

ANI PHARMACEUTICALS INC  
Form 10-Q  
August 04, 2016

**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, 2016**

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

**For the transition period from                      to                      .**

**Commission File Number 001-31812**

**ANI PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

**210 Main Street West**

**Baudette, Minnesota**

(Address of principal executive offices)

**(218) 634-3500**

(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x NO "

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

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

Large accelerated filer "

Accelerated filer x

Non-accelerated filer "

Smaller reporting company "

(Do not check if smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES " NO x

As of July 28, 2016, there were 11,514,495 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, 2016**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>PART I—FINANCIAL INFORMATION</u></b>	
Item 1. Financial Statements (unaudited)	
<u>Condensed Consolidated Balance Sheets — As of June 30, 2016 and December 31, 2015</u>	4
<u>Condensed Consolidated Statements of Earnings — For the Three and Six Months Ended June 30, 2016 and 2015</u>	5
<u>Condensed Consolidated Statements of Cash Flows — For the Six Months Ended June 30, 2016 and 2015</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>	24
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	40
Item 4. <u>Controls and Procedures</u>	41
<b><u>PART II—OTHER INFORMATION</u></b>	
Item 1. <u>Legal Proceedings</u>	41
Item 1A. <u>Risk Factors</u>	41
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	41
Item 3. <u>Defaults upon Senior Securities</u>	41
Item 4. <u>Mine Safety Disclosures</u>	41
Item 5. <u>Other Information</u>	42
Item 6. <u>Exhibits</u>	42
<u>Signatures</u>	43



## CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

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

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

*These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2015, including the factors described in "Item 1A. Risk Factors." Other risks may be described from time to time in our filings made under the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.*

## NOTE REGARDING TRADEMARKS

Cortenema®, Corticotrophin®, Corticotrophin-Zinc®, Inderal® LA, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries.

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

	June 30, 2016	December 31, 2015
Assets		
Current Assets		
Cash and cash equivalents	\$15,014	\$ 154,684
Accounts receivable, net of \$23,406 and \$13,586 of adjustments for chargebacks and other allowances at June 30, 2016 and December 31, 2015, respectively	35,562	21,932
Inventories, net	25,052	13,387
Prepaid income taxes	150	1,127
Prepaid expenses and other current assets	4,046	1,453
Total Current Assets	79,824	192,583
Property and equipment, net	8,911	7,131
Restricted cash	5,001	-
Deferred tax asset, net of valuation allowance	17,751	17,316
Intangible assets, net	194,674	66,397
Goodwill	1,838	1,838
Total Assets	\$307,999	\$ 285,265
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$4,961	\$ 2,066
Accrued expenses and other	770	617
Accrued royalties	8,110	606
Accrued compensation and related expenses	1,071	1,188
Accrued Medicaid rebates	6,509	4,631
Returned goods reserve	3,309	2,648
Total Current Liabilities	24,730	11,756
Long-term Liabilities		
Long-term royalties	2,500	-

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Convertible notes, net of discount and deferred financing costs	116,993	113,427
Total Liabilities	\$ 144,223	\$ 125,183
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, \$0.0001 par value, 33,333,334 shares authorized; 11,513,802 shares issued and outstanding at June 30, 2016; 11,498,228 shares issued and outstanding at December 31, 2015	1	1
Class C Special Stock, \$0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	-	-
Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	-	-
Additional paid-in capital	168,154	164,431
Accumulated deficit	(4,379 )	(4,350 )
Total Stockholders' Equity	163,776	160,082
Total Liabilities and Stockholders' Equity	\$ 307,999	\$ 285,265

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



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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net Revenues	\$ 31,337	\$ 19,516	\$ 51,892	\$ 38,315
Operating Expenses:				
Cost of sales (excluding depreciation and amortization)	11,795	3,141	15,205	5,892
Research and development	764	995	1,730	1,398
Selling, general, and administrative	7,628	5,551	13,532	10,302
Depreciation and amortization	5,956	1,415	10,565	2,742
Total Operating Expenses	26,143	11,102	41,032	20,334
Operating Income	5,194	8,414	10,860	17,981
Other Expense, net				
Interest expense, net	(2,830 )	(2,749 )	(5,612 )	(5,474 )
Other (expense)/income, net	(12 )	-	(10 )	68
Income Before Provision for Income Taxes	2,352	5,665	5,238	12,575
Provision for income taxes	(1,227 )	(2,094 )	(2,767 )	(4,635 )
Net Income	\$ 1,125	\$ 3,571	\$ 2,471	\$ 7,940
Basic and Diluted Earnings Per Share:				
Basic Earnings Per Share	\$ 0.10	\$ 0.31	\$ 0.22	\$ 0.70
Diluted Earnings Per Share	\$ 0.10	\$ 0.31	\$ 0.21	\$ 0.68
Basic Weighted-Average Shares Outstanding	11,402	11,344	11,398	11,335
Diluted Weighted-Average Shares Outstanding	11,541	11,549	11,514	11,556

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



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

	Six Months Ended June 30,	
	2016	2015
<b>Cash Flows From Operating Activities</b>		
Net income	\$ 2,471	\$ 7,940
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	3,322	1,597
Deferred taxes	(435 )	413
Depreciation and amortization	10,565	2,742
Non-cash interest relating to convertible notes and loan cost amortization	3,482	3,388
Changes in operating assets and liabilities:		
Accounts receivable, net	(13,630 )	(1,583 )
Inventories, net	(807 )	(5,183 )
Prepaid expenses and other current assets	(1,992 )	368
Accounts payable	2,850	(1,379 )
Accrued royalties	2,423	(220 )
Accrued compensation and related expenses	(117 )	(504 )
Current income taxes, net	977	(5,275 )
Accrued Medicaid rebates	1,878	(373 )
Accrued expenses, returned goods reserve, and other	3,319	395
<b>Net Cash and Cash Equivalents Provided by Operating Activities</b>	<b>14,306</b>	<b>2,326</b>
<b>Cash Flows From Investing Activities</b>		
Changes in restricted cash	(5,001 )	-
Acquisition of product rights and other related assets	(144,494 )	(4,500 )
Acquisition of property and equipment	(2,088 )	(310 )
<b>Net Cash and Cash Equivalents Used in Investing Activities</b>	<b>(151,583 )</b>	<b>(4,810 )</b>
<b>Cash Flows From Financing Activities</b>		
Payment of debt issuance costs	(294 )	-
Proceeds from stock option exercises	504	244
Excess tax benefit from share-based compensation awards	19	47

