

ANI PHARMACEUTICALS INC  
Form 10-Q  
May 05, 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 March 31, 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 May 1, 2015, there were 11,414,517 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 March 31, 2015**

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## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

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

*Uncertainties and risks may cause our actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include, but are not limited to, the risk that we may face with respect to importing raw materials, increased competition, delays or failure in obtaining product approval 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<sup>®</sup>, Lithobid<sup>®</sup>, Reglan<sup>®</sup>, and Vancocin<sup>®</sup> 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)*

	March 31, 2015	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	\$ 165,563	\$ 169,037
Accounts receivable, net of \$8,096 and \$8,708 of adjustments for chargebacks and other allowances at March 31, 2015 and December 31, 2014, respectively	17,371	17,297
Inventories, net	10,737	7,518
Deferred tax assets, net of valuation allowance	7,776	7,643
Prepaid expenses and other current assets	1,546	1,983
Total Current Assets	202,993	203,478
Property and equipment, net	5,281	5,223
Deferred financing costs, net	3,096	3,307
Deferred tax asset, net of valuation allowance	7,369	7,796
Intangible assets, net	45,408	42,067
Goodwill	1,838	1,838
Total Assets	\$ 265,985	\$ 263,709
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 2,288	\$ 2,654
Accrued expenses and other	1,897	1,269
Accrued compensation and related expenses	513	1,348
Current income taxes payable	481	4,253
Accrued Medicaid rebates	2,077	2,264
Returned goods reserve	1,817	1,445
Total Current Liabilities	9,073	13,233
Long-term Liabilities		
Convertible notes, net of discount	112,172	110,691
Total Liabilities	\$ 121,245	\$ 123,924

Commitments and Contingencies (Note 11)

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Stockholders' Equity

Common Stock, \$0.0001 par value, 33,333,334 shares authorized; 11,389,317 shares issued and 11,386,817 shares outstanding at March 31, 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 March 31, 2015 and December 31, 2014, respectively	-	-
Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	-	-
Treasury stock, 2,500 shares of common stock, at cost, at March 31, 2015, 0 shares of common stock at December 31, 2014	-	-
Additional paid-in capital	160,095	159,509
Accumulated deficit	(15,356 )	(19,725 )
Total Stockholders' Equity	144,740	139,785
Total Liabilities and Stockholders' Equity	\$ 265,985	\$ 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)*

	Three months ended March 31,	
	2015	2014
Net Revenues	\$ 18,799	\$ 10,899
Operating Expenses:		
Cost of sales (excluding depreciation and amortization)	2,751	2,622
Research and development	403	376
Selling, general and administrative	4,751	3,703
Depreciation and amortization	1,327	703
Total Operating Expenses	9,232	7,404
Operating Income	9,567	3,495
Other (Expense)/Income		
Interest expense, net	(2,725 )	-
Other income	68	29
Income Before Provision for Income Taxes	6,910	3,524
Provision for income taxes	(2,541 )	(165 )
Net Income	\$ 4,369	\$ 3,359
Basic and Diluted Earnings Per Share:		
Basic Earnings Per Share	\$ 0.38	\$ 0.33
Diluted Earnings Per Share	\$ 0.38	\$ 0.33
Basic Weighted-Average Shares Outstanding	11,326	9,991
Diluted Weighted-Average Shares Outstanding	11,562	10,001

*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)*

	Three months ended March 31,	
	2015	2014
<b>Cash Flows From Operating Activities</b>		
Net income	\$ 4,369	\$ 3,359
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	568	47
Deferred taxes	294	-
Depreciation and amortization	1,327	703
Non-cash interest relating to convertible notes and loan cost amortization	1,683	-
Changes in operating assets and liabilities, net of those acquired in business combination:		
Accounts receivable	(74 )	1,606
Inventories	(3,219 )	(1,572 )
Prepaid expenses	437	14
Accounts payable	(471 )	1,298
Accrued compensation and related expenses	(835 )	(307 )
Current income taxes payable	(3,772 )	35
Accrued Medicaid rebates	(187 )	17
Accrued expenses, returned goods reserve, and other	1,000	(21 )
<b>Net Cash and Cash Equivalents Provided by Operating Activities</b>	<b>1,120</b>	<b>5,179</b>
<b>Cash Flows From Investing Activities</b>		
Acquisition of product rights and other related assets	(4,500 )	(12,517 )
Acquisition of property and equipment	(112 )	(118 )
<b>Net Cash and Cash Equivalents Used in Investing Activities</b>	<b>(4,612 )</b>	<b>(12,635 )</b>
<b>Cash Flows From Financing Activities</b>		
Net proceeds from equity offering	-	46,694
Proceeds from stock option exercises	9	743
Proceeds from warrant exercise	-	180
Excess tax benefit from share-based compensation awards	9	107
<b>Net Cash and Cash Equivalents Provided by Financing Activities</b>	<b>18</b>	<b>47,724</b>

