

ANI PHARMACEUTICALS INC
Form 10-Q
November 03, 2015

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, 2015

☐ **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 (IRS Employer Identification Number)
incorporation or organization)

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 x 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 x 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 x

Non-accelerated filer "

Smaller reporting company "

(Do not check if 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 x

As of October 28, 2015, there were 11,489,204 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, 2015

TABLE OF CONTENTS

	Page
PART I —FINANCIAL INFORMATION	
Item 1. Financial Statements (unaudited)	
<u>Condensed Consolidated Balance Sheets — As of September 30, 2015 and December 31, 2014</u>	4
<u>Condensed Consolidated Statements of Operations — For the Three and Nine Months Ended September 30, 2015 and 2014</u>	5
<u>Condensed Consolidated Statements of Cash Flows — For the Nine Months Ended September 30, 2015 and 2014</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	23
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	36
Item 4. <u>Controls and Procedures</u>	36
PART II —OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	37
Item 1A. <u>Risk Factors</u>	37
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	37
Item 3. <u>Defaults upon Senior Securities</u>	37
Item 4. <u>Mine Safety Disclosures</u>	37
Item 5. <u>Other Information</u>	37
Item 6. <u>Exhibits</u>	37

Signatures

38

2

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, 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, 2014, including the factors described in "Item 1A. Risk Factors," as well as our proxy statement, filed with the SEC on April 24, 2015. 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®, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI.

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

	<i>September 30, 2015</i>	<i>December 31, 2014</i>
Assets		
Current Assets		
Cash and cash equivalents	\$ 150,913	\$ 169,037
Accounts receivable, net of \$9,980 and \$8,708 of adjustments for chargebacks and other allowances at September 30, 2015 and December 31, 2014, respectively	21,645	17,297
Inventories, net	13,741	7,518
Prepaid income taxes	972	-
Deferred tax assets, net of valuation allowance	8,266	7,643
Prepaid expenses and other current assets	1,985	1,983
Total Current Assets	197,522	203,478
Property and equipment, net	5,833	5,223
Deferred financing costs, net	2,674	3,307
Deferred tax assets, net of valuation allowance	7,118	7,796
Intangible assets, net	68,291	42,067
Goodwill	1,838	1,838
Total Assets	\$ 283,276	\$ 263,709
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 2,633	\$ 2,654
Current income taxes payable	-	4,253
Accrued expenses and other	2,221	1,269
Accrued compensation and related expenses	1,019	1,348
Accrued Medicaid rebates	4,428	2,264
Returned goods reserve	1,889	1,445
Total Current Liabilities	12,190	13,233
Long-term Liabilities		
Convertible notes, net of discount	115,193	110,691
Total Liabilities	\$ 127,383	\$ 123,924

Commitments and Contingencies (Note 11)

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Stockholders' Equity

Common Stock, \$0.0001 par value, 33,333,334 shares authorized; 11,489,204 shares issued and outstanding at September 30, 2015; 11,387,860 shares issued and outstanding at December 31, 2014	1	1
Class C Special Stock, \$0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	-	-
Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	-	-
Treasury stock, 0 shares of common stock, at cost, at September 30, 2015 and December 31, 2014, respectively	-	-
Additional paid-in capital	163,118	159,509
Accumulated deficit	(7,226)	(19,725)
Total Stockholders' Equity	155,893	139,785
 Total Liabilities and Stockholders' Equity	 \$ 283,276	 \$ 263,709

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

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

	<i>Three months ended September 30, 2015</i>		<i>Nine months ended September 30, 2015</i>	
		<i>2014</i>		<i>2014</i>
Net Revenues	\$ 19,972	\$ 17,387	\$ 58,287	\$ 34,933
Operating Expenses:				
Cost of sales (excluding depreciation and amortization)	3,260	3,061	9,152	7,800
Research and development	815	883	2,213	2,110
Selling, general and administrative	5,399	4,057	15,701	13,193
Depreciation and amortization	2,047	1,187	4,789	2,596
Total Operating Expenses	11,521	9,188	31,855	25,699
Operating Income	8,451	8,199	26,432	9,234
Other (Expense)/Income, net				
Interest (expense)/income, net	(2,766)	10	(8,240)	13
Other (expense)/income, net	(28)	82	40	72
Income Before Provision for Income Taxes	5,657	8,291	18,232	9,319
Provision for income taxes	(1,098)	(1,545)	(5,733)	(1,577)
Net Income	\$ 4,559	\$ 6,746	\$ 12,499	\$ 7,742
Basic and Diluted Earnings Per Share:				
Basic Earnings Per Share	\$ 0.40	\$ 0.59	\$ 1.09	\$ 0.71
Diluted Earnings Per Share	\$ 0.39	\$ 0.59	\$ 1.07	\$ 0.70
Basic Weighted-Average Shares Outstanding	11,384	11,235	11,352	10,824
Diluted Weighted-Average Shares Outstanding	11,563	11,302	11,559	10,865

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

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

	<i>Nine months ended September</i>	
	<i>30,</i>	
	<i>2015</i>	<i>2014</i>
Cash Flows From Operating Activities		
Net income	\$ 12,499	\$ 7,742
Adjustments to reconcile net income to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	2,717	2,719
Deferred taxes	55	-
Depreciation and amortization	4,789	2,596
Loss on disposal of property and equipment	40	-
Non-cash interest relating to convertible notes and loan cost amortization	5,135	-
Changes in operating assets and liabilities:		
Accounts receivable, net	(4,348)	(2,057)
Inventories, net	(6,223)	(3,296)
Prepaid expenses and other current assets	(2)	(19)
Accounts payable	(130)	630
Accrued compensation and related expenses	(329)	(40)
Current income taxes, net	(5,225)	1,124
Accrued Medicaid rebates	2,164	1,023
Accrued expenses, returned goods reserve, and other	1,420	870
Net Cash and Cash Equivalents Provided by Operating Activities	12,562	11,292
Cash Flows From Investing Activities		
Acquisition of product rights and other related assets	(30,500)	(34,634)
Acquisition of property and equipment	(1,078)	(782)
Net Cash and Cash Equivalents Used in Investing Activities	(31,578)	(35,416)
Cash Flows From Financing Activities		
Net proceeds from equity offering	-	46,680
Proceeds from stock option exercises	658	777
Proceeds from warrant exercise	-	180
Excess tax benefit from share-based compensation awards	234	432
Net Cash and Cash Equivalents Provided by Financing Activities	892	48,069
Change in Cash and Cash Equivalents	(18,124)	23,945

