ 31,874	\$ 26,712	83.8%

For the nine months ended September 30, 2017, cost of sales increased to \$58.6 million from \$31.9 million for the same period in 2016, an increase of \$26.7 million or 83.8%, primarily as a result of increased sales of products subject to profit-sharing arrangements, as well as increased volumes and the impact on cost of sales of the excess of fair value over cost for Inderal XL and InnoPran XL inventory acquired during the first three months of 2017 through asset acquisition transactions and subsequently sold during the period. Cost of sales as a percentage of net revenues increased to 45.2% during the nine months ended September 30, 2017, from 35.2% during same period in 2016, primarily as a result of increased sales of products subject to profit-sharing arrangements and the \$7.5 million net impact on cost of sales (5.8% as a percent of net revenues) of the excess of fair value over cost for Inderal XL, InnoPran XL, and Inderal LA inventory sold during the period. This trend will continue until such time that the inventory acquired as components of the Inderal XL and InnoPran XL asset purchases is consumed. During the nine months ended September 30, 2016, cost of sales included \$3.2 million (3.5% as a percent of net revenue) related to the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period. During the second quarter 2017, we completed sales of the Inderal LA inventory acquired as a component of the Inderal LA asset purchase.

During the nine months ended September 30, 2017, we purchased 24% of our inventory (exclusive of inventory acquired in asset purchases as described in Note 12, *Fair Value Disclosures*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report) from two suppliers. As of September 30, 2017, the amounts payable to these suppliers was \$0.8 million. In the nine months ended September 30, 2016, we purchased approximately 23% of our inventory from one supplier.

Other Operating Expenses

(in thousands)	Nine Months Ended September 30,		Change	% Change
	2017	2016		
Research and development	\$ 6,419	\$ 2,771	\$ 3,648	131.6%
Selling, general, and administrative	22,695	20,460	2,235	10.9%
Depreciation and amortization	20,906	16,531	4,375	26.5%
Total other operating expenses	\$ 50,020	\$ 39,762	\$ 10,258	25.8%

For the nine months ended September 30, 2017, other operating expenses increased to \$50.0 million from \$39.8 million for the same period in 2016, an increase of \$10.3 million, or 25.8%, primarily as a result of the following factors:

- Research and development expenses increased from \$2.8 million to \$6.4 million, an increase of 131.6%, due to timing of work on development projects, primarily the Cortrophin gel re-commercialization project. Current projects also include work on the ANDAs purchased in 2014 and 2015. We anticipate that research and development costs will continue to be greater in 2017 than in 2016, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Cortrophin products.
- Selling, general, and administrative expenses increased from \$20.5 million to \$22.7 million, an increase of 10.9%, primarily due to increases in personnel and related costs and \$0.5 million of expenses related to a proposed transaction that we ultimately decided not to pursue further. These increases were partially offset by the lack of the \$1.3 million of expenses related to the transition of our CFO in the second quarter of 2016. We anticipate that selling, general, and administrative expenses will continue to be greater in 2017 than in 2016 as we support anticipated additional revenue growth.
- Depreciation and amortization increased from \$16.5 million to \$20.9 million, an increase of 26.5%, due primarily to the amortization of the distribution license and trademark for Inderal XL, which were acquired in February 2017, the amortization of the product rights for InnoPran XL, which were acquired in February 2017, and the amortization of the rights, title, and interest in the NDA for Inderal LA, which were acquired in April 2016. We anticipate that depreciation and amortization expense will continue to be greater in 2017 than in 2016 as a result of our first quarter 2017 asset purchases.

Other Expense, net

(in thousands)	Nine Months Ended September 30,		Change	% Change
	2017	2016		
Interest expense, net	\$ (9,009)	\$ (8,468)	\$ (541)	6.4%
Other income/(expense), net	58	(31)	89	(287.1)%
Total other expense, net	\$ (8,951)	\$ (8,499)	\$ (452)	5.3%

For the nine months ended September 30, 2017, we recognized other expense, net of \$9.0 million versus other expense, net of \$8.5 million for the same period in 2016, an increase of \$0.5 million. Interest expense, net for both periods consists primarily of interest expense on our convertible debt and, to a lesser extent, interest expense on borrowings under our line of credit. For the nine months ended September 30, 2017 and 2016, there was \$0.4 million and \$0.2 million of interest capitalized into construction in progress, respectively.

Provision for Income Taxes

(in thousands)	<u>Nine Months Ended September 30,</u>		<u>Change</u>	<u>% Change</u>
	<u>2017</u>	<u>2016</u>		
Provision for income taxes	\$ (3,446)	\$ (5,268)	\$ 1,822	(34.6)%

For the nine months ended September 30, 2017, we recognized income tax expense of \$3.4 million, versus \$5.3 million for the same period in 2016, a decrease of \$1.8 million. The effective tax rate for the nine months ended September 30, 2017 was 28.7% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017. Our effective tax rate for the nine months ended September 30, 2017 was impacted primarily by the Domestic Production Activities Deduction, as well as the 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.

