

ANI PHARMACEUTICALS INC  
Form 10-Q  
August 07, 2014

**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 June 30, 2014**

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

**For the transition period from                      to                      .**

**Commission File Number 001-31812**

**ANI PHARMACEUTICALS, INC.**

**(Exact name of registrant as specified in its charter)**

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

**210 Main Street West**

**Baudette, Minnesota**

(Address of principal executive offices)

**(218) 634-3500**

(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES 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 x

(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 August 1, 2014, there were 11,313,623 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 June 30, 2014**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I — FINANCIAL INFORMATION</b>	
Item 1. Financial Statements (unaudited)	
<u>Condensed Consolidated Balance Sheets — As of June 30, 2014 and December 31, 2013</u>	4
<u>Condensed Consolidated Statements of Operations — For the Three and Six Months Ended June 30, 2014 and 2013</u>	5
<u>Condensed Consolidated Statements of Cash Flows — For the Six Months Ended June 30, 2014 and 2013</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>	33
Item 4. <u>Controls and Procedures</u>	33
<b>PART II — OTHER INFORMATION</b>	
Item 1. <u>Legal Proceedings</u>	33
Item 1A. <u>Risk Factors</u>	33
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	34
Item 3. <u>Defaults upon Senior Securities</u>	34
Item 4. <u>Mine Safety Disclosures</u>	34
Item 5. <u>Other Information</u>	34
Item 6. <u>Exhibits</u>	34
<u>Signatures</u>	35



## 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, 2013, including the factors described in "Item 1A. Risk Factors," as well as our proxy statement, filed with the SEC on April 11, 2014. 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.*

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

	June 30, 2014	December 31, 2013
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 52,961	\$ 11,105
Accounts receivable, net of \$7,694 and \$5,104 of allowances for chargebacks and other allowances at June 30, 2014 and December 31, 2013, respectively	7,794	12,513
Inventories, net	5,912	3,518
Prepaid expenses	493	580
<b>Total Current Assets</b>	<b>67,160</b>	<b>27,716</b>
Property, plant, and equipment, net	4,625	4,537
Intangible assets, net	21,800	10,409
Goodwill	1,838	1,838
<b>Total Assets</b>	<b>\$ 95,423</b>	<b>\$ 44,500</b>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Accounts payable	\$ 1,731	\$ 1,429
Accrued expenses	1,133	1,326
Returned goods reserve	951	736
Deferred revenue	13	47
<b>Total Current Liabilities</b>	<b>3,828</b>	<b>3,538</b>
<b>Commitments and Contingencies (Note 11)</b>		
<b>Stockholders' Equity</b>		
Common Stock, \$0.0001 par value, 33,333,334 shares authorized; 11,312,582 shares issued and outstanding at June 30, 2014; 9,629,174 shares issued and 9,619,941 shares outstanding at December 31, 2013	1	1
Class C Special Stock, \$0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	-	-
Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at June 30, 2014 and December 31, 2013, respectively	-	-
	-	(68 )

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Treasury stock, 0 and 9,233 shares of common stock, at cost, at June 30, 2014 and December 31, 2013, respectively

Additional paid-in capital	139,070	89,501
Accumulated deficit	(47,476 )	(48,472 )
Total Stockholders' Equity	91,595	40,962
Total Liabilities and Stockholders' Equity	\$ 95,423	\$ 44,500

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



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

	Three months ended June 30,		Six months ended June 30,	
	2014	2013	2014	2013
Net Revenues	\$ 6,647	\$ 6,152	\$ 17,546	\$ 11,713
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	2,117	2,171	4,739	4,580
Research and development	851	437	1,227	733
Selling, general and administrative	5,433	7,172	9,136	9,481
Depreciation and amortization	706	147	1,409	291
Total Operating Expenses	9,107	9,927	16,511	15,085
Operating (Loss)/Income	(2,460 )	(3,775 )	1,035	(3,372 )
Other Income/(Expense)				
Interest income/(expense)	3	(374 )	3	(467 )
Other expense	(39 )	(434 )	(10 )	(484 )
(Loss)/Income Before Provision for Income Taxes	(2,496 )	(4,583 )	1,028	(4,323 )
Benefit/(Provision) for Income Taxes	133	-	(32 )	-
Net (Loss)/Income	\$ (2,363 )	\$ (4,583 )	\$ 996	\$ (4,323 )
Computation of (Loss)/Income Attributable to Common Stockholders:				
Net (Loss)/Income	\$ (2,363 )	\$ (4,583 )	\$ 996	\$ (4,323 )
Preferred stock dividends	-	(2,370 )	-	(4,974 )
(Loss)/Income Attributable to Common Stockholders	\$ (2,363 )	\$ (6,953 )	\$ 996	\$ (9,297 )
Basic and Diluted (Loss)/Earnings Per Share:				
Basic (Loss)/Earnings Per Share	\$ (0.21 )	\$ (6.03 )	\$ 0.09	\$ (16.03 )
Diluted (Loss)/Earnings Per Share	\$ (0.21 )	\$ (6.03 )	\$ 0.09	\$ (16.03 )
Basic Weighted-Average Shares Outstanding	11,233	1,153	10,612	580
Diluted Weighted-Average Shares Outstanding	11,233	1,153	10,640	580

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

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

	For the six months ended June 30,	
	2014	2013
<b>Cash Flows From Operating Activities</b>		
Net income	\$ 996	\$ (4,323 )
Adjustments to reconcile net income to net cash and cash equivalents provided by/(used in) operating activities:		
Stock-based compensation	2,026	-
Depreciation and amortization	1,409	291
Non-cash interest relating to equity-linked securities and loan cost amortization	-	217
Non-cash compensation relating to business combination	-	4,418
Changes in operating assets and liabilities:		
Accounts receivable	4,719	(995 )
Inventories	(2,394 )	225
Prepaid expenses	87	141
Accounts payable	302	(359 )
Accrued expenses, returned goods reserve and deferred revenue	(12 )	(603 )
<b>Net Cash and Cash Equivalents Provided by/(Used in) Operating Activities</b>	<b>7,133</b>	<b>(988 )</b>
<b>Cash Flows From Investing Activities</b>		
Cash acquired in business combination	-	18,198
Acquisition of intangible assets	(12,517 )	-
Acquisition of property and equipment	(371 )	(128 )
<b>Net Cash and Cash Equivalents (Used in)/Provided by Investing Activities</b>	<b>(12,888 )</b>	<b>18,070</b>
<b>Cash Flows From Financing Activities</b>		
Net proceeds from equity offering	46,680	-
Borrowings under line of credit, net	-	(4,065 )
Treasury stock purchases	-	(433 )
Proceeds from stock option exercises	743	-
Proceeds from warrant exercises	180	-
Excess tax benefit from share-based compensation awards	8	-
<b>Net Cash and Cash Equivalents Provided by/(Used in) Financing Activities</b>	<b>47,611</b>	<b>(4,498 )</b>
<b>Change in Cash and Cash Equivalents</b>	<b>41,856</b>	<b>12,584</b>

Cash and cash equivalents, beginning of period	11,105	11
Cash and cash equivalents, end of period	\$ 52,961	\$ 12,595
Supplemental disclosure for cash flow information:		
Cash (received)/paid for interest	\$ (3	) \$ 250
Cash paid for income taxes	\$ 60	\$ -
Supplemental non-cash investing and financing activities:		
Issuance of common stock in connection with business combination	\$ -	\$ 40,034
Cancellation of Series D, Series C, Series B, and Series A preferred stock	\$ -	\$ 53,726
Acquired non-cash net assets	\$ -	\$ 11,597
Preferred stock dividends accrued	\$ -	\$ 4,974

*The accompanying notes are an integral part of these unaudited 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, the “Company,” “we,” or “us”) 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, which 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 continue to use these manufacturing assets to develop, produce, and distribute niche generic pharmaceutical products.