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Change in Cash and Cash Equivalents	(3,474 )	40,268
Cash and cash equivalents, beginning of period	169,037	11,105
Cash and cash equivalents, end of period	\$ 165,563	\$ 51,373
Supplemental disclosure for cash flow information:		
Cash paid for income taxes	\$ 6,029	\$ 60
Supplemental non-cash investing and financing activities:		
Property and equipment purchased on credit	\$ 105	\$ -

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

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS**

**Overview**

ANI Pharmaceuticals, Inc. and 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 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.

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

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

**Recent Accounting Pronouncements**

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. The standard is effective for reporting periods beginning after December 15, 2016 and early adoption is not permitted. 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 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. We are currently evaluating the impact 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.

## ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

*(unaudited)***2. REVENUE RECOGNITION AND RELATED ALLOWANCES - continued**

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 balance sheet for accruals and allowances for the three-month periods ended March 31, 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	7,090	158	258	970	347
Credits Taken Against Reserve	(7,357)	(141)	(145)	(853)	(370)
Balance at March 31, 2014	\$ 3,809	\$ 270	\$ 849	\$ 852	\$ 309



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Balance at December 31, 2014	\$ 6,865	\$ 2,264	\$ 1,445	\$ 1,487	\$ 471
Accruals/Adjustments	10,260	953	566	1,472	609
Credits Taken Against Reserve	(10,526 )	(1,140 )	(194 )	(1,825 )	(602 )
Balance at March 31, 2015	\$ 6,599	\$ 2,077	\$ 1,817	\$ 1,134	\$ 478

**Credit Concentration**

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

During the three month period ended March 31, 2015, three customers represented 28%, 24%, and 19% of net revenues. As of March 31, 2015, net accounts receivable from these customers totaled \$14.2 million. During the three month period ended March 31, 2014, three customers represented 23%, 18%, and 15% of net revenues.

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**3. INDEBTEDNESS**

*Convertible Senior Notes*

In December 2014, we issued \$143.8 million of our Convertible Senior Note 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.

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 March 31:

(in thousands)	2015
Principal amount	\$ 143,750
Unamortized debt discount	(31,578 )
Net carrying value	\$ 112,172

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***3. INDEBTEDNESS - continued**

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 months ended March 31:

(in thousands)	2015
Contractual coupon	\$1,078
Amortization of debt discount	1,481
Amortization of finance fees	211
Capitalized interest	(9 )
	<b>\$2,761</b>

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.

Our unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; the calculation of basic and diluted earnings per share excludes from the numerator net income attributable to the unvested restricted shares, and excludes the impact of those shares from the denominator.

For purposes of determining diluted earnings per share, we have elected a policy to assume that the principal portion of the Notes (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.

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.

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***4. EARNINGS PER SHARE - continued**

Earnings per share for the three months ended March 31, 2015 and 2014 are calculated for basic and diluted earnings per share as follows:

(in thousands)	Basic		Diluted	
	Three months ended March 31,		Three months ended March 31,	
	2015	2014	2015	2014
Net income	\$ 4,369	\$ 3,359	\$ 4,369	\$ 3,359
Net income allocated to warrants	-	(19 )	-	(19 )
Net income allocated to restricted stock	(23 )	(15 )	(23 )	(15 )
Net income from continuing operations allocated to common shares	\$ 4,346	\$ 3,325	\$ 4,346	\$ 3,325
Basic Weighted-Average Shares Outstanding	11,326	9,991	11,326	9,991
Dilutive effect of stock options			236	10
Diluted Weighted-Average Shares Outstanding			11,562	10,001
Earnings Per Share	\$ 0.38	\$ 0.33	\$ 0.38	\$ 0.33

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 4.6 million and 0.7 million for the three months ended March 31, 2015 and 2014. 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 March 31, 2015, we had 0.5 million options outstanding to purchase common stock, 60 thousand unvested restricted stock awards, and 2.5 million warrants to purchase common stock.

