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, 2016

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

For the transition period from to .

Commission File Number 001-31812

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

210 Main Street West
Baudette, Minnesota
(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 ☐

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 27, 2016, there were 11,580,392 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, 2016
TABLE OF CONTENTS

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Exchange Act. Such statements include, but are not limited to, statements about future operations, products, financial position, operating results, prospects, pipeline or potential markets therefor, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words, and the use of future dates.

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

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2015, 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®, Corticotrophin®, Corticotrophin-Zinc®, Inderal® LA, 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)

	September 30, 2016	*December 31, 2015*
Assets		
Current Assets		
Cash and cash equivalents	$ 16,155	$ 154,684
Accounts receivable, net of $22,385 and $13,586 of adjustments for chargebacks and other allowances at September 30, 2016 and December 31, 2015, respectively	47,477	21,932
Inventories, net	28,261	13,387
Prepaid income taxes	929	1,127
Prepaid expenses and other current assets	2,653	1,453
Total Current Assets	95,475	192,583
Property and equipment, net	9,716	7,131
Restricted cash	5,001	-
Deferred tax asset, net of valuation allowance	18,400	17,316
Intangible assets, net	188,949	66,397
Goodwill	1,838	1,838
Total Assets	$ 319,379	$ 285,265
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 4,730	$ 2,066
Accrued expenses and other	2,016	617
Accrued royalties	11,769	606
Accrued compensation and related expenses	1,426	1,188
Accrued Medicaid rebates	6,451	4,631
Returned goods reserve	4,099	2,648
Total Current Liabilities	30,491	11,756
Long-term Liabilities		
Long-term royalties	1,250	-
Convertible notes, net of discount and deferred financing costs	118,808	113,427
Total Liabilities	$ 150,549	$ 125,183
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 11,579,764 shares issued and outstanding at September 30, 2016; 11,498,228 shares issued and outstanding at December 31, 2015	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	-	-
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	-	-
Additional paid-in capital	170,665	164,431
Accumulated deficit	(1,836)	(4,350)
Total Stockholders' Equity	168,830	160,082
Total Liabilities and Stockholders' Equity	$ 319,379	$ 285,265

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)

	Three Months Ended September 30,		*Nine Months Ended September 30,*	
	2016	*2015*	*2016*	*2015*
Net Revenues	$ 38,525	$ 19,972	$ 90,417	$ 58,287
Operating Expenses:				
Cost of sales (excluding depreciation and amortization)	16,669	3,260	31,874	9,152
Research and development	1,041	815	2,771	2,213
Selling, general, and administrative	6,928	5,399	20,460	15,701
Depreciation and amortization	5,966	2,047	16,531	4,789
Total Operating Expenses	30,604	11,521	71,636	31,855
Operating Income	7,921	8,451	18,781	26,432
Other Expense, net				
Interest expense, net	(2,856)	(2,766)	(8,468)	(8,240)
Other (expense)/income, net	(21)	(28)	(31)	40
Income Before Provision for Income Taxes	5,044	5,657	10,282	18,232
Provision for income taxes	(2,501)	(1,098)	(5,268)	(5,733)
Net Income	$ 2,543	$ 4,559	$ 5,014	$ 12,499
Basic and Diluted Earnings Per Share:				
Basic Earnings Per Share	$ 0.22	$ 0.40	$ 0.44	$ 1.09
Diluted Earnings Per Share	$ 0.22	$ 0.39	$ 0.43	$ 1.07
Basic Weighted-Average Shares Outstanding	11,465	11,384	11,421	11,352
Diluted Weighted-Average Shares Outstanding	11,625	11,563	11,552	11,559

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

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

	Nine Months Ended September 30,	
	2016	*2015*
Cash Flows From Operating Activities		
Net income	$ 5,014	$ 12,499
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	4,687	2,717
Deferred taxes	(1,084)	55
Depreciation and amortization	16,531	4,789
Non-cash interest relating to convertible notes and loan cost amortization	5,421	5,135
Changes in operating assets and liabilities:		
Accounts receivable, net	(25,545)	(4,348)
Inventories, net	(4,016)	(6,223)
Prepaid expenses and other current assets	(623)	(2)
Accounts payable	2,562	(130)
Accrued royalties	6,082	(511)
Accrued compensation and related expenses	238	(329)
Current income taxes, net	198	(5,225)
Accrued Medicaid rebates	1,820	2,164
Accrued expenses, returned goods reserve, and other	4,105	1,971
Net Cash and Cash Equivalents Provided by Operating Activities	15,390	12,562
Cash Flows From Investing Activities		
Changes in restricted cash	(5,001)	-
Acquisition of product rights and other related assets	(144,494)	(30,500)
Acquisition of property and equipment	(3,177)	(1,078)
Net Cash and Cash Equivalents Used in Investing Activities	(152,672)	(31,578)
Cash Flows From Financing Activities		
Payment of debt issuance costs	(294)	-
Proceeds from stock option exercises	1,362	771
Excess tax benefit from share-based compensation awards	307	234
Repurchase of common stock under the stock repurchase program	(2,500)	-
Treasury stock purchases for restricted stock vestings and forfeitures	(122)	(113)
Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities	(1,247)	892
Change in Cash and Cash Equivalents	(138,529)	(18,124)
Cash and cash equivalents, beginning of period	154,684	169,037
Cash and cash equivalents, end of period	$ 16,155	$ 150,913
Supplemental disclosure for cash flow information:		
Cash paid for interest	$ 2,156	$ 2,048
Cash paid for income taxes, net	$ 5,847	$ 10,668
Supplemental non-cash investing and financing activities:		
Accrued royalties related to asset purchase	$ 3,882	$ -
Property and equipment purchased and included in accounts payable	$ 102	$ 109

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

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. Our targeted areas of product development currently include controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations involving extended release and combination products. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota that 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 the 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, 2015, 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, 2015. Certain prior period information has been reclassified to conform to the current period presentation.

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 have been eliminated in consolidation.

Foreign Currency

The company has subsidiaries located outside of the U.S. All existing subsidiaries currently conduct substantially all their transactions in U.S. dollars, or are otherwise dependent upon the U.S. parent for funding. Accordingly, these subsidiaries use the U.S. dollar as their functional currency. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

Foreign currency transaction gains and losses are included in the determination of net income.

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

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, Medicaid 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.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In August 2016, the Financial Accounting Standards Board ("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 are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated statements of cash flows.