On June 19, 2013, pursuant to a merger agreement dated as of April 12, 2013, ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. ("ANIP") became a wholly-owned subsidiary of BioSante Pharmaceuticals, Inc. (“BioSante”) in an all-stock, tax-free reorganization (the "Merger"). The Merger was accounted for as a reverse acquisition, pursuant to which ANIP was considered the acquiring entity for accounting purposes. BioSante was renamed ANI Pharmaceuticals, Inc. We now operate under the leadership of the ANIP management team and our board of directors is comprised of two former BioSante directors and five former ANIP directors. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. The results of operations of both companies are included in our consolidated financial statements for all periods after completion of the Merger.

**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, 2013, 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, 2013. Certain prior period information has been reclassified to conform to the current period presentation.

### **Principles of Consolidation**

The condensed consolidated financial statements include the accounts of ANI Pharmaceuticals, Inc. and its wholly owned subsidiary, ANIP. All significant inter-company accounts and transactions are eliminated in consolidation.

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

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

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited 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, allowances for contingencies and litigation, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets. Actual results could differ from those estimates.

**Recent Accounting Pronouncements**

In July 2013, the Financial Accounting Standards Board (“FASB”) issued guidance for the presentation of an unrecognized tax benefit when a net operating loss (“NOL”) carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance requires an entity to present in the financial statements an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for an NOL carryforward, a similar tax loss, or a tax credit carryforward. If the NOL carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the jurisdiction or the tax law of the jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit will be presented in the financial statements as a liability and will not be combined with deferred tax assets. This guidance does not require any additional recurring disclosures and is effective for fiscal years beginning after December 15, 2013. The adoption of this guidance did not have a material impact on our financial statements.

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers.

The standard is effective for our reporting year beginning January 1, 2017 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.

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, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured, and we have no further performance obligations. Contract manufacturing arrangements are typically less than two weeks in duration, and therefore the revenue is recognized upon completion of the aforementioned factors rather than using a proportional performance method of revenue recognition. The estimates for discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments reduce gross revenues to net revenues in the accompanying unaudited condensed consolidated statements of operations, and are presented as current liabilities or reductions in accounts receivable in the accompanying unaudited condensed consolidated balance sheets (see “Accruals for Chargebacks, Returns, and Other Allowances”). 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, Returns and Other Allowances**

Our generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, 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 six-month periods ended June 30, 2014 and 2013, respectively:

(in thousands)	Accruals for Chargebacks, Returns and Other Allowances			
	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2013	4,076	736	735	332
Accruals/Adjustments	19,327	561	2,360	742
Credits Taken Against Reserve	(17,070)	(346)	(1,974)	(734)
Balance at June 30, 2014	\$ 6,333	\$ 951	\$ 1,121	\$ 340
Balance at December 31, 2012	5,662	411	231	242

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Accruals/Adjustments	12,183		853		850		430	
Credits Taken Against Reserve	(13,003	)	(914	)	(553	)	(449	)
Balance at June 30, 2013	\$ 4,842		\$ 350		\$ 528		\$ 223	

**Credit Concentration**

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

During the three month period ended June 30, 2014, three customers represented 29%, 22%, and 14% of net revenues. During the six month period ended June 30, 2014, these same three customers represented 26%, 19%, and 16% of net revenues. As of June 30, 2014, accounts receivable from these customers totaled \$6.2 million. During the three month period ended June 30, 2013, three customers represented 31%, 16%, and 12% of net revenues. During the six month period ended June 30, 2013, these same three customers represented 28%, 17%, and 13% of net revenues.

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**3. BUSINESS COMBINATION**

**Summary**

On June 19, 2013, BioSante acquired ANIP in an all-stock, tax-free reorganization. We are operating under the leadership of the ANIP management team and the board of directors is comprised of two former directors from BioSante and five former ANIP directors.

BioSante issued to ANIP stockholders shares of BioSante common stock such that the ANIP stockholders owned 57% of the combined company's shares outstanding, and the former BioSante stockholders owned 43%. In addition, immediately prior to the Merger, BioSante distributed to its then current stockholders contingent value rights ("CVR") providing payment rights arising from a future sale, transfer, license or similar transaction(s) involving BioSante's LibiGel<sup>®</sup> (female testosterone gel).

The Merger was accounted for as a reverse acquisition pursuant to which ANIP was considered the acquiring entity for accounting purposes. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. BioSante, the accounting acquiree, was a publicly-traded pharmaceutical company focused on developing high value, medically-needed products. ANIP entered into the Merger to secure additional capital and gain access to capital market opportunities as a public company. The results of operations of both companies are included in our consolidated financial statements for all periods after completion of the Merger.

**Transaction Costs**

In conjunction with the Merger, we incurred approximately \$7.1 million in transaction costs, which were expensed in the periods in which they were incurred. These costs include:

Category	(in thousands)
----------	----------------

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Legal fees	\$ 1,227
Accounting fees	122
Consulting fees	119
Monitoring and advisory fees	390
Transaction bonuses	4,801
Other	429
Total transaction costs	\$ 7,088

Of the total expenses, \$5.5 million and \$5.7 million was incurred and expensed in the three and six months ended June 30, 2013, respectively. For the three months ended June 30, 2013, \$4.8 million was recognized as selling, general and administrative expense, \$0.3 million as interest expense, and \$0.4 million as other expense. For the six months ended June 30, 2013, \$5.0 million was recognized as selling, general and administrative expense, \$0.3 million as interest expense, and \$0.4 million as other expense. No transaction-related expenses were incurred in the three or six months ended June 30, 2014.

**ANI PHARMACEUTICALS, INC. and subsidiary****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***3. BUSINESS COMBINATION – continued****Purchase Consideration and Net Assets Acquired**

The fair value of BioSante's common stock used in determining the purchase price was \$1.22 per share, the closing price on June 19, 2013, which resulted in a total purchase consideration of \$29.8 million. The fair value of all additional consideration, including the vested BioSante stock options and CVRs, was immaterial. The following presents the final allocation of the purchase consideration to the assets acquired and liabilities assumed on June 19, 2013:

	(in thousands)
Total purchase consideration	\$ 29,795
Assets acquired	
Cash and cash equivalents	18,198
Restricted cash	2,260
Teva license intangible asset	10,900
Other tangible assets	79
Deferred tax assets, net	-
Goodwill	1,838
Total assets	33,275
Liabilities assumed	
Accrued severance	2,965
Other liabilities	515
Total liabilities	3,480
Total net assets acquired	\$ 29,795

The Teva license is related to a generic male testosterone gel product and is being amortized on a straight-line basis over its estimated useful life of 11 years. Goodwill, which is not tax deductible since the transaction was structured as a tax-free exchange, is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition. As a result of purchase accounting related to the Merger, we established deferred tax assets of \$9.6 million, deferred tax liabilities of \$3.9 million, and a valuation allowance of \$5.7 million, netting to deferred tax assets of \$0.