**5. INVENTORIES**

Inventories consist of the following as of:

(in thousands)	March 31, 2015	December 31, 2014
Raw materials	\$ 7,974	\$ 5,056
Packaging materials	783	794
Work-in-progress	318	411
Finished goods	1,984	1,368
	11,059	7,629
Reserve for excess/obsolete inventories	(322 )	(111 )
Inventories, net	\$ 10,737	\$ 7,518

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***5. INVENTORIES - continued****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 March 31, 2015, we purchased approximately 62% of our inventory from four suppliers. As of March 31, 2015, amounts payable to these suppliers was \$0.2 million. During the three months ended March 31, 2014, we purchased approximately 49% of our inventory from two suppliers.

**6. PROPERTY, PLANT, AND EQUIPMENT**

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

(in thousands)	March 31, 2015	December 31, 2014
Land	\$ 87	\$ 87
Buildings	3,682	3,682
Machinery, furniture and equipment	5,071	4,822
Construction in progress	403	426
	9,243	9,017
Less: accumulated depreciation	(3,962 )	(3,794 )
Property, Plant and Equipment, net	\$ 5,281	\$ 5,223

Depreciation expense for the three month periods ended March 31, 2015 and 2014 totaled \$0.2 million and \$0.1 million, respectively. During the three month period ended March 31, 2015, there was \$9 thousand of interest capitalized into construction in progress. In the three month period ended March 31, 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 March 31, 2015. No impairment losses were recognized during the three months ended March 31, 2015 or 2014.

**Acquisition of Abbreviated New Drug Application**

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.

## ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

## NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

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

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

(in thousands)	March 31, 2015		December 31, 2014		Weighted Average Amortization Period
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
Acquired ANDA intangible assets	\$17,077	\$ (1,662 )	\$12,577	\$ (1,312 )	10 years
Product rights	22,522	(1,694 )	22,522	(1,133 )	10 years
Teva license intangible asset	10,900	(1,735 )	10,900	(1,487 )	11 years
	\$50,499	\$ (5,091 )	\$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 ANDA 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 Teva license was acquired as part of our 2013 merger with BioSante. Definite-lived intangible assets are stated at the lower of cost or fair value, net of amortization using the straight line method over the expected useful lives of the intangible assets. Amortization expense was \$1.2 million and \$0.6 million for the three months ended March 31, 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 months ended March 31, 2015 and 2014 and therefore no impairment loss was recognized in the three months ended March 31, 2015 or 2014.

Expected future amortization expense is as follows:

(in thousands)

2015 (remainder of the year)	\$3,701
2016	4,935
2017	4,935
2018	4,935
2019	4,935
2020 and thereafter	21,967
Total	\$45,408

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**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 March 31, 2015, 0.7 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 March 31, 2015 and 2014 was \$0.5 million and \$4 thousand, respectively. Total expense related to restricted stock grants for the three months ended March 31, 2015 and 2014 was \$0.1 million and \$42 thousand, respectively.

Options to purchase one thousand shares of common stock were exercised, 28 thousand options were forfeited, and no options expired during the three months ended March 31, 2015. Options to purchase 30 thousand shares of common stock were exercised and no options were forfeited or expired during the three month period ended March 31, 2014. No restricted stock vested during the three months ended March 31, 2015 or 2014. During the three months ended March 31, 2015, three thousand shares of restricted stock were forfeited. No restricted stock was forfeited during the three months ended March 31, 2014.

**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.

No warrants to purchase shares of common stock expired unexercised during the three months ended March 31, 2015 or 2014, respectively. No warrants to purchase shares of common stock were exercised in the three months ended March 31, 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 March 31, 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.

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**10. INCOME TAXES - continued**

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 March 31, 2015 and December 31, 2014.

The effective tax rate for the three months ended March 31, 2015 was 36.8% 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 affected by the impact of state taxes and permanent differences. We have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our estimated annual effective rate. Our estimated annual effective rate is primarily driven by our forecasted pre-tax income, estimated temporary and permanent differences, and the use of our existing NOLs. Changes in the estimated annual effective rate during the year are primarily driven by periodic changes to our forecasted pre-tax income. The utilization of our NOL carryforwards will be limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code. For the comparable three months ended March 31, 2014, the effective tax rate was 4.6% of net income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2014. The effective tax rate for the period was primarily impacted by the use of the NOL carryforwards and changes in our valuation allowance, most of which was released in the fourth quarter of 2014.