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. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

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

In March 2016, the FASB issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards. Under the guidance, companies can elect to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. In addition, the guidance amends some of the other stock-based compensation awards guidance to more clearly articulate the requirements and cash flow presentation for withholding shares for tax-withholding purposes. Finally, under the guidance, all excess tax benefits and tax deficiencies related to stock-based compensation awards are to be recognized as income tax expenses or benefits in the income statement and excess tax benefits should be classified along with other income tax cash flows in the operating activities section of the statement of cash flows. We reported excess tax benefits of $0.3 million and $0.2 million in the financing activities section of our statements of cash flows for the nine months ended September 30, 2016 and 2015, respectively. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted, though all amendments of the guidance must be adopted in the same period. The adoption of certain amendments of the guidance must be applied prospectively, and adoption of the remaining amendments must be applied either on a modified retrospective basis or retrospectively to all periods presented. Previously-reported excess tax benefits may not be indicative of future excess tax benefits that will be recorded in our consolidated statements of earnings after the guidance is adopted, and we are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements.

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.

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. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

Recently Adopted Accounting Pronouncements

In March 2016, the FASB issued guidance to clarify the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. The amendments of this guidance are effective for reporting periods beginning after December 15, 2016, and early adoption is permitted. Entities are required to apply the guidance to existing debt instruments using a modified retrospective transition method as of the beginning of the fiscal year of adoption. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a modified retrospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

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

In November 2015, the FASB issued guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that all deferred taxes be presented as noncurrent, rather than separated into current and noncurrent amounts. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted. In addition, the adoption of guidance can be applied either prospectively or retrospectively to all periods presented. We adopted this guidance for the year ended December 31, 2015 on a retrospective basis, and all periods are presented under this guidance.

In July 2015, the FASB issued guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using the last in first out ("LIFO") method or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The guidance is effective for reporting periods beginning after December 15, 2016. The guidance should be applied prospectively, with earlier application permitted. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In April 2015, the FASB issued guidance as to whether a cloud computing arrangement (e.g., software as a service, platform as a service, infrastructure as a service, and other similar hosting arrangements) includes a software license and, based on that determination, how to account for such arrangements. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance is effective for reporting periods beginning after December 15, 2015, and can be adopted on either a prospective or retrospective basis. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In April 2015, the FASB issued guidance to simplify the balance sheet disclosure for debt issuance costs. Under the guidance, debt issuance costs related to a recognized debt liability are presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, in the same manner as debt discounts, rather than as an asset. In August 2015, the FASB issued guidance clarifying debt issuance costs related to line-of-credit arrangements, which guidance states that the SEC does not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit. The guidance is effective for reporting periods beginning after December 15, 2015 and must be adopted on a retrospective basis. Early adoption is permitted. We adopted this guidance for the year ended December 31, 2015 on a retrospective basis, and all periods are presented under 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.

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. 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, Medicaid 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.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the nine months ended September 30, 2015 and 2016, respectively:

(in thousands)	Accruals for Chargebacks, Rebates, Returns, and Other Allowances				
	Chargebacks	Medicaid Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2014	$ 6,865	$ 2,264	$ 1,445	$ 1,487	$ 471
Accruals/Adjustments	34,516	4,785	1,402	4,187	1,942
Credits Taken Against Reserve	(32,973)	(2,621)	(958)	(4,570)	(1,813)
Balance at September 30, 2015	$ 8,408	$ 4,428	$ 1,889	$ 1,104	$ 600
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

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

Credit Concentration

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

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, and accounts receivable from these customers totaled 72% of accounts receivable, net as of September 30, 2016. During the three months ended September 30, 2015, four customers represented 25%, 19%, 17%, and 11% of net revenues, respectively. During the nine months ended September 30, 2015, these same four customers represented 21%, 21%, 19%, and 14% 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 Additional Paid in Capital ("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 over the term of the debt, since this method was not significantly different from the effective interest method.

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

(in thousands)	September 30, 2016	December 31, 2015
Principal amount	$ 143,750	$ 143,750
Unamortized debt discount	(22,269)	(27,016)
Deferred financing costs	(2,674)	(3,307)
Net carrying value	$ 118,807	$ 113,427

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, 2016 and December 31, 2015, respectively.

3. INDEBTEDNESS – continued

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, 2016 and 2015:

	Three Months Ended		Nine Months Ended	
(in thousands)	September 30, 2016	September 30, 2015	September 30, 2016	September 30, 2015
Contractual coupon	$ 1,078	$ 1,078	$ 3,234	$ 3,234
Amortization of debt discount	1,604	1,521	4,748	4,502
Amortization of finance fees	211	211	633	633
Capitalized interest	(58)	(11)	(158)	(26)
	$ 2,835	$ 2,799	$ 8,457	$ 8,343

As of September 30, 2016, the effective interest rate on the Notes was 7.8%, 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. Borrowings under the Citizens Agreement may be used for general corporate purposes, including financing possible future acquisitions and funding working capital. 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.

The Citizens Agreement is secured by a lien on substantially all of ANI Pharmaceutical Inc.'s and its principal domestic subsidiary's assets and any future domestic subsidiary guarantors' assets. The Citizens Agreement includes covenants, subject to certain exceptions, including covenants that restrict our ability to incur additional indebtedness, acquire or dispose of assets, and make and incur capital expenditures. The Citizens Agreement also imposes a financial covenant requiring compliance with a minimum fixed charge coverage ratio of 1.10 to 1.00 during certain covenant testing that is triggered if availability under the Citizens Agreement is below the greater of 12.5% of the revolving commitment and $3.75 million for three consecutive business days.

As of September 30, 2016, we had no 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 will be amortized over the three year life of the Line of Credit. The $0.3 million of deferred debt issuance costs are included in prepaid expenses and other current assets in the accompanying unaudited interim condensed consolidated balance sheet at September 30, 2016. During the period from when we entered into the Line of Credit through September 30, 2016, we recorded $41 thousand of interest expense related to the Line of Credit.

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, 2016 and 2015 are calculated for basic and diluted earnings per share as follows:

(in thousands, except per share amounts)	Basic Three Months Ended September 30,		Diluted Three Months Ended September 30,		Basic Nine Months Ended September 30,		Diluted Nine Months Ended September 30,	
	2016	2015	2016	2015	2016	2015	2016	2015
Net income	$ 2,543	$ 4,559	$ 2,543	$ 4,559	$ 5,014	$ 12,499	$ 5,014	$ 12,499
Net income allocated to restricted stock	(17)	(30)	(17)	(30)	(34)	(82)	(34)	(82)
Net income allocated to common shares	$ 2,526	$ 4,529	$ 2,526	$ 4,529	$ 4,980	$ 12,417	$ 4,980	$ 12,417
Basic Weighted-Average Shares Outstanding	11,465	11,384	11,465	11,384	11,421	11,352	11,421	11,352
Dilutive effect of stock options and ESPP			160	179			131	207
Diluted Weighted-Average Shares Outstanding			11,625	11,563			11,552	11,559
Earnings Per Share	$ 0.22	$ 0.40	$ 0.22	$ 0.39	$ 0.44	$ 1.09	$ 0.43	$ 1.07

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 4.5 million for each of the three month periods ended September 30, 2016 and 2015 and was 4.5 million and 4.6 million for the nine months ended September 30, 2016 and 2015, 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.

5. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2016	December 31, 2015
Raw materials	$ 14,538	$ 10,192
Packaging materials	1,118	998
Work-in-progress	685	456
Finished goods	12,083	1,897
	28,424	13,543
Reserve for excess/obsolete inventories	(163)	(156)
Inventories, net	$ 28,261	$ 13,387

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, 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 the same supplier. As of September 30, 2016, the amount payable to this supplier was immaterial. During the three months ended September 30, 2015, we purchased approximately 35% of our inventory from two suppliers. During the nine months ended September 30, 2015, we purchase approximately 44% of our inventory from three suppliers.

6. PROPERTY, PLANT, AND EQUIPMENT

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

(in thousands)	September 30, 2016	December 31, 2015
Land	$ 87	$ 87
Buildings	3,682	3,682
Machinery, furniture, and equipment	7,430	5,623
Construction in progress	3,652	2,189
	14,851	11,581
Less: accumulated depreciation	(5,135)	(4,450)
Property, Plant, and Equipment, net	$ 9,716	$ 7,131

Depreciation expense was $0.2 million for each of the three month periods ended September 30, 2016 and 2015. Depreciation expense was $0.7 million and $0.5 million for the nine months ended September 30, 2016 and 2015. During the three months ended September 30, 2016 and 2015, there was $58 thousand and $11 thousand of interest capitalized into construction in progress, respectively. During the nine months ended September 30, 2016 and 2015, there was $0.2 million and $26 thousand 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.

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. We assess the recoverability of the carrying value of goodwill as of October 31 st of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value from the most recent assessment on October 31, 2015 through September 30, 2016. No impairment losses were recognized during the three or nine months ended September 30, 2016 or 2015.

Definite-lived Intangible Assets

Acquisition of Abbreviated New Drug Applications

In July 2015, we purchased the ANDAs for 22 previously marketed generic drug products from Teva Pharmaceuticals ("Teva") for $25.0 million in cash and a percentage of future gross profits from product sales. We accounted for this transaction as an asset purchase. The ANDAs are being amortized in full over their estimated useful lives of 10 years.

In March 2015, we purchased an ANDA from Teva for Flecainide for $4.5 million in cash and a percentage of future gross profits from product sales. We accounted for this transaction as an asset purchase. The ANDA is being amortized in full over its estimated useful life of 10 years.

In the first quarter of 2014, we purchased the ANDAs to produce 31 previously marketed generic drug products from Teva for $12.5 million in cash and a percentage of future gross profits from product sales. We accounted for this transaction as an asset purchase. The ANDAs are being amortized in full over their estimated useful lives of 10 years.

Acquisition of New Drug Applications and Product Rights

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. Please see Note 12 for further details regarding the transaction.

In September 2015, we entered into an agreement to purchase the NDAs for Corticotropin and Corticotropin-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. Please see Note 12 for further details regarding the transaction.

As part of our 2013 merger with BioSante, we acquired a testosterone gel product that was licensed to Teva (the "Testosterone Gel NDA"). In May 2015, we acquired from Teva the approved NDA for the previously-licensed product. Pursuant to the terms of the purchase agreement, upon commercialization, we will pay Teva a royalty of up to $5.0 million, at a rate of 5% of the consideration we receive as a result of commercial sale of the product. The $10.9 million Testosterone Gel NDA asset is being amortized in full over its estimated useful life of 11 years.

7. GOODWILL AND INTANGIBLE ASSETS – continued

In August 2014, we entered into an agreement to purchase (the "Vancocin Purchase Agreement") the product rights to Vancocin from Shire ViroPharma Incorporated for $11.0 million in cash. Pursuant to the terms of the Vancocin Purchase Agreement, we acquired the U.S. intellectual property rights and NDA associated with Vancocin, two related ANDAs, and certain equipment and inventory. We accounted for this transaction as an asset purchase. The $10.5 million product rights intangible asset is being amortized in full over its estimated useful life of 10 years.

In July 2014, we entered into an agreement to purchase (the "Lithobid Purchase Agreement") the product rights to Lithobid from Noven Therapeutics, LLC for $11.0 million in cash at closing, and $1.0 million in cash if certain approvals were received from the Food and Drug Administration ("FDA") on or before June 30, 2015. This $1.0 million contingent payment was paid in January 2015. Pursuant to the terms of the Lithobid Purchase Agreement, we acquired the intellectual property rights and NDA associated with Lithobid, as well as a small amount of raw material inventory. We accounted for this transaction as an asset purchase. The $12.0 million product rights intangible asset is being amortized in full over its estimated useful life 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. Please see Note 12 for further details regarding the transaction.

In August 2015, we entered into a distribution agreement with IDT Australia Limited ("IDT") to market several products in the U.S. The products, all of which are approved ANDAs, require various FDA filings and approvals prior to commercialization. In general, IDT will be responsible for regulatory submissions to the FDA and the manufacturing of certain products. We made an upfront payment to IDT of $1.0 million and will make additional milestone payments upon FDA approval for commercialization of certain products. Upon approval, IDT will manufacture some of the products and we will manufacture the other products. We will market and distribute all the products under our label in the United States, remitting a percentage of profits from sales of the drugs to IDT. We accounted for this transaction as an asset purchase. The $1.0 million upfront payment was recorded as a marketing and distribution rights intangible asset and is being amortized in full over its estimated useful life of seven years.

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

(in thousands)	September 30, 2016		December 31, 2015		Weighted Average
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	Amortization Period
Acquired ANDA intangible assets	$ 42,076	$ (7,340)	$ 42,076	$ (4,287)	10.0 years
NDAs and product rights	161,150	(16,548)	33,422	(5,754)	10.1 years
Marketing and distribution rights	11,042	(2,011)	1,000	(60)	4.7 years
Non-compete agreement	624	(44)	-	-	7.0 years
	$ 214,892	$ (25,943)	$ 76,498	$ (10,101)	

7. GOODWILL AND INTANGIBLE ASSETS – continued

Definite-lived intangible assets are stated at cost, net of amortization using the straight line method over the expected useful lives of the intangible assets. Amortization expense was $5.7 million and $1.9 million for the three months ended September 30, 2016 and 2015, respectively. Amortization expense was $15.8 million and $4.3 million for the nine months ended September 30, 2016 and 2015, respectively.

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three and nine months ended September 30, 2016 and 2015 and therefore no impairment loss was recognized in the three and nine months ended September 30, 2016 or 2015.