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Repurchase of common stock under the stock repurchase program	(2,500	)	-
Treasury stock purchases for restricted stock vestings and forfeitures	(122	)	(113 )
Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities	(2,393	)	178
Change in Cash and Cash Equivalents	(139,670	)	(2,306 )
Cash and cash equivalents, beginning of period	154,684		169,037
Cash and cash equivalents, end of period	\$ 15,014		\$ 166,731
Supplemental disclosure for cash flow information:			
Cash paid for interest	\$ 2,156		\$ 2,048
Cash paid for income taxes, net	\$ 2,206		\$ 9,450
Supplemental non-cash investing and financing activities:			
Accrued royalties related to asset purchase	\$ 3,882		\$ -
Property and equipment purchased and included in accounts payable	\$ 45		\$ 50

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

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

**Overview**

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, “ANI,” the “Company,” “we,” “us,” or “our”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. Our targeted areas of product development currently include controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations involving extended release and combination products. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota that are capable of producing oral solid dose products, as well as liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. Our strategy is to use our assets to develop, acquire, manufacture, and market branded and generic specialty prescription pharmaceuticals. By executing this strategy, we believe we will be able to continue to grow the business, expand and diversify our product portfolio, and create long-term value for our investors.

**Basis of Presentation**

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations, and cash flows. The consolidated balance sheet at December 31, 2015, has been derived from audited financial statements of that date. The unaudited interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our Annual Report on Form 10-K for the year ended December 31, 2015. Certain prior period information has been reclassified to conform to the current period presentation.

## **Principles of Consolidation**

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

## **Foreign Currency**

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

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**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 interim condensed consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, administrative fees and rebates, Medicaid rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, purchase price allocations, and the depreciable lives of long-lived assets. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

**Recent Accounting Pronouncements**

In March 2016, the Financial Accounting Standards Board (“FASB”) issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards. Under the guidance, all excess tax benefits and tax deficiencies related to stock-based compensation awards are to be recognized as income tax expenses or benefits in the income statement and excess tax benefits should be classified along with other income tax cash flows in the operating activities section of the statement of cash flows. Under the guidance, companies can also elect to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. In addition, the guidance amends some of the other stock-based compensation awards guidance to more clearly articulate the requirements and cash flow presentation for withholding shares for tax-withholding purposes. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted, though all amendments of the guidance must be adopted in the same period. The adoption of certain amendments of the guidance must be applied prospectively, and adoption of the remaining amendments must be applied either on a modified retrospective basis or retrospectively to all periods presented. We are currently evaluating the impact that this guidance will have on our consolidated financial statements.

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

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We are currently evaluating the impact that this guidance will have on our consolidated financial statements.

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



**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

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

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

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

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

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. We are currently evaluating the impact, if any, that this guidance will have on our consolidated 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 condensed consolidated statements of earnings, balance sheets, or cash flows.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**2. REVENUE RECOGNITION AND RELATED ALLOWANCES**

**Revenue Recognition**

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

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

**Accruals for Chargebacks, Rebates, Returns, and Other Allowances**

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

of credit to the customer.

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

(in thousands)	Accruals for Chargebacks, Rebates, Returns, and Other Allowances				
	Chargebacks	Medicaid Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2014	\$ 6,865	\$ 2,264	\$ 1,445	\$ 1,487	\$ 471
Accruals/Adjustments	21,644	2,177	776	2,913	1,231
Credits Taken Against Reserve	(22,588 )	(2,550 )	(502 )	(2,960 )	(1,217 )
Balance at June 30, 2015	\$ 5,921	\$ 1,891	\$ 1,719	\$ 1,440	\$ 485
Balance at December 31, 2015	\$ 11,381	\$ 4,631	\$ 2,648	\$ 1,653	\$ 674
Accruals/Adjustments	43,349	5,773	3,256	5,071	2,180
Credits Taken Against Reserve	(34,731 )	(3,895 )	(2,595 )	(4,274 )	(1,678 )
Balance at June 30, 2016	\$ 19,999	\$ 6,509	\$ 3,309	\$ 2,450	\$ 1,176

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued**

**Credit Concentration**

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

During the three months ended June 30, 2016, three customers represented 28%, 21%, and 18% of net revenues, respectively. During the six months ended June 30, 2016, these same three customers represented 25%, 24%, and 17% of net revenues, respectively, and accounts receivable from these customers totaled 74% of accounts receivable, net as of June 30, 2016. During the three months ended June 30, 2015, three customers represented 20%, 18%, and 15% of net revenues, respectively. During the six months ended June 30, 2015, these same three customers represented 20%, 22%, and 19% of net revenues, respectively.

**3. INDEBTEDNESS**

***Convertible Senior Notes***

In December 2014, we issued \$143.8 million of our Convertible Senior Notes due 2019 (the “Notes”) in a registered public offering. The Notes pay 3.0% interest semi-annually in arrears starting on June 1, 2015 and are due December 1, 2019. The initial conversion price was \$69.48 per share. Simultaneous with the issuance of the Notes, we entered into “bond hedge” (or purchased call) and “warrant” (or written call) transactions with an affiliate of one of the offering underwriters in order to synthetically raise the initial conversion price of the Notes to \$96.21 per share and reduce the potential common stock dilution that may arise from the conversion of the Notes.

The Notes are convertible at the option of the holder under certain circumstances and upon conversion we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof. As a result of our cash

conversion option, we separately accounted for the value of the embedded conversion option as a debt discount (with an offset to Additional Paid in Capital (“APIC”)) of \$33.6 million. Deferred financing costs are recorded as a reduction of long-term debt in the consolidated balance sheets and are being amortized as additional non-cash interest expense over the term of the debt, since this method was not significantly different from the effective interest method.