**11. COMMITMENTS AND CONTINGENCIES**

**Operating Leases**

We lease equipment under operating leases that expire in May 2017. 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 March 31, 2015.

Rent expense for the three months ended March 31, 2015 and 2014 totaled \$18 thousand and \$17 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 New Drug Applications (“NDAs”) or ANDAs. During the three months ended March 31, 2015 and 2014, net revenues for these products totaled \$10.3 million and \$6.7 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.

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARY**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**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 March 31, 2015 and 2014 were \$0.3 million and \$0.4 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 March 31, 2015 and 2014 were \$0.1 million.

**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. On October 15, 2013, the defendants removed the lawsuit to the U.S. District Court. On November 14, 2013, the state filed a motion to remand the lawsuit to the Louisiana state court. On September 30, 2014, the U.S. District Court remanded the case from the federal to the state court. 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. However, our current product liability insurance policy contains absolute exclusions for claims related to Reglan and metoclopramide. 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.

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**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 balance sheets at their net carrying value of \$112.2 million, as of March 31, 2015, the Notes are being traded on the bond market and their full fair value is \$165.9 million based on their closing price on March 31, 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 the merger with BioSatite, 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 March 31, 2015 and December 31, 2014, and for the three months ended March 31, 2015 and 2014.

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

(in thousands)

Description	<b>Fair Value at March 31, 2015</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Liabilities				
CVRs	\$ -	\$ -	\$ -	\$ -

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

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**12. FAIR VALUE DISCLOSURES – continued**

**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.

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 months ended March 31, 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.

## 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.

As of March 31, 2015, our products include both branded and generic pharmaceuticals, specifically:

#### **Generic Products**

Esterified Estrogen with Methyltestosterone  
Fluvoxamine Maleate  
Hydrocortisone Enema  
Methazolamide  
Metoclopramide Syrup  
Opium Tincture  
Etodolac  
Propafenone

#### **Branded Products**

Cortenema  
Reglan  
Lithobid  
Vancocin

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 that many generic competitors will be entering that product's market. 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 March 31,	
	2015	2014
Net revenues	\$ 18,799	\$ 10,899
Operating expenses		
Cost of sales (exclusive of depreciation and amortization)	2,751	2,622
Research and development	403	376
Selling, general and administrative	4,751	3,703
Depreciation and amortization	1,327	703
Operating income	9,567	3,495
Interest expense, net	(2,725)	-
Other income	68	29
Income before provision for income taxes	6,910	3,524
Provision for income taxes	(2,541)	(165)
Net income	\$ 4,369	\$ 3,359

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 March 31,			
	2015		2014	
Net revenues	100.0	%	100.0	%
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	14.6	%	24.1	%
Research and development	2.1	%	3.4	%
Selling, general and administrative	25.3	%	34.0	%
Depreciation and amortization	7.1	%	6.4	%
Operating income	50.9	%	32.1	%
Interest expense, net	(14.5)	)%	-	%



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Other income	0.4	%	0.2	%
Income before provision for income taxes	36.8	%	32.3	%
Provision for income taxes	(13.6)	)%	(1.5)	)%
Net income	23.2	%	30.8	%

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RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2015 AND 2014**Net Revenues**

(in thousands)	Three Months Ended March 31,				
	2015	2014	Change	% Change	
Generic pharmaceutical products	\$ 12,256	\$ 8,054	\$4,202	52.2	%
Branded pharmaceutical products	4,272	774	3,498	451.9	%
Contract manufacturing	1,205	1,619	(414 )	(25.6 )	%
Contract services and other income	1,066	452	614	135.8	%
<b>Total net revenues</b>	<b>\$ 18,799</b>	<b>\$ 10,899</b>	<b>\$7,900</b>	<b>72.5</b>	<b>%</b>

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 March 31, 2015 were \$18.8 million compared to \$10.9 million for the same period in 2014, an increase of \$7.9 million, or 72.5%, primarily as a result of the following factors:

Net revenues for generic pharmaceutical products were \$12.3 million during the three months ended March 31, 2015, an increase of 52.2% compared to \$8.1 million for the same period in 2014. The primary reason for the increase was increased Esterified Estrogen with Methyltestosterone tablets ("EEMT") revenues, due to increases in prices per bottle, as well as sales of our Methazolamide and Etodolac products, which were launched in the fourth quarter of 2014 and the first quarter of 2015, respectively. We also experienced increased sales for our HC Enema and Opium Tincture products.