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Cash and cash equivalents, beginning of period	169,037	11,105
Cash and cash equivalents, end of period	\$ 150,913	\$ 35,050

Supplemental disclosure for cash flow information:

Cash paid for interest	\$ 2,048	\$ -
Cash paid for income taxes	\$ 10,668	\$ 137

Supplemental non-cash investing and financing activities:

Contingent payable for asset purchase	\$ -	\$ 1,000
Property and equipment purchased on credit	\$ 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 subsidiary, ANIP Acquisition Company (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 narcotics, 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, narcotics, 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 condensed consolidated balance sheet at December 31, 2014, has been derived from audited financial statements of that date. The 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, 2014. 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 wholly owned subsidiary, ANIP Acquisition Company. All significant inter-company accounts and transactions are eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited interim condensed consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, rebates, returns and other allowances, allowance for inventory obsolescence, allowances for contingencies and litigation, fair value of long-lived assets, income tax provision, deferred taxes and valuation allowance, and the depreciable and amortizable lives of long-lived assets. Actual results could differ from those estimates.

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board (“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. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our 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 amendment is effective for reporting periods beginning after December 15, 2015 and may be applied on either a prospective or retrospective basis. Early adoption is permitted. We do not expect the adoption of this new accounting pronouncement to have a material impact on our 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 will be 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. The standard is effective for reporting periods beginning after December 15, 2015 and early adoption is permitted. The adoption of this new accounting pronouncement will result in a reclassification of deferred financing costs from assets to contra-liabilities.

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 LIFO 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 standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. We are currently evaluating the

impact, if any, that this new accounting pronouncement will have on our financial statements.

We have evaluated all other issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our results of operations, financial position, 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, Medicaid 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, Medicaid 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 operations, 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,” below). Historically, we have not entered into revenue arrangements with multiple elements.

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-month periods ended September 30, 2015 and 2014, 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, 2013	\$ 4,076	\$ 253	\$ 736	\$ 735	\$ 332
Accruals/Adjustments	27,431	1,434	996	3,690	1,243
Credits Taken Against Reserve	(24,722)	(411)	(554)	(3,394)	(1,152)
Balance at September 30, 2014	\$ 6,785	\$ 1,276	\$ 1,178	\$ 1,031	\$ 423
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

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-month period ended September 30, 2015, four customers represented 25%, 19%, 17%, and 11% of net revenues, respectively. During the nine-month period ended September 30, 2015, these same four customers represented 21%, 21%, 19%, and 14% of net revenues, respectively. As of September 30, 2015, net accounts receivable from these customers totaled \$16.9 million. During the three-month period ended September 30, 2014, four customers represented 26%, 23%, 16%, and 15% of net revenues. During the nine-month period ended September 30, 2014, these same four customers represented 26%, 20%, 16%, and 10% 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. After deducting the underwriting discounts and commissions and other expenses (including the net cost of the bond hedge and warrant, discussed below), the net proceeds from the offering were approximately \$122.6 million. The Notes pay 3.0% interest semi-annually in arrears on June 1 and December 1 of each year, starting on June 1, 2015 and are due December 1, 2019. The Notes are convertible into 2,068,793 shares of common stock, based on an initial conversion price of \$69.48 per share.

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

Upon conversion by the holders, we 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. The value of the embedded conversion option was determined based on the estimated fair value of the debt without the conversion feature, which was determined using market comparables to estimate the fair value of similar non-convertible debt (see Note 12). The debt discount is being amortized as additional non-cash interest expense using the effective interest method over the term of the Notes.

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

3. INDEBTEDNESS – continued

A portion of the offering proceeds was used to simultaneously enter into “bond hedge” (or purchased call) and “warrant” (or written call) transactions with an affiliate of one of the offering underwriters (collectively, the “Call Option Overlay”). We entered into the Call Option Overlay to synthetically raise the initial conversion price of the Notes to \$96.21 per share and reduce the potential common stock dilution that may arise from the conversion of the Notes. The exercise price of the bond hedge is \$69.48 per share, with an underlying 2,068,792 common shares; the exercise price of the warrant is \$96.21 per share of our common stock, also with an underlying 2,068,792 common shares. Because the bond hedge and warrant are both indexed to our common stock and otherwise would be classified as equity, we recorded both elements as equity, resulting in a net reduction to APIC of \$15.6 million.

The carrying value of the Notes is as follows as of September 30:

(in thousands)	2015
Principal amount	\$ 143,750
Unamortized debt discount	(28,557)
Net carrying value	\$ 115,193

The following table sets forth the components of total interest expense related to the Notes recognized in the accompanying consolidated statements of operations for the three and nine-months ended September 30, 2015:

(in thousands)	Three months ended September 30, 2015	Nine months ended September 30, 2015
Contractual coupon	\$ 1,078	\$ 3,234
Amortization of debt discount	1,521	4,502
Amortization of finance fees	211	633
Capitalized interest	(11)	(26)
	\$ 2,799	\$ 8,343

The effective interest rate on the Notes is 7.7%, on an annualized basis.

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, unvested restricted stock awards, stock purchase warrants, and any conversion gain on our Notes (see 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.

4.EARNINGS PER SHARE – continued

For purposes of determining diluted earnings per share, we have elected a policy to assume that the principal portion of the Notes (see 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 (see 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, 2015 and 2014 are calculated for basic and diluted earnings per share as follows:

(in thousands, except per share amounts)	Basic Three months ended September 30, 2015 2014		Diluted Three months ended September 30, 2015 2014		Basic Nine months ended September 30, 2015 2014		Diluted Nine months ended September 30, 2015 2014	
Net income	\$4,559	\$6,746	\$4,559	\$6,746	\$12,499	\$7,742	\$12,499	\$7,742
Net income allocated to warrants	-	(38)	-	(37)	-	(43)	-	(42)
Net income allocated to restricted stock	(30)	(47)	(30)	(47)	(82)	(54)	(82)	(54)
Net income from continuing operations allocated to common shares	\$4,529	\$6,661	\$4,529	\$6,662	\$12,417	\$7,645	\$12,417	\$7,646
Basic Weighted-Average Shares Outstanding	11,384	11,235	11,384	11,235	11,352	10,824	11,352	10,824
Dilutive effect of stock options			179	67			207	41
Diluted Weighted-Average Shares Outstanding			11,563	11,302			11,559	10,865
Earnings Per Share	\$0.40	\$0.59	\$0.39	\$0.59	\$1.09	\$0.71	\$1.07	\$0.70

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 and 0.7 million for the three months ended September 30, 2015 and 2014, respectively, and was 4.6 million and 0.7 million for the nine months ended September 30, 2015 and 2014, 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, and out-of-the-money warrants exercisable for common stock.