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

(in thousands)	June 30, 2016	December 31, 2015
Principal amount	\$143,750	\$ 143,750
Unamortized debt discount	(23,872 )	(27,016 )
Deferred financing costs	(2,885 )	(3,307 )
Net carrying value	\$116,993	\$ 113,427

We had accrued interest of \$0.4 million related to the Notes recorded in Accrued expenses, other in our consolidated balance sheets at both June 30, 2016 and December 31, 2015.

**ANI PHARMACEUTICALS, INC. and subsidiarIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***3. INDEBTEDNESS – continued**

The following table sets forth the components of total interest expense related to the Notes recognized in the accompanying unaudited interim condensed consolidated statements of earnings for the three and six months ended June 30, 2016 and 2015:

(in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2016	June 30, 2015	June 30, 2016	June 30, 2015
Contractual coupon	\$ 1,078	\$ 1,078	\$ 2,156	\$ 2,156
Amortization of debt discount	1,582	1,501	3,144	2,981
Amortization of finance fees	211	211	422	422
Capitalized interest	(54 )	(6 )	(100 )	(15 )
	\$ 2,817	\$ 2,784	\$ 5,622	\$ 5,544

As of June 30, 2016, the effective interest rate on the Notes was 7.8%, on an annualized basis.

***Line of Credit***

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

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

As of June 30, 2016, we had no outstanding balance on the Line of Credit. In the three months ended June 30, 2016, we deferred \$0.3 million of debt issuance costs related to the Line of Credit, which will be amortized over the three year life of the Line of Credit. The \$0.3 million of deferred debt issuance costs are included in prepaid expenses and other current assets in the accompanying unaudited interim condensed consolidated balance sheet at June 30, 2016. During the period from when we entered into the Line of Credit through June 30, 2016, we recorded \$16 thousand of interest expense related to the Line of Credit.



**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**4. EARNINGS PER SHARE**

Basic earnings per share is computed by dividing net income available to common shareholders by the weighted-average number of shares of common stock outstanding during the period.

For periods of net income, and when the effects are not anti-dilutive, we calculate diluted earnings per share by dividing net income available to common shareholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options, unvested restricted stock awards, stock purchase warrants, and any conversion gain on our Notes (Note 3), using the treasury stock method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share.

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

For purposes of determining diluted earnings per share, we have elected a policy to assume that the principal portion of the Notes (Note 3) is settled in cash. As such, the principal portion of the Notes has no effect on either the numerator or denominator when determining diluted earnings per share. Any conversion gain is assumed to be settled in shares and is incorporated in diluted earnings per share using the treasury method. The warrants issued in conjunction with the issuance of the Notes (Note 3) are considered to be dilutive when they are in-the-money relative to our average stock price during the period; the bond hedge purchased in conjunction with the issuance of the Notes is always considered to be anti-dilutive.

Earnings per share for the three and six months ended June 30, 2016 and 2015 are calculated for basic and diluted earnings per share as follows:

Basic	Diluted	Basic	Diluted
-------	---------	-------	---------

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

(in thousands, except per share amounts)	Three Months Ended June 30,		Three Months Ended June 30,		Six Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015	2016	2015	2016	2015
Net income	\$1,125	\$3,571	\$1,125	\$3,571	\$2,471	\$7,940	\$2,471	\$7,940
Net income allocated to restricted stock	(8 )	(24 )	(8 )	(23 )	(17 )	(53 )	(17 )	(52 )
Net income allocated to common shares	\$1,117	\$3,547	\$1,117	\$3,548	\$2,454	\$7,887	\$2,454	\$7,888
Basic Weighted-Average Shares Outstanding	11,402	11,344	11,402	11,344	11,398	11,335	11,398	11,335
Dilutive effect of stock options			139	205			116	221
Diluted Weighted-Average Shares Outstanding			11,541	11,549			11,514	11,556
Earnings Per Share	\$0.10	\$0.31	\$0.10	\$0.31	\$0.22	\$0.70	\$0.21	\$0.68

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, including the shares underlying the Notes, was 4.5 million and 4.6 million for the three months ended June 30, 2016 and 2015, respectively and was 4.5 million and 4.6 million for the six months ended June 30, 2016 and 2015, respectively. Anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the treasury stock method, underlying shares related to out-of-the-money bonds issued as convertible debt, and out-of-the-money warrants exercisable for common stock.

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

Inventories consist of the following as of:

(in thousands)	June 30, 2016	December 31, 2015
Raw materials	\$ 12,583	\$ 10,192
Packaging materials	935	998
Work-in-progress	588	456
Finished goods	11,204	1,897
	25,310	13,543
Reserve for excess/obsolete inventories	(258 )	(156 )
Inventories, net	\$ 25,052	\$ 13,387

**Vendor Concentration**

We source the raw materials for our products, including active pharmaceutical ingredients (“API”), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. As a result, we are dependent upon our current vendors to reliably supply the API required for ongoing product manufacturing. During the three months ended June 30, 2016, we purchased approximately 48% of our inventory from four suppliers. As of June 30, 2016, amounts payable to these four suppliers totaled \$0.3 million. During the six months ended June 30, 2016, we purchased approximately 29% of our inventory from two suppliers. As of June 30, 2016, amounts payable to these two suppliers totaled \$0.2 million. During the three months ended June 30, 2015, we purchased approximately 43% of our inventory from two suppliers. During the six months ended June 30, 2015, we purchase approximately 40% of our inventory from the same two suppliers.