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 March 31, 2015 and 2014 were \$10.3 million and \$6.7 million, respectively.

Net revenues for branded pharmaceutical products were \$4.3 million during the three months ended March 31, 2015, an increase of 451.9% compared to \$0.8 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.

Contract manufacturing revenues were \$1.2 million during the three months ended March 31, 2015, a decrease of 25.6% compared to \$1.6 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 March 31, 2015 and 2014 were \$0.3 million and \$0.4 million, respectively.

Contract services and other income were \$1.1 million during the three months ended March 31, 2015, an increase of 135.8% from \$0.5 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. 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 March 31, 2015 and 2014.

### Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended March 31,			Change	% Change
	2015	2014	Change		
Cost of sales (excl. depreciation and amortization)	\$ 2,751	\$ 2,622	\$ 129	4.9	%

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 March 31, 2015, cost of sales increased to \$2.8 million from \$2.6 million for the same period in 2014, an increase of \$0.1 million or 4.9%, primarily as a result of increased sales in the period. Cost of sales as a percentage of net revenues decreased to 14.6% during the three months ended March 31, 2015, from 24.1% 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 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 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 March 31, 2015, we purchased 62% of our inventory from four suppliers. As of March 31, 2015, amounts payable to these suppliers were \$0.2 million. In the three months ended March 31, 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 March 31,				
	2015	2014	Change	% Change	
Research and development	\$ 403	\$ 376	\$ 27	7.2	%
Selling, general and administrative	4,751	3,703	1,048	28.3	%
Depreciation and amortization	1,327	703	624	88.8	%
Total other operating expenses	\$ 6,481	\$ 4,782	\$ 1,699	35.5	%

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

For the three months ended March 31, 2015, other operating expenses increased to \$6.5 million from \$4.8 million for the same period in 2014, an increase of \$1.7 million, or 35.5%, primarily as a result of the following factors:

Selling, general and administrative expenses increased from \$3.7 million to \$4.8 million, an increase of 28.3%, primarily due to increased stock-based compensation expense in 2015, as well as increases in personnel and related costs.

Depreciation and amortization increased from \$0.7 million to \$1.3 million, an increase of 88.8%, due to amortization of the product rights for Lithobid and Vancocin, which rights were purchased during the third quarter of 2014.

Research and development expenses increased by 7.2%, due to work on development projects, including the ANDAs purchased from Teva Pharmaceuticals ("Teva") and new collaborations.

**Other (Expense)/Income**

(in thousands)	Three Months Ended March 31,				
	2015	2014	Change	% Change	
Interest expense, net	\$ (2,725 )	\$ -	\$(2,725)	(100.0)	%
Other income	68	29	39	134.5	%
Total other (expense)/ income	\$ (2,657 )	\$ 29	\$(2,686)	(9,262.1)	%

For the three months ended March 31, 2015, we recognized other expense of \$2.7 million versus other income of \$29 thousand for the same period in 2014, a change of \$2.7 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 March 31,			
	2015	2014	Change	% Change
Provision for income taxes	\$ (2,541 )	\$ (165 )	\$(2,376)	1,440.0 %

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 March 31, 2015, we recognized income tax expense of \$2.5 million, versus income tax expense of \$0.2 million for the same period in 2014, an increase of \$2.3 million. This change resulted primarily due to \$2.5 million of current income tax provision for the first quarter of 2015. The effective tax rate for the three months ended March 31, 2015 was 36.8% 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 affected by the impact of state taxes and permanent differences. Changes in the estimated annual effective rate during the year are primarily driven by periodic changes to our forecasted pre-tax income.