The effective tax rate for the nine months ended September 30, 2016 was 51.2% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2016. The effective tax rate for the period was primarily driven by permanent differences related to our former international tax structure surrounding our Cortrophin NDAs, which resulted in significant non-deductible amortization and interest expense in 2016.

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	September 30,	December 31,
	2017	2016
Cash and cash equivalents	\$ 18,031	\$ 27,365
Accounts receivable, net	62,174	45,895
Inventories, net	38,478	26,183
Prepaid income taxes	2,052	-
Prepaid expenses and other current assets	4,847	3,564
Total current assets	<u>\$ 125,582</u>	<u>\$ 103,007</u>
Accounts payable	\$ 5,821	\$ 3,389
Accrued expenses and other	2,741	927
Accrued royalties	11,741	11,956
Accrued compensation and related expenses	2,009	1,631
Current income taxes payable	-	2,398
Accrued government rebates	5,755	5,891
Returned goods reserve	8,317	5,756
Total current liabilities	<u>\$ 36,384</u>	<u>\$ 31,948</u>

At September 30, 2017, we had \$18.0 million in unrestricted cash and cash equivalents. At December 31, 2016, we had \$27.4 million in unrestricted cash and cash equivalents. We generated \$23.6 million of cash from operations in the nine months ended September 30, 2017. In February 2017, we purchased from Cranford Pharmaceuticals, LLC a distribution license, trademark and certain finished goods inventory for Inderal XL for \$20.2 million in cash. We made the \$20.2 million cash payment using cash on hand. In February 2017, we purchased from Holmdel Pharmaceuticals, LP the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for \$30.6 million in cash. We made the \$30.6 million cash payment using \$30.0 million of funds from our Line of Credit and \$0.6 million of cash on hand.

In May 2016, we entered into a credit arrangement (the "Line of Credit") with Citizens Bank Capital, a division of Citizens Asset Finance, Inc. that provided for a \$30.0 million asset-based revolving credit loan facility. In February 2017, we implemented the accordion feature and increased the Line of Credit to \$40.0 million. In September 2017, we paid down \$5.0 million on the Line of Credit. As of September 30, 2017, we had a \$25.0 million outstanding balance on the Line of Credit, and our available borrowing base was \$15.0 million. We are focused on expanding our business and product pipeline through collaborations, and also through acquisitions of products and companies. We are continually evaluating potential asset acquisitions and business combinations. To finance such acquisitions, we might raise additional equity capital, incur additional debt, or both.

In the first quarter of 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs and associated product rights and manufacturing licenses for Cortrophin gel and Cortrophin-Zinc for \$75.0 million in cash and a percentage of future net sales of the products under the NDAs, wherein we will retain a majority of the proceeds from such sales. In the first quarter of 2016 we purchased from H2-Pharma, LLC the rights to market, sell, and distribute two products for \$8.8 million in cash and the assumption of an accrued royalty of \$1.2 million, for a total of \$10.0 million in consideration. In the second quarter of 2016, we purchased from Cranford Pharmaceuticals, LLC the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods for \$60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA, which milestone payments are capped at \$16.9 million, of which we've paid \$2.6 million. In addition, at closing, we transferred \$5.0 million to an escrow account as security for future milestone payments.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue, and our revolving line of credit facility, will be sufficient to enable us to meet our working capital requirements 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:

(in thousands)	Nine Months Ended September 30,	
	2017	2016
Operating Activities	\$ 23,614	\$ 15,390
Investing Activities	\$ (57,878)	\$ (147,671)
Financing Activities	\$ 24,932	\$ (1,247)

Net Cash Provided By Operations

Net cash provided by operating activities was \$23.6 million for the nine months ended September 30, 2017, compared to \$15.4 million during the same period in 2016, an increase of \$8.2 million between the periods. This increase was principally due to increased sales volume and corresponding gross profit dollars.

Net Cash Used In Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2017 was \$57.9 million, principally due to the February 2017 payment of \$20.2 million for the asset acquisition of the product rights for Inderal XL, the February 2017 payment of \$30.6 million for the asset acquisition of the product rights for InnoPran XL, and \$6.9 million of capital expenditures during the period, primarily related to new equipment to expand our manufacturing capability as our product lines continue to grow. Net cash used in investing activities for the nine months ended September 30, 2016 was \$147.7 million, principally due to the January 2016 \$75.0 million asset acquisition of the NDAs for Cortrophin gel and Cortrophin-Zinc, the January 2016 payment of \$8.8 million to H2-Pharma, LLC for marketing and distribution rights associated with two products, the April 2016 payment of \$60.0 million for the asset acquisition of the NDA for Inderal LA, and \$3.2 million of capital expenditures during the period.