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

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

(in thousands)	June 30, 2016	December 31, 2015
Land	\$87	\$ 87
Buildings	3,682	3,682
Machinery, furniture, and equipment	7,311	5,623
Construction in progress	2,725	2,189
	13,805	11,581
Less: accumulated depreciation	(4,894 )	(4,450 )
Property, Plant, and Equipment, net	\$8,911	\$ 7,131

Depreciation expense was \$0.2 million for both the three months ended June 30, 2016 and 2015. Depreciation expense was \$0.4 million and \$0.3 million for the six months ended June 30, 2016 and 2015. During the three months ended June 30, 2016 and 2015, there was \$54 thousand and \$6 thousand of interest capitalized into construction in progress, respectively. During the six months ended June 30, 2016 and 2015, there was \$0.1 million and \$15 thousand of interest capitalized into construction in progress, respectively. Construction in progress consists of multiple projects, primarily related to new equipment to expand our manufacturing capability as our product lines continue to grow.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**7. GOODWILL AND INTANGIBLE ASSETS**

**Goodwill**

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. (“BioSante”), we recorded goodwill of \$1.8 million in our one reporting unit. We assess the recoverability of the carrying value of goodwill as of October 31<sup>st</sup> of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value from the most recent assessment on October 31, 2015 through June 30, 2016. No impairment losses were recognized during the three or six months ended June 30, 2016 or 2015.

**Definite-lived Intangible Assets**

*Acquisition of Abbreviated New Drug Applications*

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

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

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

*Acquisition of New Drug Applications and Product Rights*

In April 2016, we purchased the rights, title, and interest in the New Drug Application (“NDA”) for Inderal LA, as well as certain documentation, trademark rights, and finished goods from Cranford Pharmaceuticals, LLC for \$60.0 million in cash up front and milestone payments based on future gross profits from sales of products under the NDA. We made the \$60.0 million upfront cash payment using cash on hand, capitalized \$0.3 million of costs directly related to the transaction, and recognized \$3.9 million of minimum milestone payments for a total purchase price of \$64.2 million. We accounted for this transaction as an asset purchase and the resultant \$52.4 million NDA asset is being amortized in full over its estimated useful life of 10 years. The resultant \$0.6 million non-compete agreement associated with the transaction is being amortized in full over its estimated useful life of seven years. Please see Note 12 for further details regarding the transaction.

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

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**7. GOODWILL AND INTANGIBLE ASSETS – continued**

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

In July 2014, we entered into an agreement to purchase (the “Lithobid Purchase Agreement”) the product rights to Lithobid from Noven Therapeutics, LLC for \$11.0 million in cash at closing, and \$1.0 million in cash if certain approvals were received from the FDA on or before June 30, 2015. This \$1.0 million contingent payment was paid in January 2015. Pursuant to the terms of the Lithobid Purchase Agreement, we acquired the intellectual property rights and NDA associated with Lithobid, as well as a small amount of raw material inventory. We accounted for this transaction as an asset purchase. The \$12.0 million product rights intangible asset is being amortized in full over its estimated useful life of 10 years.

*Marketing and Distribution Rights*

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

In August 2015, we entered into a distribution agreement with IDT Australia Limited (“IDT”) to market several products in the U.S. The products, all of which are approved ANDAs, require various FDA filings and approvals prior to commercialization. In general, IDT will be responsible for regulatory submissions to the Food and Drug

Edgar Filing: ANI PHARMACEUTICALS INC - Form 10-Q

Administration (“FDA”) and the manufacturing of certain products. We made an upfront payment to IDT of \$1.0 million and will make additional milestone payments upon FDA approval for commercialization of certain products. Upon approval, IDT will manufacture some of the products and we will manufacture the other products. We will market and distribute all the products under our label in the United States, remitting a percentage of profits from sales of the drugs to IDT. We accounted for this transaction as an asset purchase. The \$1.0 million upfront payment was recorded as a marketing and distribution rights intangible asset and is being amortized in full over its estimated useful life of seven years.

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

(in thousands)	June 30, 2016		December 31, 2015		Weighted Average Amortization Period
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
Acquired ANDA intangible assets	\$42,076	\$ (6,289 )	\$42,076	\$ (4,287 )	10.0 years
NDA and product rights	161,150	(12,546 )	33,422	(5,754 )	10.1 years
Marketing and distribution rights	11,042	(1,361 )	1,000	(60 )	4.7 years
Non-compete agreement	624	(22 )	-	-	7.0 years
	\$214,892	\$ (20,218 )	\$76,498	\$ (10,101 )	



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

Definite-lived intangible assets are stated at cost, net of amortization using the straight line method over the expected useful lives of the intangible assets. Amortization expense was \$5.7 million and \$1.2 million for the three months ended June 30, 2016 and 2015, respectively. Amortization expense was \$10.1 million and \$2.4 million for the six months ended June 30, 2016 and 2015, respectively.

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

Expected future amortization expense is as follows:

(in thousands)	
2016 (remainder of the year)	\$ 11,450
2017	22,722
2018	22,367
2019	22,367
2020	21,885
2021 and thereafter	93,883
Total	\$ 194,674

**8. STOCK-BASED COMPENSATION**

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the “2008 Plan”). As of June 30, 2016, 0.3 million shares of our common stock remained available for issuance under the 2008 Plan.

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Cost of sales	\$ 24	\$ 21	\$ 14	\$ 37
Research and development	22	33	49	49
Selling, general, and administrative	2,171	975	3,259	1,511
	\$ 2,217	\$ 1,029	\$ 3,322	\$ 1,597

### Separation Agreement

On April 26, 2016, we entered into a Separation Agreement and Release (the “Separation Agreement”) with our former Chief Financial Officer (the “Former Officer”), who resigned effective May 6, 2016. Under the Separation Agreement, 25,167 stock options previously granted to the Former Officer vested on May 6, 2016. In addition, 4,050 restricted stock awards and 2,000 stock options previously granted to the Former Officer will vest on March 15, 2017, subject to certain conditions. These actions were accounted for as a modification of the underlying awards and the full expense for the modified awards was recorded in the three months ended June 30, 2016. In the second quarter of 2016, we recorded \$0.9 million of stock-based compensation expense, net of forfeitures, in relation to the Separation Agreement. During the three months ended June 30, 2016, we recognized \$0.4 million of additional expense related to the Separation Agreement and transition that was not related to stock-based compensation. All expenses related to the Separation Agreement and transition have been recognized in the three months ended June 30, 2016.