**Pro Forma Condensed Combined Financial Information (unaudited)**

The following unaudited pro forma condensed combined financial information summarizes the results of operations for the periods indicated as if the Merger had been completed as of January 1, 2012. Pro forma information reflects adjustments relating to (i) elimination of the interest on ANIP's senior and convertible debt, (ii) elimination of monitoring and advisory fees payable to two ANIP investors, (iii) elimination of transaction costs, and (iv) amortization of intangibles acquired. The pro forma amounts do not purport to be indicative of the results that would have been obtained if the Merger had occurred as of January 1, 2012 or that may be obtained in the future.

(in thousands)	Three months ended June 30, 2013	Six months ended June 30, 2013
Net revenues	\$ 6,152	\$ 11,858
Net loss	\$ (3,352	) \$ (4,870 )

**ANI PHARMACEUTICALS, INC. and subsidiary****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***4. Earnings/(LOSS) per Share**

Basic earnings/(loss) 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 and certain of our outstanding warrants contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; the calculation of basic and diluted earnings/(loss) per share excludes from the numerator net income (but not net loss) attributable to the unvested restricted shares and to the participating warrants, and excludes the impact of those shares from the denominator. The numerator for earnings per share for the three and six months ended June 30, 2014 is calculated for basic and diluted earnings per share as follows:

(in thousands)	Three months ended		Six months ended	
	June 30, 2014		June 30, 2014	
	Basic	Diluted	Basic	Diluted
Net (loss)/income	\$ (2,363 )	\$ (2,363 )	\$ 996	\$ 996
Net income allocated to warrants	-	-	(6 )	(6 )
Net income allocated to restricted stock	-	-	(5 )	(5 )
Net (loss)/income allocated to common shares	\$ (2,363 )	\$ (2,363 )	\$ 985	\$ 985

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, and stock purchase warrants, using the treasury stock method. For periods of net income, anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, out-of-the-money warrants exercisable for common stock, and certain participating securities, if the effect of including both the income allocated to the participating security and the impact of the potential common shares would be anti-dilutive. Anti-dilutive shares have been excluded from the computation of diluted earnings/(loss) per share

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. For periods of net loss, anti-dilutive shares consist of Class C Special stock, common stock options, unvested restricted stock awards, and warrants exercisable for common stock

(and prior to the Merger, equity-linked securities, convertible preferred stock, and stock purchase warrants exercisable for preferred stock), and have been excluded from the computation of diluted earnings (loss) per share. Prior to the Merger (Note 3), anti-dilutive shares included equity-linked securities, convertible preferred stock, and stock purchase warrants exercisable for preferred stock. The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings/(loss) per share, was 1.1 million and 4.4 million for the three month periods ended June 30, 2014 and 2013, respectively and 0.7 million and 4.6 million for the six month periods ended June 30, 2014 and 2013, respectively.

As of June 30, 2014, we had 434 thousand options outstanding to purchase common stock, 79 thousand unvested restricted stock awards, and 535 thousand warrants to purchase common stock.



**ANI PHARMACEUTICALS, INC. and subsidiary****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***5. INVENTORIES**

Inventories consist of the following as of:

(in thousands)	June 30, 2014	December 31, 2013
Raw materials	\$ 3,452	\$ 1,480
Packaging materials	784	766
Work-in-progress	272	162
Finished goods	1,447	1,152
	5,955	3,560
Reserve for excess/obsolete inventories	(43 )	(42 )
Inventories, net	\$ 5,912	\$ 3,518

**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 supply reliably the API required for ongoing product manufacturing. During the three months ended June 30, 2014, we purchased approximately 34% of our inventory from two suppliers. During the six months ended June 30, 2014, we purchased approximately 40% of our inventory from the same two suppliers. As of June 30, 2014, amounts payable to these suppliers was \$0.2 million. During the three months ended June 30, 2013, we purchased approximately 36% of our inventory from three suppliers. During the six months ended June 30, 2013, we purchased approximately 40% of our inventory from the same three suppliers.

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

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

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

(in thousands)	June 30, 2014	December 31, 2013
Land	\$87	\$ 87
Buildings	3,682	3,682
Machinery, furniture and equipment	4,230	3,736
Construction in progress	106	229
	8,105	7,734
Less: accumulated depreciation	(3,480 )	(3,197 )
Property, Plant and Equipment, net	\$4,625	\$ 4,537

Depreciation expense for the three month periods ended June 30, 2014 and 2013 totaled \$146 thousand and \$134 thousand, respectively. Depreciation expense for the six month periods ended June 30, 2014 and 2013 totaled \$283 thousand and \$266 thousand, respectively. During the three and six month periods ended June 30, 2014 and 2013, there was no material interest capitalized into construction in progress.

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**7. GOODWILL AND  
INTANGIBLE ASSETS**

**Goodwill**

As a result of the Merger (Note 3), 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 changes 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, 2013, through June 30, 2014. No impairment losses were recognized during the three and six months ended June 30, 2014 or 2013.

**Acquisition of Abbreviated New Drug Applications**

On December 26, 2013, we entered into an agreement to purchase (the "Teva Purchase Agreement") Abbreviated New Drug Applications ("ANDAs") to produce 31 generic drug products from Teva Pharmaceuticals ("Teva") for \$12.5 million in cash and a percentage of future gross profits from product sales. According to the terms of the Teva Purchase Agreement, Teva was required to provide soft copy materials and transfer ownership of the ANDAs to us within five business days of signing the Teva Purchase Agreement, and we were required to pay the first installment of \$8.5 million upon receipt thereof. Teva provided the soft copy materials and transferred ownership of the ANDAs to us on January 2, 2014 and we paid the first installment of \$8.5 million to Teva on January 2, 2014. Teva was also required to provide hard copy materials to us within 90 days of signing the Teva Purchase Agreement. Teva provided the hard copy materials on March 5, 2014 and we paid the \$4.0 million balance on March 6, 2014.

The drug products include 20 solid-oral immediate release products, four extended release products and seven liquid products. We performed an assessment of the assets purchased and determined that this transaction was an asset purchase and not a business combination. The ANDAs are being amortized in full over their useful lives, averaging 10 years.

**Definite-Lived Intangible Assets**

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

(in thousands)	June 30, 2014		December 31, 2013		Amortization Period
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
Acquired ANDA intangible assets	\$12,577	\$ (686 )	\$ 60	\$ (55 )	3-10 years
Reglan® intangible asset	100	(100 )	100	(100 )	2 years
Teva license intangible asset	10,900	(991 )	10,900	(496 )	11 years
	\$23,577	\$ (1,777 )	\$ 11,060	\$ (651 )	

Our acquired ANDA and Reglan 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 those acquired pursuant to the Teva Purchase Agreement. The Teva license was acquired as part of the Merger (Note 3). 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 product rights. Amortization expense was \$0.6 million and \$13 thousand for the three months ended June 30, 2014 and 2013, respectively. Amortization expense was \$1.1 million and \$25 thousand for the six months ended June 30, 2014 and 2013, respectively.