**LIQUIDITY AND CAPITAL RESOURCES**

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

(in thousands)	March 31,	December 31,
	2015	2014
Cash and cash equivalents	\$ 165,563	\$ 169,037
Accounts receivable, net	17,371	17,297
Inventories	10,737	7,518
Deferred tax assets, net of valuation allowance	7,776	7,643
Prepaid expenses and other current assets	1,546	1,983
Total current assets	\$ 202,993	\$ 203,478
Accounts payable	\$ 2,288	\$ 2,654
Accrued expenses and other	1,897	1,269



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Accrued compensation and related expenses	513	1,348
Current income taxes payable	481	4,253
Accrued Medicaid rebates	2,077	2,264
Returned goods reserve	1,817	1,445
Total current liabilities	\$9,073	\$ 13,233

At March 31, 2015, we had \$165.6 million in unrestricted cash and cash equivalents. At December 31, 2014, we had \$169.0 million in unrestricted cash and cash equivalents. We generated \$1.1 million of cash from operations in the three months ended March 31, 2015. In addition, in the first quarter of 2015, we acquired an ANDA from Teva for \$4.5 million.

We are focused on expanding our business and product pipeline through collaborations, and also through acquisitions of products and companies. We are continually evaluating potential asset acquisitions and business combinations. To finance such acquisitions, we might raise additional equity capital, incur additional debt, or both.

We believe that our financial resources, consisting of current working capital 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)	Years ended	
	December 31,	
	2015	2014
Operating Activities	\$1,120	\$5,179
Investing Activities	\$(4,612)	\$(12,635)
Financing Activities	\$18	\$47,724

### Net Cash Provided By Operations

Net cash provided by operating activities was \$1.1 million for the three months ended March 31, 2015, compared to \$5.2 million during the same period in 2014, a decrease of \$4.1 million between the periods. This decrease was due to changes in net income and changes in current assets and current liabilities. Net income from operations for the three months ended March 31, 2015 increased by \$4.1 million from the same period in 2014, after adjusting for non-cash expenses. Changes in current assets and current liabilities for the three months ended March 31, 2015 used \$7.1 million of cash compared to \$1.1 million provided in the same period in 2014, a difference of approximately \$8.2 million between the periods. Current income taxes payable decreased by \$3.8 million in the three months ended March 31, 2015, as compared with a slight increase in the prior year period. Inventory increased \$3.2 million in the three months ended March 31, 2015 as compared with an increase of \$1.6 million in the prior year period. Accounts receivable increased by \$0.1 million in the three months ended March 31, 2015 as compared with a decrease of \$1.6 million in the prior year period. Accounts payable decreased by \$0.5 million in the three months ended March 31, 2015 as compared with an increase of \$1.3 million in the prior year period. These increases to cash used were partially offset by an increase in Accrued expenses, returned goods reserve, and other of \$1.0 million in the three months ended March 31, 2015, as compared with a slight decrease in the prior year period.

### Net Cash Used In Investing Activities

Net cash used in investing activities for the three months ended March 31, 2015 was \$4.6 million, principally due to the \$4.5 million asset acquisition of the ANDA for Flecainide Acetate tablets, in addition to \$0.1 million of capital expenditures during the period. Net cash used in investing activities was \$12.6 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, in addition to capital expenditures during the period.

#### **Net Cash Provided By Financing Activities**

Net cash provided by financing activities was \$18 thousand for the three months ended March 31, 2015, resulting primarily from proceeds from stock option exercises and excess tax benefit from stock-based compensation awards during the three months ended March 31, 2015. Net cash provided by financing activities was \$47.7 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 \$0.7 million of cash from stock option exercises and \$0.2 million from warrant exercises during the three months ended March 31, 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 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. The standard is effective for reporting periods beginning after December 15, 2016 and early adoption is not permitted. We are currently evaluating the impact, if any, that this standard will have on our consolidated financial statements.

In April 2015, the FASB issued guidance to simplify the balance sheet disclosure for debt issuance costs. Under the guidance, debt issuance costs related to a recognized debt liability 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. We are currently evaluating the impact that this new accounting pronouncement will have on our financial statements.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of March 31, 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 March 31, 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 months ended March 31, 2015 by approximately \$4 thousand.

### **Item 4. Controls and Procedures**

#### ***Evaluation of Disclosure Controls and Procedures***

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal

financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of March 31, 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 March 31, 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. Other than as described below, there has been no material change to those risk factors.

### **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.

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**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: May 5, 2015 By: /s/ Arthur S. Przybyl  
Arthur S. Przybyl  
President and  
Chief Executive Officer  
(Principal Executive Officer)

Date: May 5, 2015 By: /s/ Charlotte C. Arnold  
Charlotte C. Arnold  
Vice President, Finance and  
Chief Financial Officer  
(Principal Financial Officer)

## INDEX TO EXHIBITS

<b>Exhibit No.</b>	<b>Description</b>
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