Expected future amortization expense is as follows:

(in thousands)	
2016 (remainder of the year)	$ 5,725
2017	22,722
2018	22,367
2019	22,367
2020	21,885
2021 and thereafter	93,883
Total	$ 188,949

8. STOCK-BASED COMPENSATION

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"). As of September 30, 2016, 0.2 million shares of our common stock remained available for issuance under the 2008 Plan. In addition, in July 2016, we commenced administration of our ESPP, which was approved by shareholders in our May 25, 2016 annual shareholder meeting. The Board of Directors and shareholders approved a maximum of 0.2 million shares of common stock, which were reserved and made available for issuance under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount. No shares have been issued to date. In the three months ended September 30, 2016, we recognized $12 thousand of stock-based compensation expense related to the ESPP.

The following table summarizes stock-based compensation expense, net of forfeitures, included in our accompanying unaudited interim condensed consolidated statements of earnings:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2016	2015	2016	2015
Cost of sales	$ 24	$ 23	$ 38	$ 60
Research and development	25	31	74	80
Selling, general, and adminstrative	1,316	1,066	4,575	2,577
	$ 1,365	$ 1,120	$ 4,687	$ 2,717

8. STOCK-BASED COMPENSATION– continued

Separation Agreement

On April 26, 2016, we entered into a Separation Agreement and Release (the "Separation Agreement") with our former Chief Financial Officer (the "Former Officer"), who resigned effective May 6, 2016. Under the Separation Agreement, 25,167 stock options previously granted to the Former Officer vested on May 6, 2016. In addition, 4,050 restricted stock awards and 2,000 stock options previously granted to the Former Officer will vest on March 15, 2017, subject to certain conditions. These actions were accounted for as a modification of the underlying awards and the full expense for the modified awards was recorded in the second quarter 2016. In the second quarter of 2016, we recorded $0.9 million of stock-based compensation expense, net of forfeitures, in relation to the Separation Agreement. In the second quarter 2016, we recognized $0.4 million of additional expense related to the Separation Agreement and transition that was not related to stock-based compensation. All expenses related to the Separation Agreement and transition have been recognized in the second quarter 2016.

A summary of stock option and restricted stock activity under the Plan during the nine months ended September 30, 2016 and 2015 is presented below:

(in thousands)	Options	RSAs
Outstanding December 31, 2014	458	63
Granted	130	28
Options Exercised/RSAs Vested	(81)	(10)
Forfeited	(33)	(5)
Outstanding September 30, 2015	474	76
Outstanding December 31, 2015	474	63
Granted	293	42
Options Exercised/RSAs Vested	(120)	(15)
Forfeited	(59)	(12)
Outstanding September 30, 2016	588	78

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 allows for repurchases to be conducted through open market or privately negotiated transactions. Shares acquired under the stock repurchase program are returned to the status of authorized but unissued shares of common stock. The stock repurchase program may be suspended, modified, or discontinued at any time at our discretion.

In January 2016, we purchased 65 thousand shares under the stock repurchase program for $2.5 million.

Warrants

No warrants to purchase shares of common stock were granted, exercised, or expired unexercised during the three and nine months ended September 30, 2016. Warrants to purchase 0.1 million and 0.3 million shares of common stock expired unexercised during the three and nine months ended September 30, 2015. No warrants to purchase shares of common stock were granted or exercised during the three and nine months ended September 30, 2015.

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, 2016 and December 31, 2015, we had provided a valuation allowance against certain state net operating loss ("NOL") carryforwards of approximately $0.2 million.

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, 2016 and December 31, 2015. 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.

We calculate income tax benefits related to stock-based compensation arrangements using the with and without method.

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 discreet items whose tax effect is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discreet 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 discreet items occur.

Our estimated annual effective tax rate was 53.4% of pre-tax income for the first quarter of 2016, 52.2% of pre-tax income for the second quarter of 2016, 49.6% of pre-tax income for the third quarter of 2016, and 51.2% of pre-tax income for the nine months ended September 30, 2016. The progressive decrease in our estimated annual effective tax rate during the first nine months of 2016 was primarily driven by the on-going revisions discussed above and by the tax effect of discreet items, including changes in our estimated pre-tax income resulting from various asset acquisitions that occurred during the periods and associated changes to temporary differences arising from those asset acquisitions, as well as the impact of current period awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur.

The effective tax rate for the nine-month period ended September 30, 2015 was 31.4% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2015. The 19.4% effective tax rate for the three-month period ended September 30, 2015 was primarily driven by on-going revisions to estimated pre-tax income and permanent differences, and also by state income tax rates and the impact of third quarter 2015 awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur. The difference in effective tax rate from 2015 to 2016 was due to larger permanent differences, relative to pre-tax income, in 2015 than in 2016.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

We lease equipment under operating leases that expire in September 2018 and February 2021. We also lease office space under operating leases that expire in September 2018 and April 2021. Future minimum lease payments due under these leases total $0.4 million as of September 30, 2016.

11. COMMITMENTS AND CONTINGENCIES – continued

Rent expense for the three months ended September 30, 2016 and 2015 totaled $22 thousand and $19 thousand, respectively. Rent expense for the nine months ended September 30, 2016 and 2015 totaled $61 thousand and $57 thousand, respectively.

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, 2016 and 2015, net revenues for these products totaled $8.6 million and $12.5 million, respectively. During the nine months ended September 30, 2016 and 2015, net revenues for these products totaled $26.6 million and $33.8 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 each of the three month periods ended September 30, 2016 and 2015 were $0.3 million. Our contract manufacturing revenues for these unapproved products for each of the nine month periods ended September 30, 2016 and 2015 were $1.1 million.

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 months ended September 30, 2016 and 2015 were $5 thousand and $0.1 million, respectively. Our royalties on the net sales of these unapproved products for the nine months ended September 30, 2016 and 2015 were $0.2 million and $0.3 million, respectively.

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.

Other Commitments and Contingencies

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, are facing 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. 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. 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 further 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.

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, borrowings under line of credit, and other current liabilities) approximate their carrying values because of their short-term nature. While our Notes are recorded on our accompanying unaudited interim condensed consolidated balance sheets at their net carrying value of $118.8 million as of September 30, 2016, the Notes are being traded on the bond market and their full fair value is $176.6 million, based on their closing price on September 30, 2016, a Level 1 input.

12. FAIR VALUE DISCLOSURES– continued

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, 2016 and December 31, 2015, and for the three and nine months ended September 30, 2016 and 2015.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of September 30, 2016 and December 31, 2015, by level within the fair value hierarchy:

(in thousands)

Description	Fair Value at September 30, 2016	Level 1	Level 2	Level 3
Liabilities				
CVRs	$ -	$ -	$ -	$ -

Description	Fair Value at December 31, 2015	Level 1	Level 2	Level 3
Liabilities				
CVRs	$ -	$ -	$ -	$ -

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

We do not have any financial assets and liabilities 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 three and nine months ended September 30, 2016 and 2015.