As of September 30, 2015, we have options outstanding to purchase 0.5 million shares of common stock, warrants outstanding to purchase 2.2 million shares of common stock, and 76 thousand unvested restricted stock awards outstanding.

5. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2015	December 31, 2014
Raw materials	\$ 10,563	\$ 5,056
Packaging materials	1,023	794
Work-in-progress	573	411
Finished goods	1,775	1,368
	13,934	7,629
Reserve for excess/obsolete inventories	(193)	(111)
Inventories, net	\$ 13,741	\$ 7,518

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 costs 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, 2015, we purchased approximately 35% of our inventory from two suppliers. During the nine months ended September 30, 2015, we purchased approximately 44% of our inventory from three suppliers. As of September 30, 2015, amounts payable to these three suppliers totaled \$0.7 million. During the three months ended September 30, 2014, we purchased approximately 49% of our inventory from two suppliers. During the nine months ended September 30, 2014, we purchased approximately 43% of our inventory from the same two suppliers.

6. PROPERTY, PLANT, AND EQUIPMENT

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

(in thousands)	September 30, 2015	December 31, 2014
Land	\$ 87	\$ 87
Buildings	3,682	3,682
Machinery, furniture and equipment	5,440	4,822
Construction in progress	881	426

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

	10,090		9,017	
Less: accumulated depreciation	(4,257	)	(3,794	)
Property, Plant and Equipment, net	\$ 5,833		\$ 5,223	

6.PROPERTY, PLANT, AND EQUIPMENT – continued

Depreciation expense was \$0.2 million for each of the three-month periods ended September 30, 2015 and 2014. Depreciation expense for the nine-month periods ended September 30, 2015 and 2014 totaled \$0.5 million and \$0.4 million, respectively. During the three and nine-month periods ended September 30, 2015, there was \$11 thousand and \$26 thousand of interest capitalized into construction in progress, respectively. In the three and nine-month periods ended September 30, 2014, there was no interest capitalized into construction in progress.

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 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, 2014, through September 30, 2015. No impairment losses were recognized during the three or nine months ended September 30, 2015 or 2014.

Acquisition of Abbreviated New Drug Applications

In March 2015 we purchased from Teva Pharmaceuticals (“Teva”) the Abbreviated New Drug Application (“ANDA”) for a generic product, Flecainide Acetate tablets, 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 useful life of 10 years.

In July 2015, we purchased from Teva the ANDAs for 22 previously marketed generic drug products 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 useful life of 10 years.

Testosterone Gel NDA

As part of our 2013 merger with BioSante, we acquired a testosterone gel product that was licensed to Teva (the “Teva license”). In May 2015, we acquired from Teva the approved New Drug Application (“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 million, at a rate of 5% of the consideration we receive as a result of commercial sale of the product. We have assessed the value of the Teva license under the new structure and determined that the asset was not impaired as of the May 2015 acquisition date. We will continue to assess the asset for potential impairment on an on-going basis.

Marketing and Distribution Rights

In August 2015, we entered into a distribution agreement with IDT Australia Limited (“IDT”) to market several products in the U.S. (the “IDT Agreement”). The products have associated ANDAs that require various FDA approvals prior to commercialization. In general, IDT will be responsible for regulatory submissions of the products 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 be responsible for marketing and distributing all the products under our label, in the United States, providing a percentage of profits from sales of the drugs to IDT. The \$1.0 million upfront payment was recorded as a marketing and distribution rights intangible asset and will be amortized in full over its seven-year useful life.

7. GOODWILL AND INTANGIBLE ASSETS – continued**Definite-Lived Intangible Assets**

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

(in thousands)	September 30, 2015		December 31, 2014		Weighted Average Amortization Period
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
Acquired ANDA intangible assets	\$ 42,077	\$ (3,138)	\$ 12,577	\$ (1,312)	10 years
Product rights	22,522	(2,816)	22,522	(1,133)	10 years
Testosterone gel NDA	10,900	(2,230)	10,900	(1,487)	10 years
Marketing and distribution rights	1,000	(24)	-	-	7 years
	\$ 76,499	\$ (8,208)	\$ 45,999	\$ (3,932)	

Our acquired ANDA intangible assets consist of the exclusive rights, including all of the applicable technical data and other relevant information, to produce certain pharmaceutical products that we acquired from various companies, including the group of ANDAs acquired from Teva in the first quarter of 2014 and the additional ANDAs acquired in 2015. The product rights assets consist of the exclusive rights, including all of the applicable technical data and other relevant information, to produce certain branded pharmaceutical products that we acquired from various companies, including the Lithobid and Vancocin products acquired in the third quarter of 2014. The testosterone gel NDA was acquired in May 2015. 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 \$1.9 million and \$1.0 million for the three months ended September 30, 2015 and 2014, respectively. Amortization expense was \$4.3 million and \$2.2 million for the nine months ended September 30, 2015 and 2014, 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, 2015 and 2014 and therefore no impairment loss was recognized in the three and nine months ended September 30, 2015 or 2014.

Expected future amortization expense is as follows:

(in thousands)
2015 (remainder of the year) \$ 1,894

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

2016	7,578
2017	7,578
2018	7,578
2019	7,578
2020 and thereafter	36,085
Total	\$68,291

8. STOCK-BASED COMPENSATION

All stock options and restricted stock are granted under the ANI Pharmaceuticals, Inc. Fourth Amended and Restated 2008 Stock Incentive Plan (the “2008 Plan”). As of September 30, 2015, 0.5 million shares of our common stock remained available for issuance under the 2008 Plan.