**ANI PHARMACEUTICALS, INC. and subsidiary****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***7. GOODWILL AND INTANGIBLE ASSETS – continued**

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three months or six months ended June 30, 2014 and 2013 and therefore no impairment loss was recognized in the three or six months ended June 30, 2014 or 2013.

Expected future amortization expense is as follows:

(in thousands)	
2014 (remainder of the year)	\$1,122
2015	2,243
2016	2,243
2017	2,243
2018	2,243
2019 and thereafter	11,706
Total	\$21,800

**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 June 30, 2014, 659 thousand shares of our common stock remained available for issuance under the 2008 Plan.

On April 1, 2014, the Board of Directors approved grants of options to purchase 59 thousand shares of common stock and 30 thousand shares of restricted stock to our officers and options to purchase 16 thousand shares of common stock to non-employee directors. While the stock options were granted with no restrictions, the restricted stock was granted subject to shareholder approval of an increase in the total restricted stock available for grant under the 2008 Plan. The increase in total restricted stock available for grant under the 2008 Plan was approved by shareholders at the May 22, 2014 annual meeting and the restricted stock was granted as of May 22, 2014.

On July 12, 2013 and August 1, 2013, our Board of Directors approved grants to employees of stock options to purchase 325 thousand shares of ANI stock under the 2008 Plan, subject to shareholder approval of an increase in the total shares available for issuance under the 2008 Plan. The increase in total shares was approved by shareholders at the May 22, 2014 annual meeting, at which time we began recognizing stock-based compensation expense related to these awards.

In 2013, the Board of Directors granted options to purchase 21 thousand shares of common stock and 50 thousand shares of restricted stock to non-officer directors under the 2008 Plan.

Total expense related to stock options for both the three and six months ended June 30, 2014 was \$1.9 million, \$1.3 million of which was a catch-up charge related to the 325 thousand stock options previously approved by the Board of Directors on July 12, 2013 and August 1, 2013 and granted at the May 22, 2014 annual meeting. Total expense related to restricted stock grants for the three and six months ended June 30, 2014 was \$79 thousand and \$121 thousand, respectively. Total expense related to both stock options and restricted stock grants was \$0 for the three and six months ended June 30, 2013.

No options were exercised and 60 thousand options expired during the three months ended June 30, 2014. Options to purchase 30 thousand shares of common stock were exercised and 60 thousand options expired during the six month period ended June 30, 2014. No options were exercised and no options expired during the three and six months ended June 30, 2013. No restricted stock vested or was forfeited during the three and six months ended June 30, 2014 or 2013.

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**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.

In January 2014, warrants to purchase an aggregate of 20 thousand shares of common stock were exercised at \$9.00 per share. Warrants to purchase an aggregate of 19 thousand and 131 thousand shares of common stock expired unexercised during the three and six months ended June 30, 2014, respectively.

**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. Based upon historical losses and uncertainty of future taxable income, we have fully reserved for all net deferred tax assets as of June 30, 2014 and December 31, 2013. 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 remain subject to examination by taxing jurisdictions for the years 1998 and all

subsequent periods 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 amounts accrued relating to interest and penalties as of June 30, 2014 and December 31, 2013.

The effective tax rates for the three and six months ended June 30, 2014 were (5.3)% and 2.9% of pre-tax (loss)/income reported in the period, respectively, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2014. The Company has elected to exclude the impacts from significant pre-tax non-recognized subsequent events from its 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 and six month periods ended June 30, 2013, we did not have tax provisions due to the projected loss for the year, accumulated losses, which resulted in NOL carryforwards, and a full valuation allowance.



**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**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 \$242 thousand as of June 30, 2014.

Rent expense for the three months ended June 30, 2014 and 2013 totaled \$19 thousand and \$10 thousand, respectively. Rent expense for the six months ended June 30, 2014 and 2013 totaled \$36 thousand and \$14 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. In March 2014, we formally requested a pre-IND meeting with the FDA to discuss applying for an NDA for our Opium Tincture product. During the three months ended June 30, 2014 and 2013, net revenues for these products totaled \$3.8 million and \$1.8 million, respectively. During the six months ended June 30, 2014 and 2013, net revenues for these products totaled \$10.5 million and \$3.3 million, respectively.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 compliance policy guide, *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 and labeling standards, the FDA will not take action against us under the current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for these unapproved products for the three months ended June 30, 2014 and 2013 were \$0.1 million and \$0.8 million, respectively. Our contract manufacturing revenues for these unapproved products for the six months ended June 30, 2014 and 2013 were \$0.5 million and \$1.2 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 June 30, 2014 and 2013 were \$0.1 million. Our royalties on the net sales of these unapproved products for each of the six months ended June 30, 2014 and 2013 were \$0.1 million and \$0.2 million.

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**11. COMMITMENTS AND CONTINGENCIES – continued**

In October 2012, we received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of the Opium 10mg/mL Solution 118mL product (“Opium Tincture”), which is a non-NDA Product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research. Our counsel sent a letter to the FDA on November 9, 2012 in support of our position. On April 2, 2014, we received communication from the FDA confirming that the inspection was closed.

**Shareholder Class Action and Derivative Lawsuits**

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes, naming BioSante Pharmaceuticals, Inc. and our former President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of our disclosures relating to the efficacy of LibiGel<sup>®</sup> and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of our securities resulting in violations of Section 10(b) of the Exchange Act, Rule 10b-5 and Section 20(a) of the Exchange Act.

Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff sought to represent a class of persons who purchased our securities between February 12, 2010 and December 15, 2011, and sought unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys’ fees on behalf of such purchasers. On November 6, 2012, the plaintiff filed a consolidated amended complaint. On December 28, 2012, we and Mr. Simes filed motions to dismiss the consolidated amended complaint. On September 11, 2013, the Illinois district court judge granted defendants’ motions to dismiss, without prejudice, and gave plaintiffs 28 days to file an amended complaint. The plaintiffs did not file an amended complaint and the matter has been concluded.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of BioSante, filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption Weinstein v. BioSante Pharmaceuticals, Inc. et al., naming our directors as defendants and BioSante as a nominal defendant. A substantially

similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints alleged breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints sought unspecified damages, punitive damages, costs and disbursements, and unspecified reforms and improvements in our corporate governance and internal control procedures.

On September 24, 2012, the United States District Court consolidated the two shareholder derivative cases before it and on November 20, 2012, the plaintiffs filed their consolidated amended complaint. On January 11, 2013, the defendants filed a motion to dismiss the amended complaint. On September 11, 2013, the Illinois district court judge granted defendants' motions to dismiss, without prejudice, and gave plaintiffs 28 days to file an amended complaint. The plaintiffs did not file an amended complaint and the district court matter has been concluded.

On November 27, 2012, the plaintiff in the shareholder derivative action pending in Illinois state court filed an amended complaint. On January 18, 2013, the defendants filed a motion to dismiss the amended complaint. On July 1, 2013, the Illinois state court judge granted defendants' motions to dismiss, without prejudice, and gave plaintiffs until July 31, 2013 to file an amended complaint. On September 9, 2013, the Illinois state court judge granted defendants' motion to dismiss, with prejudice. On October 9, 2013, the plaintiffs filed a notice of appeal to Illinois state appellate court. The plaintiffs reached a settlement with the Company's insurance carrier in June 2014, which consisted of a one-time payment of \$60,000. On July 2, 2014, the Illinois state appellate court granted the plaintiffs motion for voluntary dismissal with prejudice, which concluded the matter.