12. FAIR VALUE DISCLOSURES– continued

Acquired Non-Financial Assets Measured at Fair Value

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 unaudited interim condensed consolidated balance sheet as of September 30, 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. 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 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, 2016 and therefore no impairment loss was recognized for the three and nine months ended September 30, 2016. We recorded $10.9 million of finished goods. The fair value of the finished goods was determined based on the estimated sales 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. 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 will be amortized in full over its seven year useful life. We also recorded a $0.3 million prepaid balance related to a partially paid purchase order for inventory.

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. 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 will be amortized in full over their 10 year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the period from the date of acquisition to September 30, 2016 and therefore no impairment loss was recognized for the three and nine months ended September 30, 2016.

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 (Note 7). 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. In addition, we capitalized $42 thousand of costs directly related to the transaction. We accounted for this transaction as an asset purchase. In order to determine the fair value of the rights for purposes of purchase price allocation, we used the present value of the estimate cash flows related to the product rights, using a discount rate of 10%. No value was ascribed to the early-stage development project because the development is still at the preliminary stage, with no expenses incurred or research performed to date. The marketing and distribution rights will be amortized in full over their average estimated useful lives of approximately four years, 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 from the date of acquisition to September 30, 2016 and therefore no impairment loss was recognized for the three and nine months ended September 30, 2016.

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, 2015.

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. Our targeted areas of product development currently include controlled substances, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota that 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 the business, expand and diversify our product portfolio, and create long-term value for our investors.

As of September 30, 2016, our products include both branded and generic pharmaceuticals, specifically:

Generic Products	Branded Products
Erythromycin Ethylsuccinate	Cortenema
Esterified Estrogen with Methyltestosterone	Inderal LA
Etodolac	Lithobid
Fenofibrate	Reglan
Flecainide	Vancocin
Fluvoxamine	
Hydrocortisone Enema	
Hydrocortisone Rectal Cream (1% and 2.5%)	
Hydroxyprogesterone Caproate Injection	
Mesalamine Enema	
Methazolamide	
Metoclopramide Syrup	
Nilutamide	
Nimodipine	
Opium Tincture	
Oxycodone Capsules	
Oxycodone Oral Solution	
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 seek 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.*** Whenever possible, we seek to develop and manufacture products at our own manufacturing plants in order to maximize the capacity and utilization of our facilities, to ensure quality control in our products, and to maximize profit potential.
- ***Competition.*** When determining whether to develop or acquire an individual product, we research the existing and expected market share of generic competitors. We seek to develop products for which we can obtain a large market share, and may decline to develop a product if we anticipate many generic competitors. Our highly specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies would be able to compete.

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,	
	2016	2015	2016	2015
Net revenues	$ 38,525	$ 19,972	$ 90,417	$ 58,287
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	16,669	3,260	31,874	9,152
Research and development	1,041	815	2,771	2,213
Selling, general, and administrative	6,928	5,399	20,460	15,701
Depreciation and amortization	5,966	2,047	16,531	4,789
Operating income	7,921	8,451	18,781	26,432
Interest expense, net	(2,856)	(2,766)	(8,468)	(8,240)
Other (expense)/income, net	(21)	(28)	(31)	40
Income before provision for income taxes	5,044	5,657	10,282	18,232
Provision for income taxes	(2,501)	(1,098)	(5,268)	(5,733)
Net income	$ 2,543	$ 4,559	$ 5,014	$ 12,499

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,	
	2016	2015	2016	2015
Net revenues	100.0%	100.0%	100.0%	100.0%
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	43.2%	16.3%	35.2%	15.7%
Research and development	2.7%	4.1%	3.1%	3.8%
Selling, general, and administrative	18.0%	27.0%	22.6%	26.9%
Depreciation and amortization	15.5%	10.3%	18.3%	8.2%
Operating income	20.6%	42.3%	20.8%	45.4%
Interest expense, net	(7.4)%	(13.9)%	(9.4)%	(14.2)%
Other (expense)/income, net	(0.1)%	(0.1)%	-%	0.1%
Income before provision for income taxes	13.1%	28.3%	11.4%	31.3%
Provision for income taxes	(6.4)%	(5.5)%	(5.8)%	(9.8)%
Net income	6.7%	22.8%	5.6%	21.5%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015

Net Revenues

(in thousands)	Three Months Ended September 30,			
	2016	2015	Change	% Change
Generic pharmaceutical products	$ 30,191	$ 15,102	$ 15,089	99.9%
Branded pharmaceutical products	6,834	2,253	4,581	203.3%
Contract manufacturing	1,427	1,280	147	11.5%
Contract services and other income	73	1,337	(1,264)	(94.5)%
Total net revenues	$ 38,525	$ 19,972	$ 18,553	92.9%

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, 2016 were $38.5 million compared to $20.0 million for the same period in 2015, an increase of $18.5 million, or 92.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $30.2 million during the three months ended September 30, 2016, an increase of 99.9% compared to $15.1 million for the same period in 2015. The primary reason for the increase was sales of Propranolol ER and other products launched in the second quarter of 2016, sales of Nilutamide and Erythromycin Ethylsuccinate, both of which were launched in the third quarter of 2016, as well as sales of Vancomycin, which was launched under our own label in the fourth quarter of 2015. These increases were tempered by volume decreases in Esterified Estrogen with Methyltestosterone (“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 Food and Drug Administration (“FDA”) approved New Drug Applications (“NDAs”). The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the three months ended September 30, 2016 and 2015 were $8.6 million and $12.5 million, respectively.

- Net revenues for branded pharmaceutical products were $6.8 million during the three months ended September 30, 2016, an increase of 203.3% compared to $2.3 million for the same period in 2015. The primary reason for the increase was sales of Inderal LA, which was launched in the second quarter of 2016.

- Contract manufacturing revenues were $1.4 million during the three months ended September 30, 2016, an increase of 11.5% compared to $1.3 million for the same period in 2015, 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 each of the three month periods ended September 30, 2016 and 2015 were $0.3 million.

- Contract services and other income were $0.1 million during the three months ended September 30, 2016, a decrease of 94.7% from $1.3 million for the same period in 2015, due primarily to the lack of royalties received on sales of the authorized generic of Vancocin. In the fourth quarter of 2015, we launched an authorized generic of Vancocin under our own label, which replaced the authorized generic product previously on the market.

  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 for the three months ended September 30, 2016 and 2015 were $5 thousand and $0.1 million, respectively.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended September 30,			
	2016	2015	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 16,669	$ 3,260	$ 13,409	411.3%

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

For the three months ended September 30, 2016, cost of sales increased to $16.7 million from $3.3 million for the same period in 2015, an increase of $13.4 million or 411.3%, 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 LA and Propranolol ER inventory acquired in 2016 through an asset acquisition transaction, and subsequently sold during the period. Cost of sales as a percentage of net revenues increased to 43.2% during the three months ended September 30, 2016, from 16.3% during same period in 2015, primarily as a result of increased sales of products subject to profit-sharing arrangements, a trend we expect to continue, and the $1.1 million impact on cost of sales (2.9% as a percent of net revenues) of the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period, a trend which will continue until such time that the inventory purchased from Cranford Pharmaceuticals, LLC (“Cranford”) as a component of the Inderal LA NDA asset purchase is consumed.