Total expense related to stock options for the three months ended September 30, 2015 was \$0.9 million, \$23 thousand of which was recognized as cost of sales, \$31 thousand as research and development expense, and \$0.8 million as sales, general, and administrative (“SG&A”) expense. Total expense related to stock options for the nine months ended September 30, 2015 was \$2.1 million, \$60 thousand of which was recognized as cost of sales, \$80 thousand as research and development expense, and \$2.0 million as SG&A expense. Total expense related to stock options for the three months ended September 30, 2014 was \$0.6 million, \$18 thousand of which was recognized as cost of sales, \$10 thousand as research and development expense, and \$0.6 million as SG&A expense. Total expense related to stock options for the nine months ended September 30, 2014 was \$2.5 million, \$1.3 million of which was a non-recurring catch-up adjustment related to the 325 thousand stock options previously approved by the Board of Directors on July 12, 2013 and August 1, 2013, which were approved at the May 22, 2014 annual meeting. Of the \$2.5 million of stock option expense recognized in the nine months ended September 30, 2014, \$0.1 million was recognized as cost of sales, \$0.1 million as research and development expense, and \$2.3 million as SG&A expense. Total expense related to restricted stock grants for the three and nine months ended September 30, 2015 was \$0.3 million and \$0.6 million, respectively, all of which was recognized as SG&A expense. Total expense related to restricted stock grants for the three and nine months ended September 30, 2014 was \$0.1 million and \$0.2 million, respectively, all of which was recognized as SG&A expense.

A summary of stock option and restricted stock activity under the Plan during the nine months ended September 30, 2015 and 2014 is presented below:

(in thousands)	Options	RSAs
Outstanding December 31, 2013	120	50
Granted	115	30
Options previously granted, approved by shareholders	325	-
Options Exercised/RSAs Vested	(36)	-
Expired	(64)	-
Outstanding September 30, 2014	460	80
Outstanding December 31, 2014	458	63
Granted	130	28
Options Exercised/RSAs Vested	(81)	(10)
Forfeited	(33)	(5)
Outstanding September 30, 2015	474	76

9.STOCKHOLDER’S EQUITY

On March 10, 2014, we completed a follow-on public offering of 1.6 million shares of our common stock at a public offering price of \$31.00 per share (the “March 2014 Offering”). We received gross proceeds of \$50.0 million, or net proceeds of \$46.7 million after deducting costs of \$3.3 million, including the underwriters’ fees and commissions, as well as expenses directly related to the March 2014 Offering . The number of shares sold in the March 2014 Offering includes the exercise in full by the underwriters of their option to purchase an additional 0.2 million shares of common stock.

9. STOCKHOLDER'S EQUITY – continued

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, respectively. No warrants to purchase shares of common stock expired unexercised during the three and nine months ended September 30, 2014. No warrants to purchase shares of common stock were exercised in the three and nine months ended September 30, 2015. In January 2014, warrants to purchase an aggregate of 20 thousand shares of common stock were exercised at \$9.00 per share.

10. INCOME TAXES

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

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of both September 30, 2015 and December 31, 2014, we had provided a valuation allowance against certain state net operating loss carryforwards of approximately \$0.1 million. For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate expected for the entire year. We calculate income tax benefits related to stock-based compensation arrangements using the with and without method.

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 financial statements. 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 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, 2015 and December 31, 2014.

We have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our estimated annual effective rate. The utilization of our NOL carryforwards will be limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code.

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 current quarter changes in forecasted pre-tax income, estimated permanent differences, and state income tax rates, as well as from the impact of current quarter exercises of incentives and non-qualified stock options and disqualifying dispositions of incentive stock options. For the comparable three and nine-month periods ended September 30, 2014, the effective tax rates were 18.6% and 16.9% of pre-tax income reported in the period, respectively, calculated based on the estimated annual effective rate anticipated for the year ended December 31, 2014.

11.COMMITMENTS AND CONTINGENCIES

Asset Acquisition of New Drug Applications

In September 2015, we entered into an asset purchase agreement with Merck Sharp & Dohme B.V. (“Merck”) to purchase, subject to typical closing conditions including regulatory approvals, certain NDAs and associated product rights and manufacturing licenses for \$75.0 million in cash and a percentage of future net sales of the products under the NDAs. The asset acquisition is expected to close in January 2016. We anticipate that we will make the \$75.0 million cash payment using cash in hand.

Specifically, we will acquire Merck’s right, title and interest in the NDA for purified corticotropin gel, 40 units/mL and 80 units/mL and the NDA for corticotropin-zinc hydroxide, 40 units/mL, along with certain documentation and trademark applications relating to the products under the NDAs. We will also receive a non-exclusive, irrevocable, perpetual right and license to certain manufacturing technology relating to the manufacture of the products under the NDAs.

Operating Leases

We lease equipment under operating leases that expire in May 2017 and September 2018. We also lease office space under operating leases that expire beginning in February 2016 through September 2018. Future minimum lease payments due under these leases total \$0.2 million as of September 30, 2015.

Rent expense for the three months ended September 30, 2015 and 2014 totaled \$19 thousand and \$17 thousand, respectively. Rent expense for the nine months ended September 30, 2015 and 2014 totaled \$57 thousand and \$53 thousand, respectively.

Government Regulation

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

Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone tablets (“EEMT”) and Opium Tincture, are marketed without approved NDAs or ANDAs. During the three months ended September 30, 2015 and 2014, net revenues for these products totaled \$12.5 million and \$8.9 million, respectively. During the nine months ended September 30, 2015 and 2014, net revenues for these products totaled \$33.8 million and \$19.4 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.

11.COMMITMENTS AND CONTINGENCIES – continued

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for these unapproved products for the three months ended September 30, 2015 and 2014 were \$0.3 million and \$0.2 million, respectively. Our contract manufacturing revenues for these unapproved products for the nine months ended September 30, 2015 and 2014 were \$1.1 million and \$0.7 million, respectively.

We receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products for each of the three months ended September 30, 2015 and 2014 were \$0.1 million. Our royalties on the net sales of these unapproved products for the nine months ended September 30, 2015 and 2014 were \$0.3 million and \$0.2 million, respectively.

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 consolidated balance sheets at their net carrying value of \$115.2 million as of September 30, 2015, the Notes are being traded on the bond market and their full fair value is \$131.4 million, based on their closing price on September 30, 2015, a Level 1 input.