**ANI PHARMACEUTICALS, INC. and subsidiarIES****NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS***(unaudited)***8. STOCK-BASED COMPENSATION— continued**

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

(in thousands)	Options	RSAs
Outstanding December 31, 2014	458	63
Granted	120	28
Options Exercised/RSAs Vested	(31 )	(10 )
Forfeited	(33 )	(5 )
Outstanding June 30, 2015	514	76
Outstanding December 31, 2015	474	63
Granted	273	42
Options Exercised/RSAs Vested	(54 )	(15 )
Forfeited	(50 )	(12 )
Outstanding June 30, 2016	643	78

**9. STOCKHOLDER'S EQUITY****Stock Repurchase Program**

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

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

## Warrants

No warrants to purchase shares of common stock were granted, exercised, or expired unexercised during the three and six month ended June 30, 2016. Warrants to purchase 0.1 million shares of common stock expired unexercised during both the three and six months ended June 30, 2015. No warrants to purchase shares of common stock were grant or exercised during the three and six months ended June 30, 2015.

## 10.

## INCOME TAXES

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. The utilization of our NOL carryforwards will be limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code. As of both June 30, 2016 and December 31, 2015, we had provided a valuation allowance against certain state net operating loss (“NOL”) carryforwards of approximately \$0.1 million.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return, as well as guidance on derecognition, classification, interest and penalties, and financial statement reporting disclosures. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any such amounts accrued as of June 30, 2016 and December 31, 2015. We are subject to taxation in various jurisdictions and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

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

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate expected for the entire year. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and estimated permanent differences, and excludes certain discreet items whose tax effect is recognized in the interim period in which they occur. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. Our estimated annual effective tax rate changes throughout the year

as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discreet items occur. Our estimated annual effective tax rate was 53.4% of pre-tax income for the first quarter of 2016, was 52.2% of pre-tax income for the second quarter of 2016, and was 52.8% of pre-tax income for the six months ended June 30, 2016. The decrease in our estimated annual effective tax rate during the first half 2016 was primarily driven by the on-going revisions discussed above, and by the tax effect of discreet items, including changes in our estimated pre-tax income resulting from various asset acquisitions that occurred during the periods and associated changes to temporary differences arising from those asset acquisitions, as well as the impact of current period awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**11. COMMITMENTS AND CONTINGENCIES**

**Operating Leases**

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

Rent expense for each of the three months ended June 30, 2016 and 2015 totaled \$20 thousand. Rent expense for the six months ended June 30, 2016 and 2015 totaled \$40 thousand and \$38 thousand, respectively.

**Government Regulation**

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**11. COMMITMENTS AND CONTINGENCIES – continued**

**Unapproved Products**

Two of our products, Esterified Estrogen with Methyltestosterone tablets (“EEMT”) and Opium Tincture, are marketed without approved NDAs or ANDAs. During the three months ended June 30, 2016 and 2015, net revenues for these products totaled \$9.0 million and \$11.0 million, respectively. During the six months ended June 30, 2016 and 2015, net revenues for these products totaled \$18.0 million and \$21.3 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 Sec. 440.100 titled “Marketed New Drugs without Approved NDAs or ANDAs.” Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. We believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for these unapproved products for each of the three months ended June 30, 2016 and 2015 were \$0.5 million. Our contract manufacturing revenues for these unapproved products for each of the six months ended June 30, 2016 and 2015 were \$0.8 million.

We receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products for each of the three months ended June 30, 2016 and 2015 were \$0.1 million. Our royalties on the net sales of these unapproved products for each of the six months ended June 30, 2016 and 2015 were \$0.2 million.

### **Louisiana Medicaid Lawsuit**

On September 11, 2013, the Attorney General of the State of Louisiana filed a lawsuit in Louisiana state court against numerous pharmaceutical companies, including us, under various state laws, alleging that each defendant caused the state's Medicaid agency to provide reimbursement for drug products that allegedly were not approved by the FDA and therefore allegedly not reimbursable under the federal Medicaid program. The lawsuit relates to three cough and cold prescription products manufactured and sold by our former Gulfport, Mississippi operation, which was sold in September 2010. Through its lawsuit, the state seeks unspecified damages, statutory fines, penalties, attorneys' fees, and costs. While we cannot predict the outcome of the lawsuit at this time, we could be subject to material damages, penalties, and fines. We intend to vigorously defend against all claims in the lawsuit.



**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**11. COMMITMENTS AND CONTINGENCIES – continued**

**Other Commitments and Contingencies**

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, are facing allegations from plaintiffs in various states, including California, New Jersey, and Pennsylvania, claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA's February 2009 Black Box warning requirement. In August 2012, we were dismissed with prejudice from all New Jersey cases. We consider our exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide that we manufactured prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) our market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once we received a request for change of labeling from the FDA, we submitted our proposed changes within 30 days, and such changes were subsequently approved by the FDA.

At the present time, we are unable to assess the likely outcome of the cases in the remaining states. Our insurance company has assumed the defense of this matter. We cannot provide assurances that the outcome of these matters will not have an adverse effect on our business, financial condition, and operating results. Furthermore, like all pharmaceutical manufacturers, we may be exposed to other product liability claims in the future, which could further limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial condition, and operating results.

**12. FAIR VALUE DISCLOSURES**

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the

various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, borrowings under line of credit, and other current liabilities) approximate their carrying values because of their short-term nature. While our Notes are recorded on our accompanying unaudited interim condensed consolidated balance sheets at their net carrying value of \$117.0 million as of June 30, 2016, the Notes are being traded on the bond market and their full fair value is \$155.4 million, based on their closing price on June 30, 2016, a Level 1 input.

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

Our contingent value rights (“CVRs”), which were granted coincident with our merger with BioSante and expire in June 2023, are considered contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of our projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs, and the changes in such fair value, was immaterial as of June 30, 2016 and December 31, 2015, and for the three and six months ended June 30, 2016 and 2015.