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. Changes in API suppliers usually must be approved by the FDA. As a result, we are dependent upon our current vendors to reliably supply the API required for ongoing product manufacturing. In addition, certain of our API for our drug products, including those that are marketed without approved NDAs or Abbreviated New Drug Applications ("ANDAs"), are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections.

During the three months ended September 30, 2016, we purchased 28% of our inventory from one supplier. As of September 30, 2016, the amount payable to this supplier was immaterial. In the three months ended September 30, 2015, we purchased approximately 35% of our inventory from two suppliers.

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 approve quotas large enough to support our continued manufacture of Opium Tincture, Oxycodone capsules, and Oxycodone oral solution.

Other Operating Expenses

(in thousands)	Three Months Ended September 30,			
	2016	2015	Change	% Change
Research and development	$ 1,041	$ 815	$ 226	27.7%
Selling, general, and administrative	6,928	5,399	1,529	28.3%
Depreciation and amortization	5,966	2,047	3,919	191.5%
Total other operating expenses	$ 13,935	$ 8,261	$ 5,674	68.7%

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, 2016, other operating expenses increased to $13.9 million from $8.3 million for the same period in 2015, an increase of $5.6 million, or 68.7%, primarily as a result of the following factors:

- Research and development expenses increased from $0.8 million to $1.0 million, an increase of 27.7%, due to timing of work on development projects. Current projects include work on the ANDAs purchased in 2014 and 2015, as well as collaborations with partners. We anticipate that research and development costs will continue to be greater in 2016 than 2015, in support of our strategy to expand our product portfolio.

- Selling, general, and administrative expenses increased from $5.4 million to $6.9 million, an increase of 28.3%, primarily due to increased stock-based compensation expense and increases in personnel and related costs. We anticipate that selling, general, and administrative expenses will continue to be greater in 2016 than in 2015 as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $2.0 million to $6.0 million, an increase of 191.5%, due primarily to the amortization of the NDAs for Corticotropin and Corticotropin-Zinc and marketing and distribution rights acquired from H2-Pharma, LLC, both of which were acquired in January 2016, and the amortization of the rights, title, and interest in the NDA for Inderal LA, which was acquired in April 2016. We anticipate that depreciation and amortization expense will continue to be greater in 2016 than in 2015 as a result of our first and second quarter 2016 asset purchases.

Other Expense, net

(in thousands)	Three Months Ended September 30,			
	2016	2015	Change	% Change
Interest expense, net	$ (2,856)	$ (2,766)	$ (90)	3.3%
Other expense, net	(21)	(28)	7	(25.0)%
Total other expense	$ (2,877)	$ (2,794)	$ (83)	3.0%

For the three months ended September 30, 2016, we recognized other expense of $2.9 million versus other expense of $2.8 million for the same period in 2015, a change of $0.1 million. Interest expense, net for both periods consists primarily of interest expense on our convertible debt.

Provision for Income Taxes

(in thousands)	Three Months Ended September 30,			
	2016	2015	Change	% Change
Provision for income taxes	$ (2,501)	$ (1,098)	$ (1,403)	127.8%

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. 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 discreet items whose tax effect is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discreet 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 discreet items occur.

For the three months ended September 30, 2016, we recognized income tax expense of $2.5 million, versus $1.1 million for the same period in 2015, an increase of $1.4 million. Of the $2.5 million of total tax expense, $2.9 million is current expense and $0.4 million is a net deferred benefit.

Our estimated annual effective tax rate was 53.4% of pre-tax income for the first quarter of 2016, 52.2% of pre-tax income for the second quarter of 2016, 49.6% of pre-tax income for the third quarter of 2016, and 51.2% of pre-tax income for the nine months ended September 30, 2016. The progressive decrease in our estimated annual effective tax rate during the first nine months of 2016 was primarily driven by the on-going revisions discussed above, and by the tax effect of discreet items, including changes in our estimated pre-tax income resulting from various asset acquisitions that occurred during the periods and associated changes to temporary differences arising from those asset acquisitions, as well as the impact of current period awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur.

The effective tax rate for the nine-month period ended September 30, 2015 was 31.4% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2015. The 19.4% effective tax rate for the three-month period ended September 30, 2015 was primarily driven by on-going revisions to estimated pre-tax income and permanent differences, and also by state income tax rates and the impact of third quarter 2015 awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur. The difference in effective tax rate from 2015 to 2016 was due to larger permanent differences, relative to pre-tax income, in 2015 than in 2016.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2016 AND 2015

Net Revenues

(in thousands)	Nine Months Ended September 30,			
	2016	2015	Change	% Change
Generic pharmaceutical products	$ 65,905	$ 41,122	$ 24,783	60.3%
Branded pharmaceutical products	19,919	8,662	11,257	130.0%
Contract manufacturing	3,977	3,576	401	11.2%
Contract services and other income	616	4,927	(4,311)	(87.5)%
Total net revenues	$ 90,417	$ 58,287	$ 32,130	55.1%

Net revenues for the nine months ended September 30, 2016 were $90.4 million compared to $58.3 million for the same period in 2015, an increase of $32.1 million, or 55.1%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $65.9 million during the nine months ended September 30, 2016, an increase of 60.3% compared to $41.1 million for the same period in 2015. The primary reason for the increase was sales of Propranolol ER and other products launched in the second quarter of 2016, sales of Nilutamide and Erythromycin Ethylsuccinate, both of which were launched in the third quarter of 2016, as well as sales of Vancomycin, which was launched under our own label in the fourth quarter of 2015. 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 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, 2016 and 2015 were $26.6 million and $33.8 million, respectively.

- Net revenues for branded pharmaceutical products were $19.9 million during the nine months ended September 30, 2016, an increase of 130.0% compared to $8.7 million for the same period in 2015. The primary reason for the increase was sales of Inderal LA, which was launched in the second quarter of 2016. The increase was partially offset by lower unit sales of Reglan due to decreased purchases by a customer and increased Medicaid utilization and Medicaid rebates for Lithobid and Vancocin. We experience periodic larger orders for our Vancocin product that relate to clinical trials. Such orders constituted $2.4 million and $2.1 million of our branded pharmaceutical product revenue for the nine months ended September 30, 2016 and 2015, respectively, and we cannot be sure that such purchases will occur in future periods.

- Contract manufacturing revenues were $4.0 million during the nine months ended September 30, 2016, an increase of 11.2% compared to $3.6 million for the same period in 2015, 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 each of the nine month periods ended September 30, 2016 and 2015 were $1.1 million.