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

Our contingent value rights (“CVRs”), which were granted coincident with our merger with BioSante, 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, 2015 and December 31, 2014, and for the three and nine months ended September 30, 2015 and 2014.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of September 30, 2015 and December 31, 2014, by level within the fair value hierarchy:

(in thousands)				
Description	Fair Value at September 30, 2015	Level 1	Level 2	Level 3
Liabilities				
CVRs	\$ -	\$ -	\$ -	\$ -

Description	Fair Value at December 31, 2014	Level 1	Level 2	Level 3
Liabilities				
CVRs	\$ -	\$ -	\$ -	\$ -

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

In December 2014, we issued \$143.8M of Notes (see Note 3). Because we have the option to cash settle the potential conversion of the Notes in cash, we separated the embedded conversion option feature from the debt feature and account for each component separately, based on the fair value of the debt component assuming no conversion option. The calculation of the fair value of the debt component required the use of Level 3 inputs, and was determined by calculating the fair value of similar non-convertible debt, using a theoretical interest rate of 9%. The theoretical interest rate was determined from market comparables to estimate what the interest rate would have been if there was no conversion option embedded in the Notes. The fair value of the embedded conversion option was calculated using the residual value method and is classified as equity.

12. FAIR VALUE DISCLOSURES - continued

A portion of the offering proceeds was used to simultaneously enter into “bond hedge” (or purchased call) and “warrant” (or written call) transactions with an affiliate of one of the offering underwriters (see Note 3). The exercise price of the bond hedge is \$69.48 per share, with an underlying 2,068,792 common shares; the exercise price of the warrant is \$96.21 per share of our common stock, also with an underlying 2,068,792 common shares.

We calculated the fair value of the bond hedge based on the price we paid to purchase the call. We calculated the fair value of the warrant based on the price at which the affiliate purchased the warrants from us. Because the bond hedge and warrant are both indexed to our common stock and otherwise would be classified as equity, we recorded both elements as equity, resulting in a net reduction to APIC of \$15.6 million.

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, 2015 and 2014.

In March 2015, we purchased from Teva the ANDA for Flecainide Acetate tablets for \$4.5 million in cash and a percentage of future gross profits from product sales. The value of the ANDA was based on the purchase price of \$4.5 million.

In July 2015, we purchased from Teva the ANDAs for 22 previously marketed generic drug products for \$25.0 million in cash and a percentage of future gross profits from product sales. The value of the ANDAs was based on the total purchase price of \$25.0 million.

13.SUBSEQUENT EVENT

In October 2015, our Board of Directors authorized a program to repurchase up to \$25.0 million of our common stock. The authorization allows for repurchases to be conducted through open market or privately negotiated transactions through December 31, 2016. The stock repurchase program may be suspended, modified or discontinued at any time at our discretion.

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, 2014.

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its wholly-owned, consolidated subsidiary, ANIP Acquisition Company (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 narcotics, 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, narcotics, 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.

Our products include both branded and generic pharmaceuticals, specifically:

Generic Products

Esterified Estrogen with Methyltestosterone
Etodolac

Fluvoxamine Maleate
Hydrocortisone Enema
Methazolamide

Metoclopramide Syrup

Branded Products

Cortenema
Reglan

Lithobid
Vancocin

Opium Tincture

Oxycodone Hydrochloride Oral Solution

Propafenone

Vancomycin

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

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

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

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

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

Manufacturing. We generally seek to develop and manufacture products at our own manufacturing plants in order to maximize the capacity and utilization of our facilities, 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,	
	2015	2014	2015	2014
Net revenues	\$ 19,972	\$ 17,387	\$ 58,287	\$ 34,933
Operating expenses				
Cost of sales (excluding depreciation and amortization)	3,260	3,061	9,152	7,800
Research and development	815	883	2,213	2,110
Selling, general and administrative	5,399	4,057	15,701	13,193
Depreciation and amortization	2,047	1,187	4,789	2,596
Operating income	8,451	8,199	26,432	9,234
Interest (expense)/income, net	(2,766)	10	(8,240)	13
Other (expense)/income, net	(28)	82	40	72
Income before provision for income taxes	5,657	8,291	18,232	9,319
Provision for income taxes	(1,098)	(1,545)	(5,733)	(1,577)
Net income	\$ 4,559	\$ 6,746	\$ 12,499	\$ 7,742

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net revenues	100.0 %	100.0 %	100.0 %	100.0 %

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Operating expenses

Cost of sales (excluding depreciation and amortization)	16.3	%	17.6	%	15.7	%	22.3	%
Research and development	4.1	%	5.1	%	3.8	%	6.0	%
Selling, general and administrative	27.0	%	23.3	%	26.9	%	37.8	%
Depreciation and amortization	10.3	%	6.8	%	8.2	%	7.4	%
Operating income	42.3	%	47.2	%	45.4	%	26.5	%
Interest (expense)/income, net	(13.9)	)%	0.1	%	(14.2)	)%	-	%
Other (expense)/income, net	(0.1)	)%	0.4	%	0.1	%	0.2	%
Income before provision for income taxes	28.3	%	47.7	%	31.3	%	26.7	%
Provision for income taxes	(5.5)	)%	(8.9)	)%	(9.8)	)%	(4.6)	)%
Net income	22.8	%	38.8	%	21.5	%	22.1	%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014**Net Revenues**

(in thousands)	Three Months Ended September 30,		Change	% Change	
	2015	2014			
Generic pharmaceutical products	\$ 15,102	\$ 10,188	\$4,914	48.2	%
Branded pharmaceutical products	2,253	4,806	(2,553)	(53.1	)%
Contract manufacturing	1,280	1,350	(70)	(5.2	)%
Contract services and other income	1,337	1,043	294	28.2	%
Total net revenues	\$ 19,972	\$ 17,387	\$2,585	14.9	%

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, 2015 were \$20.0 million compared to \$17.4 for the same period in 2014, an increase of \$2.6 million, or 14.9%, primarily as a result of the following factors:

Net revenues for generic pharmaceutical products were \$15.1 million during the three months ended September 30, 2015, an increase of 48.2% compared to \$10.2 million for the same period in 2014. The primary reason for the increase was increased Esterified Estrogen with Methyltestosterone tablets ("EEMT") revenues, due to new customer contracts that began in the third quarter, as well as sales of Methazolamide, launched in the fourth quarter of 2014, and Etodolac and Propafenone both of which were launched in the first quarter of 2015. We also experienced increased sales for our HC Enema product, due to price increases.

As described in Note 11, *Commitments and Contingencies*, in the unaudited 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 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, 2015 and 2014 were \$12.5 million and \$8.9 million, respectively.

Net revenues for branded pharmaceutical products were \$2.3 million during the three months ended September 30, 2015, a decrease of 53.1% compared to \$4.8 million for the same period in 2014. The primary reasons for the decrease were lower unit sales of Reglan, due to decreased purchases by a customer, and decreases in unit sales and increased Medicaid utilization and Medicaid rebates for both Lithobid and Vancocin, each of which are trends we expect to continue.