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**11. COMMITMENTS AND CONTINGENCIES – continued**

**Louisiana Medicaid Lawsuit**

On September 11, 2013, the Attorney General of the State of Louisiana filed a lawsuit in Louisiana state court against numerous pharmaceutical companies, including us, under various state laws, alleging that each defendant caused the state's Medicaid agency to provide reimbursement for drug products that allegedly were not approved by the FDA and therefore allegedly not reimbursable under the federal Medicaid program. The lawsuit relates to three cough and cold prescription products manufactured and sold by our former Gulfport, Mississippi operation, which was sold in September 2010. Through its lawsuit, the state seeks unspecified damages, statutory fines, penalties, attorneys' fees and costs. 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. While we cannot predict the outcome of the lawsuit at this time, it 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 us, are facing allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name Reglan prior to the FDA's February 2009 Black Box warning requirement. We have been named and served in 92 separate complaints, including three in Pennsylvania, nine in New Jersey, and 80 in California, covering 2,944 plaintiffs in total. 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 manufactured by us 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 remaining cases. Our insurance company has assumed the defense of this matter. In addition, our insurance company renewed our product liability insurance on September 1, 2012 and 2013 with absolute exclusions for claims related to Reglan and metoclopramide. We are unable to predict the outcome of these matters and the possible loss or range of loss, if any, associated with their resolution or any potential effect the legal action may have on our operations. Furthermore, we cannot provide assurances that the outcome of these matters will not have an adverse effect on our business, results of operations, financial condition, and cash flow. Like all pharmaceutical

manufacturers, we in the future may be exposed to other product liability claims, which could harm our business, results of operations, financial condition, and cash flows.

## **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.

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

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.

**ANI PHARMACEUTICALS, INC. and subsidiary****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***12. FAIR VALUE DISCLOSURES – continued**

Our CVRs, which were granted coincident with the Merger, 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 and for the three and six months ended June 30, 2014.

Prior to the Merger, ANIP's warrants to purchase common and preferred stock were classified as derivative liabilities and were measured at fair value using level 3 inputs. The fair value of stock purchase warrants was determined using a two-step process that included valuing ANIP's equity using both market and discounted cash flow methods, and then apportioning that value, using an equity allocation model, to each of ANIP's classes of stock. These models require the use of unobservable inputs such as fair value of ANIP's common and preferred stock, expected term, anticipated volatility, future interest and interest rates, expected cash flows and the number of outstanding common and preferred shares as of a future date. We determined that the fair value of the derivative liabilities, and the changes in such fair value, was immaterial as of and for the three and six months ended June 30, 2013. All such stock purchase warrants expired in connection with the Merger.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of June 30, 2014 and December 31, 2013, by level within the fair value hierarchy:

(in thousands)				
Description	Fair Value at June 30, 2014	Level 1	Level 2	Level 3
Liabilities				

CVRs	\$	-	\$	-	\$	-	\$	-
------	----	---	----	---	----	---	----	---

Description	Fair Value at December 31, 2013	Level 1	Level 2	Level 3				
Liabilities								
CVRs	\$	-	\$	-	\$	-	\$	-

**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 six months ended June 30, 2014 and 2013.



**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**13. COLLABORATIVE ARRANGEMENTS**

*Sofgen Pharmaceuticals*

In April 2014, we entered into a collaboration agreement with Sofgen Pharmaceuticals (“Sofgen”) to develop an oral soft gel prescription product (the “April 2014 Sofgen Agreement”). The product will be subject to an ANDA filing once developed. In general, Sofgen will be responsible for the development, manufacturing and regulatory submission of the product, including preparation of the ANDA, and we will provide payments based on the completion of certain milestones. Upon approval, Sofgen will manufacture the drug and we will be responsible for the marketing and distribution, under our label, of the product in the United States, providing a percentage of profits from sales of the drug to Sofgen.

Under the April 2014 Sofgen Agreement, Sofgen will own all the rights, title and interest in the product. During the term of the April 2014 Sofgen Agreement, both parties are prohibited from developing, selling or distributing any product in the United States that is identical or bioequivalent to the product covered under the April 2014 Sofgen Agreement. The April 2014 Sofgen Agreement can be terminated or amended under certain specified circumstances. The April 2014 Sofgen Agreement has an initial term of ten years from the launch of the product, which term will automatically renew for two year terms until either party terminates the agreement.

We recognize the costs incurred with respect to the April 2014 Sofgen Agreement as expense and classify the expenses based on the nature of the costs. We have recorded \$9 thousand of research and development expense related to the April 2014 Sofgen Agreement. No revenue has yet been recognized with respect to the April 2014 Sofgen Agreement.

*Dexcel Pharma Technologies Ltd*

In June 2014, we entered into a collaboration agreement with Dexcel Pharma Technologies Ltd (“Dexcel”) to commercialize and sell a generic drug product (the “June 2014 Dexcel Agreement”). The product is subject to FDA approval of an ANDA filing. In general, Dexcel will be responsible for the manufacturing and regulatory submission

of the product, including obtaining approval of the ANDA, and we will provide payments based on the completion of certain milestones. Upon approval, Dexcel will manufacture the drug and we will be responsible for the marketing and distribution, under our label, of the product in the United States, providing a percentage of profits from sales of the drug to Dexcel.

Under the June 2014 Dexcel Agreement, Dexcel will own all the rights, title and interest in the product. During the term of the June 2014 Dexcel Agreement, both parties are prohibited from developing, selling, or distributing any product in the United States that is identical or bioequivalent to the product covered under the June 2014 Dexcel Agreement. The June 2014 Dexcel Agreement can be terminated or amended under certain specified circumstances. The June 2014 Dexcel Agreement has an initial term of five years from the launch of the product, which term can be renewed for two year terms if both parties agree, until either party terminates the agreement.

We recognize the costs incurred with respect to the June 2014 Dexcel Agreement as expense and classify the expenses based on the nature of the costs. We have not yet incurred any expense related to the June 2014 Dexcel Agreement and no revenue has yet been recognized with respect to the June 2014 Dexcel Agreement.

#### **14.**

#### **SUBSEQUENT EVENTS**

##### **Acquisition of Lithobid® Product Rights**

In July 2014, we entered into an agreement to purchase (the "Lithobid Purchase Agreement") the product rights to Lithobid from Noven Therapeutics, LLC ("Noven") for \$11.0 million in cash up front, and \$1.0 million in cash if certain approvals are received from the FDA on or before June 30, 2015. Pursuant to the terms of the Lithobid Purchase Agreement, we acquired the intellectual property rights and NDA associated with Lithobid, as well as raw material inventory. The product rights intangible asset will be amortized over its estimated useful life of ten years.