- Contract services and other income were $0.6 million during the nine months ended September 30, 2016, a decrease of 87.5% from $4.9 million for the same period in 2015, due primarily to the lack of royalties received on sales of the authorized generic of Vancocin. In the fourth quarter of 2015, we launched an authorized generic of Vancocin under our own label, which replaced the authorized generic product previously on the market. This decrease was partially offset by royalties related to sales of Fenofibrate, the authorized generic of Lipofen®, the marketing and distribution rights to which we acquired in January 2016. 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 for the nine months ended September 30, 2016 and 2015 were $0.2 million and $0.3 million, respectively.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Nine Months Ended September 30,			
	2016	2015	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 31,874	$ 9,152	$ 22,722	248.3%

For the nine months ended September 30, 2016, cost of sales increased to $31.9 million from $9.2 million for the same period in 2015, an increase of $22.7 million or 248.3%, 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 LA and Propranolol ER inventory acquired in 2016 through an asset acquisition transaction, and subsequently sold during the period. Cost of sales as a percentage of net revenues increased to 35.2% during the nine months ended September 30, 2016, from 15.7% during same period in 2015, primarily as a result of increased sales of products subject to profit-sharing arrangements, a trend we expect to continue, and the $3.2 million impact on cost of sales (3.5% as a percent of net revenues) of the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period, a trend which will continue until such time that the inventory purchased from Cranford as a component of the Inderal LA NDA asset purchase is consumed.

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

During the nine months ended September 30, 2016, we purchased 23% of our inventory, exclusive of inventory acquired in an asset purchase, from one supplier. As of September 30, 2016, the amount payable to this supplier was immaterial. In the nine months ended September 30, 2015, we purchased approximately 44% of our inventory from three suppliers.

In order to manufacture Opium Tincture, Oxycodone capsules, and Oxycodone oral solution, we must receive approval from the 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 approve quotas large enough to support our continued manufacture of Opium Tincture, Oxycodone capsules, and Oxycodone oral solution.

Other Operating Expenses

(in thousands)	Nine Months Ended September 30,			
	2016	2015	Change	% Change
Research and development	$ 2,771	$ 2,213	$ 558	25.2%
Selling, general, and administrative	20,460	15,701	4,759	30.3%
Depreciation and amortization	16,531	4,789	11,742	245.2%
Total other operating expenses	$ 39,762	$ 22,703	$ 17,059	75.1%

For the nine months ended September 30, 2016, other operating expenses increased to $39.8 million from $22.7 million for the same period in 2015, an increase of $17.1 million, or 75.1%, primarily as a result of the following factors:

- Research and development expenses increased from $2.2 million to $2.8 million, an increase of 25.2%, due to timing of work on development projects. Current projects include work on the ANDAs purchased in 2014 and 2015, as well as collaborations with partners. We anticipate that research and development costs will continue to be greater in 2016 than 2015, in support of our strategy to expand our product portfolio.

- Selling, general, and administrative expenses increased from $15.7 million to $20.5 million, an increase of 30.3%, primarily due to increased stock-based compensation expense and increases in personnel and related costs, including $1.3 million of expenses related to the transition of our CFO in the second quarter of 2016. While all expense related to the transition was recognized in the second quarter of 2016, we anticipate that selling, general, and administrative expenses will continue to be greater in 2016 than in 2015 as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $4.8 million to $16.5 million, an increase of 245.2%, due primarily to the amortization of the NDAs for Corticotropin and Corticotropin-Zinc and marketing and distribution rights acquired from H2-Pharma, LLC, both of which were acquired in January 2016, and the amortization of the rights, title, and interest in the NDA for Inderal LA, which was acquired in April 2016, as well as amortization of the ANDAs acquired in July 2015. We anticipate that depreciation and amortization expense will continue to be greater in 2016 than in 2015 as a result of our first and second quarter 2016 asset purchases.

Other Expense, net

(in thousands)	Nine Months Ended September 30,			
	2016	2015	Change	% Change
Interest expense, net	$ (8,468)	$ (8,240)	$ (228)	2.8%
Other (expense)/income, net	(31)	40	(71)	(177.5)%
Total other expense	$ (8,499)	$ (8,200)	$ (299)	3.6%

For the nine months ended September 30, 2016, we recognized other expense of $8.5 million, an increase of $0.3 million from other expense of $8.2 million for the same period in 2015. Interest expense, net for both periods consists primarily of interest expense on our convertible debt.

Provision for Income Taxes

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.

(in thousands)	Nine Months Ended September 30,			
	2016	2015	Change	% Change
Provision for income taxes	$ (5,268)	$ (5,733)	$ 465	(8.1)%

For the nine months ended September 30, 2016, we recognized income tax expense of $5.3 million, versus income tax expense of $5.7 million for the same period in 2015, a decrease of $0.4 million. Of the $5.3 million of total tax expense, $6.0 million is current expense and $0.7 million is a net deferred benefit.

Our estimated annual effective tax rate was 53.4% of pre-tax income for the first quarter of 2016, 52.2% of pre-tax income for the second quarter of 2016, 49.6% of pre-tax income for the third quarter of 2016, and 51.2% of pre-tax income for the nine months ended September 30, 2016. The progressive decrease in our estimated annual effective tax rate during the first nine months of 2016 was primarily driven by on-going revisions to estimated pre-tax income and permanent differences, by changes in temporary differences, and by the tax effect of discreet items, including changes in our estimated pre-tax income resulting from various asset acquisitions that occurred during the periods and associated changes to temporary differences arising from those asset acquisitions, as well as the impact of current period awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur.

The effective tax rate for the nine-month period ended September 30, 2015 was 31.4% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2015. The effective tax rate for the period was primarily driven by on-going revisions to estimated pre-tax income and permanent differences, and also by state income tax rates and the impact of awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur. The difference in effective tax rate from 2015 to 2016 was due to larger permanent differences, relative to pre-tax income, in 2015 than in 2016.

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	September 30, 2016	December 31, 2015
Cash and cash equivalents	$ 16,155	$ 154,684
Accounts receivable, net	47,477	21,932
Inventories, net	28,261	13,387
Prepaid income taxes	929	1,127
Prepaid expenses and other current assets	2,653	1,453
Total current assets	$ 95,475	$ 192,583
Accounts payable	$ 4,730	$ 2,066
Accrued expenses and other	2,016	617
Accrued royalties	11,769	606
Accrued compensation and related expenses	1,426	1,188
Accrued Medicaid rebates	6,451	4,631
Returned goods reserve	4,099	2,648
Total current liabilities	$ 30,491	$ 11,756

At September 30, 2016, we had $16.2 million in unrestricted cash and cash equivalents. At December 31, 2015, we had $154.7 million in unrestricted cash and cash equivalents. We generated $15.4 million of cash flows from operations in the nine months ended September 30, 2016. In the first quarter of 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs and associated product rights and manufacturing licenses for Corticotropin and Corticotropin-Zinc for $75.0 million in cash and a percentage of future net sales of the products under the NDAs. 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. In addition, at closing, we transferred $5.0 million to an escrow account as security for future milestone payments.