Contract manufacturing revenues were \$1.3 million during the three months ended September 30, 2015, a decrease of 5.2% compared to \$1.4 million for the same period in 2014, due to timing of orders from contract manufacturing customers in the period. As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the three months ended September 30, 2015 and 2014 were \$0.3 million and \$0.2 million, respectively.

Contract services and other income were \$1.3 million during the three months ended September 30, 2015, an increase of 28.2% from \$1.0 million for the same period in 2014, due primarily to royalties on sales of the authorized generic of Vancocin, the product rights to which were acquired in the third quarter of 2014. In November 2015, we launched an authorized generic for Vancocin under our own label, which will replace the authorized generic product currently on the market.

As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products were \$0.1 million for each of the three month periods ended September 30, 2015 and 2014.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended September 30,				
	2015	2014	Change	% Change	
Cost of sales (excl. depreciation and amortization)	\$ 3,260	\$ 3,061	\$ 199	6.5	%

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

For the three months ended September 30, 2015, cost of sales increased to \$3.3 million from \$3.1 million for the same period in 2014, an increase of \$0.2 million or 6.5%, primarily as a result of increased sales in the period. Cost of sales as a percentage of net revenues decreased to 16.3% during the three months ended September 30, 2015, from 17.6% during same period in 2014, primarily as a result of a favorable shift in product mix toward higher margin products,

principally EEMT.

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, which can take 18 months or longer. 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 three months ended September 30, 2015, we purchased 35% of our inventory from two suppliers. As of September 30, 2015, amounts payable to these two suppliers totaled \$0.7 million. In the three months ended September 30, 2014, we purchased 49% of our inventory from two suppliers. Each year, we must submit a request to the Drug Enforcement Agency (“DEA”) for a quota to purchase the amount of API needed to manufacture Opium Tincture. Without an approved quota from the DEA, we would not be able to purchase API from our supplier. As a result, we are dependent upon the DEA to annually approve a sufficient quota of API to support the continued manufacture of Opium Tincture.

Other Operating Expenses

(in thousands)	Three Months Ended September 30,		Change	% Change	
	2015	2014			
Research and development	\$ 815	\$ 883	\$ (68)	(7.7)	%
Selling, general and administrative	5,399	4,057	1,342	33.1	%
Depreciation and amortization	2,047	1,187	860	72.5	%
Total other operating expenses	\$ 8,261	\$ 6,127	\$ 2,134	34.8	%

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, 2015, other operating expenses increased to \$8.3 million from \$6.1 million for the same period in 2014, an increase of \$2.1 million, or 34.8%, primarily as a result of the following factors:

Depreciation and amortization increased from \$1.2 million to \$2.0 million, an increase of 72.5%, due primarily to amortization of the Flecainide ANDA and the basket of ANDAs acquired from Teva in the first and third quarters of 2015, respectively.

Research and development expenses decreased slightly from \$0.9 million to \$0.8 million, a decrease of 7.7%, due to timing of work on development projects. Current projects include work on the ANDAs purchased from Teva in 2014

and 2015 and collaborations with partners.

Selling, general and administrative expenses increased from \$4.1 million to \$5.4 million, an increase of 33.1%, primarily due to increased expenses associated with business development activities, increased stock-based compensation expense, and increases in personnel and related costs.

Other (Expense)/Income

(in thousands)	Three Months Ended September 30,					
	2015		2014	Change	% Change	
Interest (expense)/income, net	\$ (2,766	)	\$ 10	\$(2,776)	NM	(1)
Other (expense)/income, net	(28	)	82	(110)	(134.1)	)%
Total other (expense)/income, net	\$ (2,794	)	\$ 92	\$(2,886)	NM	(1)

(1) Not Meaningful

For the three months ended September 30, 2015, we recognized other expense of \$2.8 million versus other income of \$0.1 million for the same period in 2014, a change of \$2.9 million. This change resulted primarily from \$2.8 million of interest expense recognized on our convertible debt balance during the period.

Income Taxes

(in thousands)	Three Months Ended September 30,					
	2015		2014	Change	% Change	
Provision for income taxes	\$ (1,098	)	\$ (1,545	) \$ 447	(28.9	)%

Our provision for income taxes consists of current and deferred components, which include changes in our deferred tax assets (“DTAs”), our deferred tax liabilities (“DTLs”), and our valuation allowance. In the fourth quarter of 2014, we reversed the majority of the valuation allowance we had recorded against our net DTAs. The reversal was the result of our determination that it is more likely than not that we will realize the benefits of our net DTAs as a result of our expectation of future profitability, among other factors. Prior to the reversal, we had fully reserved for all our net DTAs.

For the three months ended September 30, 2015, we recognized income tax expense of \$1.1 million, versus \$1.5 million for the same period in 2014, a decrease of \$0.4 million. Of the \$1.1 million of total tax expense, \$1.3 million is current expense and \$0.2 million is a net deferred benefit. The effective tax rate for the three months ended September 30, 2015 was 19.4% 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 current quarter changes in forecasted pre-tax income, estimated permanent differences, and state income tax rates, as well as from the impact of current quarter exercises of incentive and non-qualified stock options and

disqualifying dispositions of incentive stock options. The effective tax rate for the three months ended September 30, 2014 was 18.6% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2014.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014**Net Revenues**

(in thousands)	Nine Months Ended September 30,		Change	% Change	
	2015	2014			
Generic pharmaceutical products	\$ 41,122	\$ 23,077	\$18,045	78.2	%
Branded pharmaceutical products	8,662	6,149	2,513	40.9	%
Contract manufacturing	3,576	4,121	(545)	(13.2	)%
Contract services and other income	4,927	1,586	3,341	210.7	%
Total net revenues	\$ 58,287	\$ 34,933	\$23,354	66.9	%

Net revenues for the nine months ended September 30, 2015 were \$58.3 million compared to \$34.9 million for the same period in 2014, an increase of \$23.4 million, or 66.9%, primarily as a result of the following factors:

Net revenues for generic pharmaceutical products were \$41.1 million during the nine months ended September 30, 2015, an increase of 78.2% compared to \$23.1 million for the same period in 2014. The primary reason for the increase was increased EEMT revenues, due to both increases in prices per bottle and to new customer contracts that started in the third quarter of 2015, as well as sales of Methazolamide, launched in the fourth quarter of 2014, and Etodolac and Propafenone, both of which were launched in the first quarter of 2015. We also experienced increased sales for our HC Enema product, due to price increases.