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

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

(in thousands)

Description	<b>Fair Value at June 30, 2016</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
Liabilities				
CVRs	\$ -	\$ -	\$ -	\$ -

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

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

We do not have any financial assets and liabilities measured at fair value on a non-recurring basis.

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

We do not have any non-financial assets and liabilities that are measured at fair value on a recurring basis.

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

We measure our long-lived assets, including property, plant, and equipment, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three and six months ended June 30, 2016 and 2015.

*Acquired Non-Financial Assets Measured at Fair Value*

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

*(unaudited)*

**12. FAIR VALUE DISCLOSURES– continued**

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

In January 2016, we purchased from H2-Pharma, LLC the rights to market, sell, and distribute the authorized generic of Lipofen® and a generic hydrocortisone rectal cream product, along with the rights to an early-stage development project, for total consideration of \$10.0 million (Note 7). The consideration consisted of a cash payment of \$8.8 million and the assumption of \$1.2 million in existing royalties owed on the acquired rights. In addition, we capitalized \$42 thousand of costs directly related to the transaction. We accounted for this transaction as an asset purchase. In order to determine the fair value of the rights for purposes of purchase price allocation, we used the present value of the estimate cash flows related to the product rights, using a discount rate of 10%. No value was ascribed to the early-stage development project because the development is still at the preliminary stage, with no expenses incurred or research performed to date. The marketing and distribution rights will be amortized in full over their average estimated useful lives of approximately four years, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified from the date of acquisition to June 30, 2016 and therefore no impairment loss was recognized for the three and six months ended June 30, 2016.

**13. SUBSEQUENT EVENT**

In July 2016, we commenced administration of our 2016 Employee Stock Purchase Plan (the “ESPP”), which was approved by shareholders in our May 25, 2016 annual shareholder meeting. The Board of Directors and shareholders approved a maximum of 0.2 million shares of common stock, which were reserved and made available for issuance under the ESPP.



## Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this Form 10-Q quarterly report. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2015.*

### EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is an integrated speciality pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. Our targeted areas of product development currently include controlled substances, oncolytics (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota that are capable of producing oral solid dose products, as well as liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment.

Our strategy is to use our assets to develop, acquire, manufacture, and market branded and generic speciality prescription pharmaceuticals. By executing this strategy, we believe we will be able to continue to grow the business, expand and diversify our product portfolio, and create long-term value for our investors.

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

<b>Generic Products</b>	<b>Branded Products</b>
Esterified Estrogen with Methyltestosterone	Cortenema
Etodolac	Inderal LA
Fenofibrate	Lithobid
Flecainide	Reglan
Fluvoxamine	Vancocin

Hydrocortisone Rectal Cream (1% and 2.5%)

Hydrocortisone Enema

Hydroxyprogesterone Caproate Injection

Mesalamine Enema

Methazolamide

Metoclopramide Syrup

Nimodipine

Opium Tincture

Oxycodone Capsules

Oxycodone Oral Solution

Propafenone

Propranolol ER

Vancomycin

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

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

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



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

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

**Manufacturing.** Whenever possible, we seek to develop and manufacture products at our own manufacturing plants in order to maximize the capacity and utilization of our facilities, to ensure quality control in our products, and to maximize profit potential.

**Competition.** When determining whether to develop or acquire an individual product, we research the existing and expected market share of generic competitors. We seek to develop products for which we can obtain a large market share, and may decline to develop a product if we anticipate many generic competitors. Our highly specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies would be able to compete.

GENERAL

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2016	2015	2016	2015
Net revenues	\$ 31,337	\$ 19,516	\$ 51,892	\$ 38,315
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	11,795	3,141	15,205	5,892
Research and development	764	995	1,730	1,398
Selling, general, and administrative	7,628	5,551	13,532	10,302
Depreciation and amortization	5,956	1,415	10,565	2,742
Operating income	5,194	8,414	10,860	17,981
Interest expense, net	(2,830 )	(2,749 )	(5,612 )	(5,474 )
Other (expense)/income, net	(12 )	-	(10 )	68
Income before provision for income taxes	2,352	5,665	5,238	12,575
Provision for income taxes	(1,227 )	(2,094 )	(2,767 )	(4,635 )
Net income	\$ 1,125	\$ 3,571	\$ 2,471	\$ 7,940

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

	Three Months Ended June 30,				Six Months Ended June 30,			
	2016		2015		2016		2015	
Net revenues	100.0	%	100.0	%	100.0	%	100.0	%
Operating expenses								
Cost of sales (exclusive of depreciation and amortization)	37.7	%	16.1	%	29.3	%	15.4	%
Research and development	2.4	%	5.1	%	3.3	%	3.6	%
Selling, general, and administrative	24.4	%	28.4	%	26.1	%	26.9	%
Depreciation and amortization	19.0	%	7.3	%	20.4	%	7.2	%
Operating income	16.5	%	43.1	%	20.9	%	46.9	%
Interest expense, net	(9.0)	)%	(14.1)	)%	(10.8)	)%	(14.3)	)%
Other (expense)/income, net	-	%	-	%	-	%	0.2	%
Income before provision for income taxes	7.5	%	29.0	%	10.1	%	32.8	%
Provision for income taxes	(3.9)	)%	(10.7)	)%	(5.3)	)%	(12.1)	)%

Net income	3.6	%	18.3	%	4.8	%	20.7	%
------------	-----	---	------	---	-----	---	------	---

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2016 AND 2015**Net Revenues**

(in thousands)	Three Months Ended June 30,				
	2016	2015	Change	% Change	
Generic pharmaceutical products	\$ 22,463	\$ 13,764	\$8,699	63.2	%
Branded pharmaceutical products	7,488	2,136	5,352	250.6	%
Contract manufacturing	1,166	1,091	75	6.9	%
Contract services and other income	220	2,525	(2,305 )	(91.3	)%
Total net revenues	\$ 31,337	\$ 19,516	\$11,821	60.6	%

We derive substantially all of our revenues from sales of generic and branded pharmaceutical products, contract manufacturing, and contract services, which include product development services, laboratory services, and royalties on net sales of certain products.