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. As of September 30, 2016, we had no outstanding balance on the Line of Credit, and our available borrowing base was $30.0 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.

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,	
	2016	2015
Operating Activities	$ 15,390	$ 12,562
Investing Activities	$ (152,672)	$ (31,578)
Financing Activities	$ (1,247)	$ 892

Net Cash Provided By Operations

Net cash provided by operating activities was $15.4 million for the nine months ended September 30, 2016, compared to $12.6 million provided by operating activities during the same period in 2015, an increase of $2.8 million between the periods. This increase was principally due to increased sales volume and corresponding gross profit dollars, somewhat tempered by increased expenditures in support of the growth of the business.

Net Cash Used In Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2016 was $152.7 million, principally due to the January 2016 asset acquisition of the NDAs for Corticotropin and Corticotropin-Zinc for $75.3 million, 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, an increase in restricted cash of $5.0 million from the transfer of $5.0 million to an escrow account as security for future milestone payments in relation to the Inderal LA asset acquisition, and $2.1 million of capital expenditures during the period. Net cash used in investing activities was $31.6 million during the same period in 2015, principally due to the $4.5 million asset acquisition of the ANDA for Flecainide, the $25.0 million asset acquisition of a basket of ANDAs, the $1.0 million payment for marketing and distribution rights for several generic products, and $1.1 million of capital expenditures during the period.

Net Cash (Used In)/Provided By Financing Activities

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. Net cash provided by financing activities was $0.9 million during the same period in 2015, resulting primarily from $0.8 million of proceeds from stock option exercises and excess tax benefit from stock-based compensation awards.

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, 2015. 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, 2015.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

Recent Accounting Pronouncements Not Yet Adopted

In August 2016, the Financial Accounting Standards Board ("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 are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated statements of cash flows.

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. We are currently evaluating the impact, if any, that the adoption of this guidance will have 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. Under the guidance, companies can elect to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. In addition, the guidance amends some of the other stock-based compensation awards guidance to more clearly articulate the requirements and cash flow presentation for withholding shares for tax-withholding purposes. Finally, under the guidance, all excess tax benefits and tax deficiencies related to stock-based compensation awards are to be recognized as income tax expenses or benefits in the income statement and excess tax benefits should be classified along with other income tax cash flows in the operating activities section of the statement of cash flows. We reported excess tax benefits of $0.3 million and $0.2 million in the financing activities section of our statements of cash flows for the nine months ended September 30, 2016 and 2015, respectively. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted, though all amendments of the guidance must be adopted in the same period. The adoption of certain amendments of the guidance must be applied prospectively, and adoption of the remaining amendments must be applied either on a modified retrospective basis or retrospectively to all periods presented. Previously-reported excess tax benefits may not be indicative of future excess tax benefits that will be recorded in our consolidated statements of earnings after the guidance is adopted, and we are currently evaluating the impact that the adoption of this guidance will have on our consolidated financial statements.

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.

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. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

Recently Adopted Accounting Pronouncements

In March 2016, the FASB issued guidance to clarify the requirements for assessing whether contingent call or put options that can accelerate the payment of principal on debt instruments are clearly and closely related to their debt hosts. The amendments of this guidance are effective for reporting periods beginning after December 15, 2016, and early adoption is permitted. Entities are required to apply the guidance to existing debt instruments using a modified retrospective transition method as of the beginning of the fiscal year of adoption. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a modified retrospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In November 2015, the FASB issued guidance simplifying the balance sheet classification of deferred taxes. The new guidance requires that all deferred taxes be presented as noncurrent, rather than separated into current and noncurrent amounts. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted. In addition, the adoption of guidance can be applied either prospectively or retrospectively to all periods presented. We adopted this guidance for the year ended December 31, 2015 on a retrospective basis, and all periods are presented under this guidance.

In July 2015, the FASB issued guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using the last in first out ("LIFO") method or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The guidance is effective for reporting periods beginning after December 15, 2016. The guidance should be applied prospectively, with earlier application permitted. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In April 2015, the FASB issued guidance as to whether a cloud computing arrangement (e.g., software as a service, platform as a service, infrastructure as a service, and other similar hosting arrangements) includes a software license and, based on that determination, how to account for such arrangements. If a cloud computing arrangement includes a software license, then the customer should account for the software license element of the arrangement consistent with the acquisition of other software licenses. If a cloud computing arrangement does not include a software license, the customer should account for the arrangement as a service contract. The guidance is effective for reporting periods beginning after December 15, 2015, and can be adopted on either a prospective or retrospective basis. We adopted this guidance in the first quarter of 2016, effective as of January 1, 2016, on a prospective basis. The adoption of this new guidance did not have a material impact on our consolidated financial statements.

In April 2015, the FASB issued guidance to simplify the balance sheet disclosure for debt issuance costs. Under the guidance, debt issuance costs related to a recognized debt liability are presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, in the same manner as debt discounts, rather than as an asset. In August 2015, the FASB issued guidance clarifying debt issuance costs related to line-of-credit arrangements, which guidance states that the SEC does not object to an entity deferring and presenting debt issuance costs as an asset and subsequently amortizing the deferred debt issuance costs ratably over the term of the line-of-credit arrangement, regardless of whether there are any outstanding borrowings on the line-of-credit. The guidance is effective for reporting periods beginning after December 15, 2015 and must be adopted on a retrospective basis. Early adoption is permitted. We adopted this guidance for the year ended December 31, 2015 on a retrospective basis, and all periods are presented under this guidance.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

In addition to the specified contractual obligations set forth in the contractual obligations information provided 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, 2015, the following obligations were incurred or discharged during nine months ending September 30, 2016:

- 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.

As of September 30, 2016 and December 31, 2015, 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, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, only interest rate risk could have a significant impact on our results of operations.

As of September 30, 2016, our principal 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 increase accordingly.

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. 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, 2016, we had no outstanding balance on the Line of Credit.

We are exposed to risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the three and nine months ended September 30, 2016 by approximately $1 thousand and $3 thousand, respectively.

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, 2016. 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, 2016 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, 2015 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. Unregistered Sales of Equity and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

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

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 3, 2016

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

Date: November 3, 2016

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

INDEX TO EXHIBITS

Exhibit No.	Description
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

Exhibit 31.1

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

I, Arthur S. Przybyl, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2016

/s/ Arthur S. Przybyl

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

Exhibit 31.2

CERTIFICATION OF CHIEF EXECUTIVE 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 3, 2016

/s/ Stephen P. Carey

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended September 30, 2016 (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 3, 2016

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

Dated: November 3, 2016

/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.