As described in Note 11, *Commitments and Contingencies*, in the unaudited 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, 2015 and 2014 were \$33.8 million and \$19.4 million, respectively.

Net revenues for branded pharmaceutical products were \$8.7 million during the nine months ended September 30, 2015, an increase of 40.9% compared to \$6.1 million for the same period in 2014. The primary reasons for the increase were sales from our Lithobid and Vancocin products, respectively, the product rights to which were acquired during the third quarter of 2014. This 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, both of which are trends we expect to continue.

Contract manufacturing revenues were \$3.6 million during the nine months ended September 30, 2015, a decrease of 13.2% compared to \$4.1 million for the same period in 2014, due to timing of orders from contract manufacturing customers in the period. As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the nine months ended September 30, 2015 and 2014 were \$1.1 million and \$0.7 million, respectively.

Contract services and other income were \$4.9 million during the nine months ended September 30, 2015, an increase of 210.7% from \$1.6 million for the same period in 2014, due primarily to royalties received on sales of the authorized generic of Vancocin, the product rights to which were acquired in the third quarter of 2014. In the second quarter of 2015, our authorized generic partner for Vancocin adjusted its estimates for chargebacks, rebates, and other deductions from gross sales for the last five months of 2014, which resulted in a non-recurring \$1.4 million increase in royalty revenue. In November 2015, we launched an authorized generic for Vancocin under our own label, which will replace the authorized generic product currently on the market.

As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products were \$0.3 million and \$0.2 million for the nine month periods ended September 30, 2015 and 2014, respectively.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Nine Months Ended September 30,				
	2015	2014	Change	% Change	
Cost of sales (excl. depreciation and amortization)	\$ 9,152	\$ 7,800	\$ 1,352	17.3	%

For the nine months ended September 30, 2015, cost of sales increased to \$9.2 million from \$7.8 million for the same period in 2014, an increase of \$1.4 million or 17.3%, primarily as a result of increased sales in the period. Cost of sales as a percentage of net revenues decreased to 15.7% during the nine months ended September 30, 2015, from 22.3% during same period in 2014, primarily as a result of price increases for EEMT and a favorable shift in product mix toward higher margin products, including EEMT and our two branded products, Lithobid and Vancocin, which we acquired in the third quarter of 2014.

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, which can take 18 months or longer. 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, 2015, we purchased 44% of our inventory from three suppliers. As of September 30, 2015, amounts payable to these three suppliers totaled \$0.7 million. In the nine months ended September 30, 2014, we purchased 43% of our inventory from two suppliers.

Each year, we must submit a request to the DEA for a quota to purchase the amount of API needed to manufacture Opium Tincture. Without an approved quota from the DEA, we would not be able to purchase API from our supplier. As a result, we are dependent upon the DEA to annually approve a sufficient quota of API to support the continued manufacture of Opium Tincture.

Other Operating Expenses

(in thousands)	Nine Months Ended September 30,				
	2015	2014	Change	% Change	
Research and development	\$ 2,213	\$ 2,110	\$ 103	4.9	%
Selling, general and administrative	15,701	13,193	2,508	19.0	%
Depreciation and amortization	4,789	2,596	2,193	84.5	%
Total other operating expenses	\$ 22,703	\$ 17,899	\$ 4,804	26.8	%

For the nine months ended September 30, 2015, other operating expenses increased to \$22.7 million from \$17.9 million for the same period in 2014, an increase of \$4.8 million, or 26.8%, primarily as a result of the following factors:

Depreciation and amortization increased from \$2.6 million to \$4.8 million, an increase of 84.5%, due to amortization of the product rights for Lithobid and Vancocin, which rights were purchased during the third quarter of 2014, as well as amortization of the Flecainide ANDA and the basket of ANDAs, acquired from Teva in the first and third quarters of 2015, respectively.

Selling, general and administrative expenses increased from \$13.2 million to \$15.7 million, an increase of 19.0%, primarily due to increased expenses associated with business development activities, increased stock-based compensation expense, and increases in personnel and related costs, partially offset by a non-recurring \$1.3 million catch-up adjustment in the second quarter of 2014 for non-cash stock-based compensation expense recognized upon shareholder approval of an increase in shares available for issuance under our stock compensation plan.

Research and development expenses increased from \$2.1 million to \$2.2 million, an increase of 4.9%, due to work on development projects, including the ANDAs purchased from Teva in 2014 and 2015 and collaborations with partners.

Other (Expense)/Income, net

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

(in thousands)

	Nine Months Ended September 30,					
	2015		2014	Change	% Change	
Interest (expense)/income, net	\$ (8,240	)	\$ 13	\$(8,253)	NM	(1)
Other income, net	40		72	(32)	(44.4)%	
Total other (expense)/income, net	\$ (8,200	)	\$ 85	\$(8,285)	NM	(1)

(1) Not Meaningful

For the nine months ended September 30, 2015, we recognized other expense of \$8.2 million versus other income of \$0.1 million for the same period in 2014, a change of \$8.3 million. This change resulted primarily from \$8.3 million of interest expense recognized on our convertible debt balance during the period.

Income Taxes

(in thousands)	Nine Months Ended September 30,				
	2015		2014	Change	% Change
Provision for income taxes	\$ (5,733	)	\$ (1,577	) \$(4,156)	263.5 %

Our provision for income taxes consists of current and deferred components, which include changes in our DTAs, our DTLs, and our valuation allowance. In the fourth quarter of 2014, we reversed the majority of the valuation allowance we had recorded against our net DTAs. The reversal was the result of our determination that it is more likely than not that we will realize the benefits of our net DTAs as a result of our expectation of future profitability, among other factors. Prior to the reversal, we had fully reserved for all our net DTAs.

For the nine months ended September 30, 2015, we recognized income tax expense of \$5.7 million, versus \$1.6 million for the same period in 2014, an increase of \$4.2 million. Of the \$5.7 million of total tax expense, \$5.4 million is current expense and \$0.3 million is net deferred expense. The effective tax rate for the nine months 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 changes in forecasted pre-tax income, estimated permanent differences, and state income tax rates, as well as from the impact of exercises of non-qualified stock options and disqualifying dispositions of incentive stock options. Changes in the estimated annual effective rate during the year are primarily driven by periodic changes to our forecasted pre-tax income. The effective tax rate for the nine months ended September 30, 2014 was 16.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2014.