Net Cash Provided By/(Used In) By Financing Activities

Net cash provided by financing activities was \$24.9 million for the nine months ended September 30, 2017, principally due to the \$25.0 million net draw-down on the line of credit. Net cash used in financing activities was \$1.2 million for the nine months ended September 30, 2016, principally due to the \$2.5 million repurchase of the Company's common stock under our Stock Repurchase Program and \$0.3 million of debt issuance costs paid in relation to the Line of Credit, partially offset by \$1.4 million of proceeds from stock option exercises.

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 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 our unaudited interim condensed consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, administrative fees and rebates, returns and other allowances, allowance for inventory obsolescence, accruals for contingent liabilities and litigation, fair value of long-lived assets, income tax provision, deferred taxes and valuation allowance, purchase price allocations, and the depreciable and amortizable 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, 2016. 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, 2016.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

Recent Accounting Pronouncements Not Yet Adopted

In May 2017, the Financial Accounting Standards Board ("FASB") issued guidance clarifying when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The guidance does not change the accounting for modifications, but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The guidance must be adopted on a prospective basis.

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. 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 will likely change the way we assess the collectability of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

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. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets. We have not yet begun to evaluate the specific impacts of this guidance.

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. In September 2017, the FASB issued guidance amending and rescinding prior SEC staff announcements and observer comments related to revenue recognition, pursuant to the SEC Staff Announcement at the July 20, 2017 Emerging Issues Task Force meeting. We will adopt this guidance as of January 1, 2018. We are currently undertaking a comprehensive review of our contracts with customers to determine the impact of this standard on our revenue recognition. While we currently expect that the adoption of this guidance will change the way we analyze, document, and disclose revenue recognition under customer contracts, based upon our analysis to date, we do not currently anticipate the adoption of this guidance to have a material effect on our consolidated financial statements. It is important to note that our work on this is ongoing and our final assessment is not yet complete. We have not yet determined the manner in which we will adopt this guidance.

Recently Adopted Accounting Pronouncements

In January 2017, the FASB issued guidance to simplify the measurement of goodwill. The guidance eliminates Step 2 from the goodwill impairment test. Instead, under the amendments in this guidance, an entity should perform its annual or interim goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however the loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. Additionally, an entity should consider income tax effects from any tax deductible goodwill on the carrying amount of the reporting unit when measuring the goodwill impairment loss. The guidance also eliminates the requirements for any reporting unit with a zero or negative carrying amount to perform a qualitative assessment and, if it fails that qualitative test, to perform Step 2 of the goodwill impairment test. An entity is required to disclose the amount of goodwill allocated to each reporting unit with a zero or negative carrying amount of net assets. The guidance is effective for public business entities for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted for interim or annual goodwill impairment tests performed for testing dates after January 1, 2017. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In January 2017, the FASB issued guidance clarifying the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions or disposals of assets or businesses. The guidance provides a screen to determine when an integrated set of assets and activities is not a business, provides a framework to assist entities in evaluating whether both an input and substantive process are present, and narrows the definition of the term output. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, and early adoption is permitted. The guidance must be adopted on a prospective basis. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In November 2016, the FASB issued guidance to reduce diversity in practice that exists in the classification and presentation of changes in restricted cash on the statement of cash flows. The revised guidance requires that amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the beginning of period and end of period total amounts shown on the statement of cash flows. The guidance was effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. If an entity adopted the guidance in an interim period, any adjustments should have been reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017, on a retrospective basis, and all periods have been presented under this guidance. The adoption of this new guidance resulted in the inclusion of our \$5.0 million of restricted cash in the cash and cash equivalents balance in our consolidated statement of cash flows for all reporting periods presented in 2017 and onward.

In August 2016, the FASB issued guidance on the classification of certain cash receipts and cash payments in the statement of cash flows, including those related to debt prepayment or debt extinguishment costs, contingent consideration payments made after a business combination, proceeds from the settlement of insurance claims, proceeds from the settlement of corporate-owned life insurance, and distributions received from equity method investees. The guidance is effective for public business entities for fiscal years beginning after December 15, 2017, and for interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. If an entity adopts the guidance in an interim period, any adjustments should be reflected as of the beginning of the fiscal year that includes that interim period. The guidance must be adopted on a retrospective basis and must be applied to all periods presented, but may be applied prospectively if retrospective application would be impracticable. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017, on a retrospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards, consisting of changes in the accounting for excess tax benefits and tax deficiencies, and changes in the accounting for forfeitures associated with share-based awards, among other things. We adopted this guidance in the first quarter of 2017, effective as of January 1, 2017. Pursuant to the adoption requirements for excess tax benefits and tax deficiencies, we no longer recognize excess tax benefits or tax deficiencies in Additional Paid in Capital ("APIC"); rather, we recognize them prospectively as a component of our current period provision/(benefit) before income taxes. We did not reverse our current APIC pool, which was \$3.1 million as of December 31, 2016, and we presented the impact of classifying excess tax benefits as an operating activity in the statement of cash flows on a prospective basis. Pursuant to the adoption requirements for forfeitures, we now account for forfeitures as they occur rather than using an estimated forfeiture rate; as a result of the change in accounting, we recorded a \$14 thousand cumulative-effect adjustment increasing our accumulated deficit as of January 1, 2017. The adoption of the remaining amendments did not have a material impact on our consolidated financial statements.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2017, and December 31, 2016, 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 and equity risk could have a significant impact on our results of operations.