**ANI PHARMACEUTICALS, INC. and subsidiary**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**14. SUBSEQUENT EVENTS – continued**

**Acquisition of Vancocin® Product Rights**

In August 2014, we entered into an agreement to purchase (the “Vancocin Purchase Agreement”) the product rights to Vancocin from Shire ViroPharma Incorporated (“Shire”) for \$11.0 million in consideration. Pursuant to the terms of the Vancocin Purchase Agreement, we acquired the U.S. intellectual property rights and NDA associated with Vancocin, two related ANDAs, and certain equipment and inventory. The product rights intangible asset will be amortized over its estimated useful life of ten years.

## 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 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, 2013.*

### OVERVIEW

ANI Pharmaceuticals, Inc. and subsidiary (the "Company," "we," or "us") is an integrated specialty pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. Our targeted areas of product development currently include narcotics, oncologytics (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 continue to use these manufacturing assets to develop, produce, and distribute niche generic pharmaceutical products. These areas of focus reflect our specialized manufacturing experience and capabilities and offer a large number of attractive niche generic product opportunities.

Our product portfolio consists of both branded and generic pharmaceuticals, including:

#### **Generic Products**

Esterified Estrogen with Methyltestosterone Tablets  
Fluvoxamine Maleate Tablets  
Hydrocortisone Enema  
Metoclopramide Syrup

#### **Branded Products**

Cortenema®  
Reglan® Tablets

Opium Tincture

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

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

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

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

**Profit Potential.** We research the availability and cost of active pharmaceutical ingredients along with anticipated market share in determining which products to develop or acquire. In determining the potential profit of a product, our management forecasts 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		Six Months Ended	
	June 30, 2014	2013	June 30, 2014	2013
Net Revenues	\$ 6,647	\$ 6,152	\$ 17,546	\$ 11,713
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	2,117	2,171	4,739	4,580
Research and development	851	437	1,227	733
Selling, general and administrative	5,433	7,172	9,136	9,481
Depreciation and amortization	706	147	1,409	291
Operating (Loss)/ Income	(2,460 )	(3,775 )	1,035	(3,372 )
Interest income/(expense)	3	(374 )	3	(467 )
Other expense	(39 )	(434 )	(10 )	(484 )
Net (Loss)/Income Before Benefit/(Provision) for Income Taxes	(2,496 )	(4,583 )	1,028	(4,323 )
Benefit/(Provision) for income taxes	133	-	(32 )	-
Net (Loss)/Income	\$ (2,363 )	\$ (4,583 )	\$ 996	\$ (4,323 )

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 June				Six Months Ended June			
	30, 2014		2013		30, 2014		2013	
Net Revenues	100.0	%	100.0	%	100.0	%	100.0	%
Operating Expenses								
Cost of sales (excluding depreciation and amortization)	31.8	%	35.3	%	27.0	%	39.1	%
Research and development	12.8	%	7.1	%	7.0	%	6.3	%
Selling, general and administrative	81.7	%	116.6	%	52.1	%	80.9	%
Depreciation and amortization	10.6	%	2.4	%	8.0	%	2.5	%
Operating (Loss)/Income	(37.0	)%	(61.4	)%	5.9	%	(28.8	)%

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Interest income/(expense)	-	%	(6.1	)%	-	%	(4.0	)%
Other expense	(0.5	)%	(7.0	)%	-	%	(4.1	)%
Net (Loss)/Income Before Benefit/(Provision) for Income Taxes	(37.6	)%	(74.5	)%	5.9	%	(36.9	)%
Benefit/(Provision) for income taxes	2.0	%	-	%	(0.2	)%	-	%
Net (Loss)/Income	(35.5	)%	(74.5	)%	5.7	%	(36.9	)%

24

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2014 AND 2013**Net Revenues**

(in thousands)	Three Months Ended June 30,				
	2014	2013	Change	% Change	
Generic pharmaceutical products	\$ 4,836	\$ 2,829	\$ 2,007	70.9	%
Branded pharmaceutical products	569	1,115	(546 )	(49.0 )	%
Contract manufacturing	1,152	1,809	(657 )	(36.3 )	%
Contract services and other income	90	399	(309 )	(77.4 )	%
Total net revenues	\$ 6,647	\$ 6,152	\$ 495	8.0	%

We have historically derived 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 contract manufactured products.

Net revenues for the three months ended June 30, 2014 were \$6.6 million compared to \$6.2 million for the same period in 2013, an increase of \$0.5 million, or 8.0%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$4.8 million during the three months ended June 30, 2014, an increase of 70.9% compared to \$2.8 million for the same period in 2013. The primary reason for the increase was increased sales of Esterified Estrogen with Methyltestosterone tablets (“EEMT”), which was the result of increases in both market share and prices per bottle, due to a decrease in competition. In addition, we experienced increased sales for our HC Enema, Opium Tincture and Metoclopramide products. In the third quarter of 2013, a significant competitor stopped producing EEMT, which led to a material increase in our market share and enabled us to significantly increase the price we charge for the product. However, in the second quarter of 2014, the same competitor re-entered the market, which negatively impacted our EEMT unit sales and revenues during the period, which impact we expect will continue. Revenues for the three months ended June 30, 2014 were also reduced by \$3.9 million in charges related to price protection contract obligations for EEMT.

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 and labeling 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 June 30, 2014 and 2013 were \$3.8 million and \$1.8 million, respectively.

Net revenues for branded pharmaceutical products were \$0.6 million during the three months ended June 30, 2014, a decrease of 49.0% compared to \$1.1 million for the same period in 2013. The primary reasons for the decrease were lower unit sales of our Cortenema product and of Reglan tablets.

Contract manufacturing revenues were \$1.2 million during the three months ended June 30, 2014, a decrease of 36.3% compared to \$1.8 million for the same period in 2013, due to decreased orders from contract manufacturing customers during 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 June 30, 2014 and 2013 were \$0.1 million and \$0.8 million, respectively.

Contract services and other income were \$0.1 million during the three months ended June 30, 2014, a decrease of 77.4% from \$0.4 million for the same period in 2013, due to decreased contract service fees. 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 for each of the three month periods ended June 30, 2014 and 2013 were \$0.1 million.

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

(in thousands)	Three Months Ended June 30,			% Change
	2014	2013	Change	
Cost of sales (excl. depreciation and amortization)	\$ 2,117	\$ 2,171	\$ (54 )	(2.5 )%

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 consolidated statements of operations.

For the three months ended June 30, 2014, cost of sales decreased slightly to \$2.1 million from \$2.2 million for the same period in 2013, a decrease of \$0.1 million or 2.5%, primarily as a result of decreases in the cost of raw material for Opium Tincture and lower contract manufacturing sales. Cost of sales as a percentage of net revenues decreased to 31.8% during the three months ended June 30, 2014, from 35.3% during same period in 2013, primarily as a result of price increases for EEMT, a favorable shift in generic product mix toward higher margin products, as well as decreases in the cost of raw material for Opium Tincture.