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	September 30, 2015	December 31, 2014
Cash and cash equivalents	\$ 150,913	\$ 169,037
Accounts receivable, net	21,645	17,297
Inventories, net	13,741	7,518
Prepaid income taxes	972	-
Deferred tax assets, net of valuation allowance	8,266	7,643
Prepaid expenses and other current assets	1,985	1,983
Total current assets	\$ 197,522	\$ 203,478
Accounts payable	\$ 2,633	\$ 2,654
Accrued expenses and other	2,221	1,269
Accrued compensation and related expenses	1,019	1,348
Current income taxes payable	-	4,253
Accrued Medicaid rebates	4,428	2,264
Returned goods reserve	1,889	1,445
Total current liabilities	\$ 12,190	\$ 13,233

At September 30, 2015, we had \$150.9 million in unrestricted cash and cash equivalents. At December 31, 2014, we had \$169.0 million in unrestricted cash and cash equivalents. We generated \$12.6 million of cash from operations in the nine months ended September 30, 2015. In the first quarter of 2015, we acquired an ANDA from Teva for \$4.5 million. In the third quarter of 2015, we acquired a basket of ANDAs from Teva for \$25.0 million.

In September 2015, we entered into an asset purchase agreement with Merck Sharp & Dohme B.V. to purchase, subject to typical closing conditions including regulatory approvals, certain NDAs and associated product rights and manufacturing licenses for \$75.0 million in cash and a percentage of future net sales of the products under the NDAs. The asset acquisition is expected to close in January 2016. We anticipate that we will make the \$75.0 million cash payment using cash on hand.

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.

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

We believe that our financial resources, consisting of current working capital and anticipated future operating revenue, 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,	
	2015	2014
Operating Activities	\$ 12,562	\$ 11,292
Investing Activities	\$ (31,578)	\$ (35,416)
Financing Activities	\$ 892	\$ 48,069

Net Cash Provided By Operations

Net cash provided by operating activities was \$12.6 million for the nine months ended September 30, 2015, compared to \$11.3 million during the same period in 2014, an increase of \$1.3 million between the periods. This increase was due to changes in net income, partially offset by changes in current assets and current liabilities. Net income from operations for the nine months ended September 30, 2015 increased by \$12.2 million from the same period in 2014, after adjusting for non-cash expenses.

Changes in current assets and current liabilities for the nine months ended September 30, 2015 used \$12.7 million of cash compared to \$1.8 million in the same period in 2014, a difference of approximately \$10.9 million between the periods. Inventory increased \$6.2 million in the nine months ended September 30, 2015 as compared with an increase of \$3.3 million in the prior year period. Changes in current income taxes, net were a \$5.2 million use of cash in the nine months ended September 30, 2015, as compared with providing \$1.1 million in the prior year period. Accounts receivable increased by \$4.3 million in the nine months ended September 30, 2015 as compared with an increase of \$2.1 million in the prior year period. Accounts payable decreased by \$0.1 million in the nine months ended September 30, 2015 as compared with an increase of \$0.6 million in the prior year period. Accrued compensation and related expenses decreased by \$0.3 million in the nine months ended September 30, 2015, as compared with a decrease of \$40 thousand in the prior year period. These increases to cash used were partially offset by a \$2.2 million increase in accrued Medicaid rebates in the nine months ended September 30, 2015, as compared with a \$1.0 million increase in the prior year period, as well as a \$1.4 million increase in accrued expense, returned goods, and other, as compared with a \$0.9 million increase in the prior year period.

Net Cash Used In Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2015 was \$31.6 million, principally due to the March 2015 \$4.5 million asset acquisition of the ANDA for Flecainide Acetate tablets, the July 2015 asset acquisition of a basket of ANDAs for \$25.0 million, the August 2015 payment of \$1.0 million for marketing and distribution rights, and \$1.1 million of capital expenditures during the period. Net cash used in investing activities was \$35.4 million during the same period in 2014, relating primarily to the \$12.5 million asset acquisition from Teva of ANDAs related to 31 generic products, \$22 million in asset purchases related to Lithobid and Vancocin, and \$0.8 million of capital expenditures during the period.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was \$0.9 million for the nine months ended September 30, 2015, resulting primarily from \$0.7 million of proceeds from stock option exercises and \$0.2 million of excess tax benefit from stock-based compensation awards. Net cash provided by financing activities was \$48.1 million during the same period in 2014, resulting primarily from \$46.7 million of net proceeds received in our March 10, 2014 follow-on public offering. We also received \$0.8 million of cash from stock option exercises, \$0.4 million of excess tax benefit from stock-based compensation awards, and \$0.2 million from warrant exercises during the nine months ended September 30, 2014.

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 condensed consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, 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, 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, 2014. 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, 2014.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (“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. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our 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 amendment is effective for reporting periods beginning after December 15, 2015 and may be applied on either a prospective or retrospective basis. Early adoption is permitted. We do not expect the adoption of this new accounting pronouncement to have a material impact on our 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 will be 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. The standard is effective for reporting periods beginning after December 15, 2015 and early adoption is permitted. The adoption of this new accounting pronouncement will result in a reclassification of deferred financing costs from assets to contra-liabilities.

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 LIFO 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 standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2015 and December 31, 2014, 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

As of September 30, 2015, our only 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 we 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.

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, 2015 by approximately \$3 thousand and \$10 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, 2015. 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, 2015 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 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, 2014 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, 2015 By: /s/ Arthur S. Przybyl
Arthur S. Przybyl
President and
Chief Executive Officer
(Principal Executive Officer)

Date: November 3, 2015 By: /s/ Charlotte C. Arnold
Charlotte C. Arnold
Vice President, Finance and
Chief Financial Officer
(Principal Financial Officer)

INDEX TO EXHIBITS

Exhibit No.	Description
10.1*	Asset Purchase Agreement between Teva Pharmaceuticals, Inc. and ANI Pharmaceuticals, Inc. Dated as of July 10, 2015.
10.2*	Asset Purchase Agreement between Merck Sharp & Dohme B.V. and ANI Pharmaceuticals, Inc. Dated as of September 18, 2015.
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

*Confidential Treatment requested as to certain portions of this exhibit. Such portions have been redacted and filed separately with the Commission.