As of September 30, 2017, our largest debt obligation was related to our Notes. In order to reduce the potential equity dilution that would result upon conversion of the Senior Convertible Notes issued in December 2014, we entered into note hedge transactions with a financial institution affiliated with one of the underwriters of the Senior Convertible Note 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 Senior Convertible 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 Senior Convertible 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 approximately 2.1 million 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 on the Notes 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 May 12, 2016, we entered into a credit agreement (the "Line of Credit") with Citizens Business Capital, a division of Citizens Asset Finance, Inc. (the "Citizens Agreement"). The Citizens Agreement provides for a \$30.0 million asset-based revolving credit loan facility. In February 2017, we implemented the accordion feature and increased the Line of Credit to \$40.0 million. Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.25%, 1.50%, or 1.75% per annum, depending upon availability under the Citizens Agreement or an alternative base rate plus either 0.25%, 0.50%, or 0.75% per annum, depending upon availability under the Citizens Agreement. We will incur a commitment fee on undrawn amounts equal to 0.25% per annum. As of September 30, 2017, we had a \$25.0 million outstanding balance on the Line of Credit. If the interest rate on our \$25.0 million loan outstanding were to increase by 10%, we would incur \$19 thousand and \$43 thousand of additional interest expense in the three and nine months ended September 30, 2017, respectively.

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 both the three and nine months ended September 30, 2017 by approximately \$1 thousand.

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, 2017. 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, 2017 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

In addition to the other information set forth in this report, please carefully consider the factors described in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2016 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

On November 2, 2017, we entered into Change in Control Severance Agreements (the "Severance Agreements") with each of our current Named Executive Officers (each an NEO, and collectively the "NEOs").

Under the Severance Agreements, if an NEO, in connection with a change in control of ANI or within 24 months following a change in control, is involuntarily terminated without cause or voluntarily terminates his or her employment for good reason (a "qualifying termination"), then such NEO would be entitled to receive: (i) any unpaid base salary and payment for unused vacation under the Company's vacation policy through the date of termination; (ii) a payment equal to the NEO's target annual cash incentive opportunity for the year in which the termination occurred, pro-rated for the portion of the year elapsed through the date of termination, to be paid on the date of termination; (iii) continuation of base salary for 24 months after the date of termination (or in the case of the Chief Executive Officer, continuation of base salary for 36 months); and (iv) an annual payment equal to the NEO's target annual bonus opportunity in effect immediately prior to the change in control, to be paid on each of the next two anniversaries of the date of termination (or in the case of the Chief Executive Officer, on each of the next three anniversaries). In addition to the foregoing, equity awards of an NEO will immediately vest and become exercisable upon a qualifying termination. If the NEO elects to continue group health care coverage under COBRA, the NEO will also be reimbursed for the portion of the premiums that the Company would have paid if the participant had continued to be an employee of the Company for a period of 24 months, or earlier in certain circumstances.

Any payment under the Severance Agreements would be in lieu of any other severance or termination payment that may be due or become payable to the NEO. In addition, the Severance Agreements will provide that, in the event that the severance and other benefits provided for in the Severance Agreements would be subject to the excise tax imposed by Section 4999 of the Internal Revenue Code, the benefits under the Severance Agreements will be grossed-up so that the NEO will receive the same after-tax amount as he would have received had no excise tax been payable. Payments under the Severance Agreements will be contingent upon an NEO's execution of a release of claims in favor of the Company and compliance by the terminated NEO with the non-solicitation, non-competition, and confidentiality covenants in the Severance Agreement.

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.

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 2, 2017

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

Date: November 2, 2017

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

INDEX TO EXHIBITS

<u>Exhibit No.</u>	<u>Description</u>
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

**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 2, 2017

/s/ Arthur S. Przybyl

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

**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 2, 2017

/s/ Stephen P. Carey

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

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

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended September 30, 2017 (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 2, 2017

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

Dated: November 2, 2017

/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.