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 APIs 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 June 30, 2014, we purchased 34% of our inventory from two suppliers. As of June 30, 2014, amounts payable to these suppliers were \$0.2 million. In the three months ended June 30, 2013, we purchased 36% of our inventory from three 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 June 30,				
	2014	2013	Change	% Change	
Research and development	\$ 851	\$ 437	\$414	94.7	%
Selling, general and administrative	5,433	7,172	(1,739)	(24.2)	%
Depreciation and amortization	706	147	559	380.3	%
Total other operating expenses	\$ 6,990	\$ 7,756	\$(766 )	(9.9 )	%

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

For the three months ended June 30, 2014, other operating expenses decreased to \$7.0 million from \$7.8 million for the same period in 2013, a decrease of \$0.8 million, or 9.9%, primarily as a result of the following factors:

Selling, general and administrative expenses decreased from \$7.2 million to \$5.4 million, primarily due to the lack of \$4.8 million of Merger-related expenses incurred in the prior year period. This was partially offset by increases in personnel and consulting, legal, and other fees related to becoming a public company, as well as a \$1.3 million catch-up charge for non-cash stock-based compensation, which was recognized upon shareholder approval of an increase in shares available for issuance under our stock compensation plan.

This decrease was partially offset by:

Research and development expenses increased from \$0.4 million to \$0.9 million, due to work on new development projects, including the ANDAs purchased from Teva Pharmaceuticals (“Teva”) in January 2014, new collaborations with Sterling Pharmaceuticals and Sofgen, and a filing fee for an ANDA submission of an anti-cancer drug.

Depreciation and amortization increased from \$0.1 million to \$0.7 million, an increase of 380.3%, due to amortization of the ANDAs purchased from Teva and amortization of the Teva license acquired in the Merger.

**Other Income/(Expense)**

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

(in thousands)	Three Months Ended June 30,			
	2014	2013	Change	% Change
Interest income/(expense)	\$ 3	\$ (374 )	\$ 377	(100.8 )%
Other income/(expense)	(39 )	(434 )	395	(91.0 )%
Total other income/(expense)	\$ (36 )	\$ (808 )	\$ 772	(95.5 )%

For the three months ended June 30, 2014, we recognized other expense of \$36 thousand versus \$808 thousand for the same period in 2013, a change of \$772 thousand, or 95.5%. This change resulted primarily from the following factors:

Interest income/(expense) changed from interest expense of \$374 thousand to interest income of \$3 thousand as a result of interest earned on our cash balance in 2014, as well as paying down our revolving line of credit in the second quarter of 2013, in connection with the Merger. Interest expense in the three months ended June 30, 2013 also included a termination fee and accelerated amortization of deferred loan costs.

Other expense decreased from \$434 thousand to \$39 thousand, due primarily to the absence of payments of \$390 thousand to certain of our investors for monitoring and advisory fees in 2013. Upon completion of the Merger, our obligation to pay monitoring and advisory fees was terminated.

RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2014 AND 2013**Net Revenues**

(in thousands)	Six Months Ended June 30,		Change	% Change	
	2014	2013			
Generic pharmaceutical products	\$ 12,880	\$ 5,493	\$ 7,387	134.5	%
Branded pharmaceutical products	1,353	1,979	(626 )	(31.6	)%
Contract manufacturing	2,771	3,549	(778 )	(21.9	)%
Contract services and other income	542	692	(150 )	(21.7	)%
Total net revenues	\$ 17,546	\$ 11,713	\$ 5,833	49.8	%

We have historically derived 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 contract manufactured products.

Net revenues for the six months ended June 30, 2014 were \$17.5 million compared to \$11.7 million for the same period in 2013, an increase of \$5.8 million, or 49.8%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$12.9 million during the six months ended June 30, 2014, an increase of 134.5% compared to \$5.5 million for the same period in 2013. The primary reason for the increase was increased sales of EEMT, which was the result of increases in both market share and prices per bottle due to a decrease in competition. In addition, we experienced increased sales for our Opium Tincture, HC Enema, Metoclopramide, and Fluvoxamine Maleate products. In the third quarter of 2013, a significant competitor stopped producing EEMT, which led to a material increase in our market share and enabled us to significantly increase the price we charge for the product. However, in the first half of 2014, the same competitor re-entered the market, which negatively impacted our EEMT unit sales and revenues during the period, which impact we expect will continue. Revenues for the six months ended June 30, 2014 also were reduced by \$3.9 million in charges related to price protection contract obligations for EEMT.

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 and labeling 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 six months ended June 30, 2014 and 2013 were \$10.5 million and \$3.3 million, respectively.

Net revenues for branded pharmaceutical products were \$1.4 million during the six months ended June 30, 2014, a decrease of 31.6% compared to \$2.0 million for the same period in 2013. The primary reasons for the decrease were lower unit sales of our Cortenema product and of Reglan tablets.

Contract manufacturing revenues were \$2.8 million during the six months ended June 30, 2014, a decrease of 21.9% compared to \$3.5 million for the same period in 2013, due to decreased orders from contract manufacturing customers during 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 six months ended June 30, 2014 and 2013 were \$0.5 million and \$1.2 million, respectively.

Contract services and other income were \$0.5 million during the six months ended June 30, 2014, a decrease of 21.7% from \$0.7 million for the same period in 2013, due to decreased contract service fees, partially offset by increased billings related to achievement of project milestones for one of our customers in the first 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 for each of the six month periods ended June 30, 2014 and 2013 were \$0.1 million and \$0.2 million.

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

(in thousands)	Six Months Ended June 30,			
	2014	2013	Change	% Change
Cost of sales (excl. depreciation and amortization)	\$ 4,739	\$ 4,580	\$ 159	3.5 %

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 consolidated statements of operations.

For the six months ended June 30, 2014, cost of sales increased slightly to \$4.7 million from \$4.6 million for the same period in 2013, an increase of \$0.2 million or 3.5%, primarily as a result of an increase in sales of generic pharmaceutical products. Cost of sales as a percentage of net revenues decreased to 27.0% during the six months ended June 30, 2014, from 39.1% during same period in 2013, primarily as a result of price increases for EEMT, a favorable shift in product mix toward higher margin products, as well as decreases in the cost of raw material for Opium Tincture.

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 APIs 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 six months ended June 30, 2014, we purchased 40% of our inventory from two suppliers. As of June 30, 2014, amounts payable to these suppliers were \$0.2 million. In the six months ended June 30, 2013, we purchased 40% of our inventory from three 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)	Six Months Ended June 30,			
	2014	2013	Change	% Change
Research and development	\$ 1,227	\$ 733	\$ 494	67.4 %
Selling, general and administrative	9,136	9,481	(345 )	(3.6 )%
Depreciation and amortization	1,409	291	1,118	384.2 %
Total other operating expenses	\$ 11,772	\$ 10,505	\$ 1,267	12.1 %

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

For the six months ended June 30, 2014, other operating expenses increased to \$11.8 million from \$10.5 million for the same period in 2013, an increase of \$1.3 million, or 12.1%, primarily as a result of the following factors:

Research and development expenses increased from \$0.7 million to \$1.2 million, due to work on new development projects, including the Teva products, new collaborations with Sterling Pharmaceuticals and Sofgen, and a filing fee for an ANDA submission of an anti-cancer drug.

Depreciation and amortization increased from \$0.3 million to \$1.4 million, an increase of 384.2%, due to amortization of the ANDAs purchased from Teva in the first quarter of 2014 and amortization of the Teva license acquired in the Merger.

These increases were partially offset by:

Selling, general and administrative expenses decreased, from \$9.5 million to \$9.1 million, primarily due to the lack of \$5.0 million of Merger-related expenses incurred in the prior year period. This was partially offset by increases in personnel and consulting, legal, and other fees related to becoming a public company, as well as a \$1.3 million catch-up charge for non-cash stock-based compensation, which was recognized upon shareholder approval of an increase in shares available for issuance under our stock compensation plan.