Net revenues for the three months ended June 30, 2016 were \$31.3 million compared to \$19.5 million for the same period in 2015, an increase of \$11.8 million, or 60.6%, primarily as a result of the following factors:

Net revenues for generic pharmaceutical products were \$22.5 million during the three months ended June 30, 2016, an increase of 63.2% compared to \$13.8 million for the same period in 2015. The primary reason for the increase was sales of Propranolol ER and other products launched in the second quarter of 2016, as well as sales of Vancomycin, which was launched under our own label in the fourth quarter of 2015.

As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market EEMT and Opium Tincture without Food and Drug Administration ("FDA") approved New Drug Applications ("NDAs"). The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the three months ended June 30, 2016 and 2015 were \$9.0 million and \$11.0 million, respectively.

Net revenues for branded pharmaceutical products were \$7.5 million during the three months ended June 30, 2016, an increase of 250.6% compared to \$2.1 million for the same period in 2015. The primary reason for the increase was sales of Inderal LA, which was launched in the second quarter of 2016, as well as increased unit sales of Vancocin. The increase was partially offset by lower unit sales of Reglan due to decreased purchases by a customer and increased Medicaid utilization and Medicaid rebates for Lithobid and Vancocin.

Contract manufacturing revenues were \$1.2 million during the three months ended June 30, 2016, an increase of 6.9% compared to \$1.1 million for the same period in 2015, due to timing of orders from contract manufacturing customers in the period. As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for each of the three months ended June 30, 2016 and 2015 were \$0.5 million.

Contract services and other income were \$0.2 million during the three months ended June 30, 2016, a decrease of 91.3% from \$2.5 million for the same period in 2015, due primarily to the lack of royalties received on sales of the authorized generic of Vancocin. In the fourth quarter of 2015, we launched an authorized generic of Vancocin under our own label, which replaced the authorized generic product previously on the market. This decrease was partially offset by royalties related to sales of Fenofibrate, the authorized generic of Lipofen®, the marketing and distribution rights to which we acquired in January 2016. We launched Fenofibrate under our own label in the second quarter of 2016.

As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products for each of the three months ended June 30, 2016 and 2015 were \$0.1 million.

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

(in thousands)	Three Months Ended June 30,			
	2016	2015	Change	% Change
Cost of sales (excl. depreciation and amortization)	\$ 11,795	\$ 3,141	\$ 8,654	275.5 %

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

For the three months ended June 30, 2016, cost of sales increased to \$11.8 million from \$3.1 million for the same period in 2015, an increase of \$8.7 million or 275.5%, primarily as a result of increased sales of products subject to

profit-sharing arrangements, as well as the impact on cost of sales of the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period. Cost of sales as a percentage of net revenues increased to 37.7% during the three months ended June 30, 2016, from 16.1% during same period in 2015, primarily as a result of increased sales of products subject to profit-sharing arrangements, a trend we expect to continue, and the \$2.1 million impact on cost of sales (6.6% as a percent of net revenues) of the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period, a trend which will continue until such time that the inventory purchased from Cranford Pharmaceuticals, LLC (“Cranford”) as a component of the Inderal LA NDA asset purchase is consumed.

We source the raw materials for our products, including active pharmaceutical ingredients (“API”), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA. As a result, we are dependent upon our current vendors to reliably supply the API required for ongoing product manufacturing. In addition, certain of our API for our drug products, including those that are marketed without approved NDAs or Abbreviated New Drug Applications (“ANDAs”), are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections.

During the three months ended June 30, 2016, we purchased 48% of our inventory from four suppliers. As of June 30, 2016, amounts payable to these four suppliers totaled \$0.3 million. In the three months ended June 30, 2015, we purchased 43% of our inventory from two suppliers.

In order to manufacture Opium Tincture, Oxycodone capsules, and Oxycodone oral solution, we must receive approval from the Drug Enforcement Agency (“DEA”) for a quota to purchase the amount of opium and oxycodone needed to manufacture the respective products. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are dependent upon the DEA to approve quotas large enough to support our continued manufacture of Opium Tincture, Oxycodone capsules, and Oxycodone oral solution.

### Other Operating Expenses

(in thousands)	Three Months Ended June 30,				
	2016	2015	Change	% Change	
Research and development	\$ 764	\$ 995	\$(231 )	(23.2 )	%
Selling, general, and administrative	7,628	5,551	2,077	37.4	%
Depreciation and amortization	5,956	1,415	4,541	320.9	%
Total other operating expenses	\$ 14,348	\$ 7,961	\$ 6,387	80.2	%

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, 2016, other operating expenses increased to \$14.3 million from \$8.0 million for the same period in 2015, an increase of \$6.3 million, or 80.2%, primarily as a result of the following factors:



Research and development expenses decreased from \$1.0 million to \$0.8 million, a decrease of 23.2%, due to timing of work on development projects. Current projects include work on the ANDAs purchased in 2014 and 2015, as well as collaborations with partners. We anticipate that research and development costs will increase in 2016, in support of our strategy to expand our product portfolio.

Selling, general, and administrative expenses increased from \$5.6 million to \$7.6 million, an increase of 37.4%, primarily due to increased stock-based compensation expense and increases in personnel and related costs, including \$1.3 million of expenses related to the transition of our Chief Financial Officer (“CFO”) in the second quarter of 2016. While all expense related to the transition was recognized in the three months ended June 30, 2016, we anticipate that selling, general, and administrative expenses will continue to be greater in 2016 than in 2015 as we support anticipated additional revenue growth.

Depreciation and amortization increased from \$1.4 million to \$6.0 million, an increase of 320.9%, due primarily to the amortization of the NDAs for Corticotropin and Corticotropin-Zinc and the marketing and distribution rights acquired from H2-Pharma, LLC, both of which were acquired in January 2016, and the amortization of the rights, title, and interest in the NDA for Inderal LA, which was acquired in April 2016, as well as amortization of the ANDAs acquired in July 2015. We anticipate that depreciation and amortization expense will continue to be greater in 2016 than in 2015 as a result of our first and second quarter 2016 asset purchases.