**Other Income/(Expense)**

(in thousands)	Six Months Ended June 30,			
	2014	2013	Change	% Change
Interest income/(expense)	\$ 3	\$ (467 )	\$ 470	(100.6 )%
Other income/(expense)	(10 )	(484 )	474	(97.9 )%
Total other income/(expense)	\$ (7 )	\$ (951 )	\$ 944	(99.3 )%

For the six months ended June 30, 2014, we recognized other expense of \$7 thousand versus of \$951 thousand for the same period in 2013, a change of \$944 thousand, or 99.3%. This change resulted primarily from the following factors:

Interest expense decreased from \$467 thousand of expense to \$3 thousand of income as a result of interest earned on our cash balance in 2014, as well as paying down our revolving line of credit in the second quarter of 2013, in connection with the Merger. Interest expense in the six months ended 2013 also included a termination fee and accelerated amortization of deferred loan costs.

Other expense decreased from \$484 thousand to \$10 thousand, due primarily to the absence of payments of \$390 thousand to certain of our investors for monitoring and advisory fees in 2013. Upon completion of the Merger, our obligation to pay monitoring and advisory fees was terminated.

## LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	June 30, 2014	December 31, 2013
Cash and cash equivalents	\$52,961	\$ 11,105
Accounts receivable, net	7,794	12,513
Inventories	5,912	3,518
Prepaid expenses	493	580
Total current assets	\$67,160	\$ 27,716
Accounts payable	\$1,731	\$ 1,429
Accrued expenses	1,133	1,326
Returned goods reserve	951	736
Deferred revenue	13	47
Total current liabilities	\$3,828	\$ 3,538

At June 30, 2014, we had \$53.0 million in unrestricted cash and cash equivalents. At December 31, 2013, we had \$11.1 million in unrestricted cash and cash equivalents. We received net proceeds of \$46.7 million from a follow-on public offering that closed on March 10, 2014. In addition, we acquired ANDAs related to 31 products for \$12.5 million from Teva and generated \$7.1 million of cash from operations. In July 2014, we acquired the product rights for Lithobid for \$11.0 million and will pay an additional \$1.0 million if certain approvals are received from the FDA. In August 2014, we acquired the U.S. intellectual property rights and NDA associated with Vancocin, two related ANDAs, and certain equipment and inventory for \$11.0 million.

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)	Six Months ended June 30,	
	2014	2013
Operating Activities	\$ 7,133	\$ (988 )
Investing Activities	\$ (12,888 )	\$ 18,070
Financing Activities	\$ 47,611	\$ (4,498 )

### Net Cash Provided By/(Used In) Operations

Net cash provided by operating activities was \$7.1 million for the six months ended June 30, 2014, compared to \$1.0 million used in operating activities during the same period in 2013, an increase in cash provided of \$8.1 million between the periods. This increase was due to changes in net income and changes in current assets and current liabilities. Net income from operations for the six months ended June 30, 2014 increased by \$3.8 million from the same period in 2013, after adjusting for non-cash expenses. Changes in current assets and current liabilities for the six months ended June 30, 2014 provided cash of \$2.7 million compared to a use of cash of \$1.6 million for the same period in 2013, an increase of approximately \$4.3 million between the periods. Accounts receivable decreased by \$4.7 million in the six months ended June 30, 2014 as compared with an increase of \$1.0 million in the prior year period, due to price-protection contract obligations for EEMT, as well as increased collections. Accounts payable increased by \$0.3 million in the six months ended June 30, 2014 as compared with a decrease of \$0.4 million in the prior year period. Accrued expenses remained flat in the six months ended June 30, 2014, as compared with a decrease of \$0.6 million in the prior year period. These increases to cash provided were partially offset by an increase to inventory of \$2.4 million in the six months ended June 30, 2014 as compared with a \$0.2 million decrease in the prior year period.

### **Net Cash (Used In)/Provided By Investing Activities**

Net cash used in investing activities for the six months ended June 30, 2014 was \$12.9 million, principally due to the \$12.5 million asset acquisition of the Teva ANDA products, in addition to \$0.4 million of capital expenditures during the period. Net cash provided by investing activities was \$18.1 million during the same period in 2013, relating primarily to the net cash acquired in the Merger, partially offset by capital expenditures.

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

Net cash provided by financing activities was \$47.7 million for the six months ended June 30, 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 six months ended June 30, 2014. Net cash used in financing activities was \$4.5 million during the same period in 2013, resulting primarily from the repayment in June 2013 of our revolving line of credit in connection with the Merger.

### **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 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, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets.

A summary of our significant accounting policies is included in Item 8. Consolidated Financial Statements, Note 1 — Description of Business and Summary of Significant Accounting Policies, in our Annual Report on Form 10-K for the year ended December 31, 2013. 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, 2013.

RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In July 2013, the Financial Accounting Standards Board (“FASB”) issued guidance for the presentation of an unrecognized tax benefit when a net operating loss (“NOL”) carryforward, a similar tax loss, or a tax credit carryforward exists. The guidance requires an entity to present in the financial statements an unrecognized tax benefit, or a portion of an unrecognized tax benefit, as a reduction to a deferred tax asset for an NOL carryforward, a similar tax loss, or a tax credit carryforward. If the NOL carryforward, a similar tax loss, or a tax credit carryforward is not available at the reporting date under the tax law of the jurisdiction or the tax law of the jurisdiction does not require the entity to use, and the entity does not intend to use, the deferred tax asset for such purpose, the unrecognized tax benefit will be presented in the financial statements as a liability and will not be combined with deferred tax assets. This guidance does not require any additional recurring disclosures and is effective for fiscal years beginning after December 15, 2013. The adoption of this guidance did not have a material impact on our financial statements.

**CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS**

As of June 30, 2014 and December 31, 2013, 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**

Not required due to Smaller Reporting Company status.

**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 June 30, 2014. 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 June 30, 2014 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, 2013 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.

*Our ability to utilize our net operating loss and tax credit carryforwards in the future is subject to substantial limitations and we may not be able to use certain identified net operating loss and tax credit carryforwards in the future, which could result in increased tax payments in future periods.*

Under Section 382 of the Internal Revenue Code, if a corporation undergoes an ownership change (generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation’s ability to use its pre-change net operating loss (“NOL”) carryforwards and other pre-change tax attributes to offset its post-change income may be limited. On June 19, 2013, BioSante experienced an ownership change. Accordingly, our ability to utilize BioSante’s NOL and tax credit carryforwards attributable to periods prior to June 19, 2013 is subject to substantial limitations. In addition, as a result of the offering that closed on March 10, 2014, we believe that ANIP Acquisition Company experienced an ownership change. Accordingly, our ability to utilize ANIP Acquisition Company’s NOL and tax credit carryforwards attributable to periods prior to the offering is subject to substantial limitations. These limitations, in turn, could result in increased future tax payments, which could be material.

**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: August 7, 2014 By: /s/ Arthur S. Przybyl  
Arthur S. Przybyl  
President and  
Chief Executive Officer  
(Principal Executive Officer)

Date: August 7, 2014 By: /s/ Charlotte C. Arnold  
Charlotte C. Arnold  
Vice President 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