**Other Expense, net**

(in thousands)	Three Months Ended June 30,			
	2016	2015	Change	% Change
Interest expense, net	\$ (2,830 )	\$ (2,749 )	\$ (81 )	2.9 %
Other expense, net	(12 )	-	(12 )	(100.0 )%
Total other expense	\$ (2,842 )	\$ (2,749 )	\$ (93 )	3.4 %

For the three months ended June 30, 2016, we recognized other expense of \$2.8 million versus other expense of \$2.7 million for the same period in 2015, a change of \$0.1 million. Interest expense, net for both periods consists primarily of interest expense on our convertible debt.

**Provision for Income Taxes**

(in thousands)	Three Months Ended June 30,			
	2016	2015	Change	% Change
Provision for income taxes	\$ (1,227 )	\$ (2,094 )	\$ 867	(41.4 )%

Our provision for income taxes consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance.

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate expected for the entire year. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and estimated permanent differences, and excludes certain discrete items whose tax effect is recognized in the interim period in which they occur. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. Our estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discrete items occur.

For the three months ended June 30, 2016, we recognized income tax expense of \$1.2 million, versus \$2.1 million for the same period in 2015, a decrease of \$0.9 million. Of the \$1.2 million of total tax expense, \$1.6 million is current expense and \$0.4 million is a net deferred benefit.

Our estimated annual effective tax rate was 53.4% of pre-tax income for the first quarter of 2016, was 52.2% of pre-tax income for the second quarter of 2016, and was 52.8% of pre-tax income for the six months ended June 30, 2016. The decrease in our estimated annual effective tax rate during the first half 2016 was primarily driven by the on-going revisions discussed above, and by the tax effect of discreet items, including changes in our estimated pre-tax income resulting from various asset acquisitions that occurred during the periods and associated changes to temporary differences arising from those asset acquisitions, as well as the impact of current period awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur. The effective tax rate for the three months ended June 30, 2015 was 37.0% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2015.

RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2016 AND 2015**Net Revenues**

(in thousands)	Six Months Ended June 30,			% Change	
	2016	2015	Change		
Generic pharmaceutical products	\$ 35,715	\$ 26,021	\$9,694	37.3	%
Branded pharmaceutical products	13,084	6,408	6,676	104.2	%
Contract manufacturing	2,550	2,295	255	11.1	%
Contract services and other income	543	3,591	(3,048 )	(84.9 )	%
Total net revenues	\$ 51,892	\$ 38,315	\$ 13,577	35.4	%

Net revenues for the six months ended June 30, 2016 were \$51.9 million compared to \$38.3 million for the same period in 2015, an increase of \$13.6 million, or 35.4%, primarily as a result of the following factors:

Net revenues for generic pharmaceutical products were \$35.7 million during the six months ended June 30, 2016, an increase of 37.3% compared to \$26.0 million for the same period in 2015. The primary reason for the increase was sales of Propranolol ER and other products launched in the second quarter of 2016, as well as sales of Vancomycin, which was launched under our own label in the fourth quarter of 2015.

As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market EEMT and Opium Tincture without FDA-approved NDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the six months ended June 30, 2016 and 2015 were \$18.0 million and \$21.3 million, respectively.

Net revenues for branded pharmaceutical products were \$13.1 million during the six months ended June 30, 2016, an increase of 104.2% compared to \$6.4 million for the same period in 2015. The primary reason for the increase was sales of Inderal LA, which was launched in the second quarter of 2016, as well as increased unit sales of Vancocin.

The increase was partially offset by lower unit sales of Reglan due to decreased purchases by a customer and increased Medicaid utilization and Medicaid rebates for Lithobid and Vancocin. We experience periodic larger orders for our Vancocin product that relate to clinical trials. Such orders constituted \$2.4 million and \$1.5 million of our branded pharmaceutical product revenue for the six months ended June 30, 2016 and 2015, respectively, and we cannot be sure that such purchases will occur in future periods.

Contract manufacturing revenues were \$2.6 million during the six months ended June 30, 2016, an increase of 11.1% compared to \$2.3 million for the same period in 2015, due to timing of orders from contract manufacturing customers in the period. As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for each of the six months ended June 30, 2016 and 2015 were \$0.8 million.

Contract services and other income were \$0.5 million during the six months ended June 30, 2016, a decrease of 84.9% from \$3.6 million for the same period in 2015, due primarily to the lack of royalties received on sales of the authorized generic of Vancocin. In the fourth quarter of 2015, we launched an authorized generic of Vancocin under our own label, which replaced the authorized generic product previously on the market. This decrease was partially offset by royalties related to sales of Fenofibrate, the authorized generic of Lipofen®, the marketing and distribution rights to which we acquired in January 2016. We launched Fenofibrate under our own label in the second quarter of 2016.

As described in Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products for each of the six months ended June 30, 2016 and 2015 were \$0.2 million.

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

(in thousands)	Six Months Ended June 30,				
	2016	2015	Change	% Change	
Cost of sales (excl. depreciation and amortization)	\$ 15,205	\$ 5,892	\$9,313	158.1	%

For the six months ended June 30, 2016, cost of sales increased to \$15.2 million from \$5.9 million for the same period in 2015, an increase of \$9.3 million or 158.1%, primarily as a result of increased sales of products subject to profit-sharing arrangements, as well as the impact on cost of sales of the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period. Cost of sales as a percentage of net revenues increased to 29.3% during the six months ended June 30, 2016, from 15.4% during same period in 2015, primarily as a result of increased sales of products subject to profit-sharing arrangements, a trend we expect to continue, and the \$2.1 million impact on cost of sales (4.0% as a percent of net revenues) of the excess of fair value over cost for Inderal LA and Propranolol ER inventory sold during the period, a trend which will continue until such time that the inventory purchased from Cranford as a component of the Inderal LA NDA asset purchase is consumed.

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

During the six months ended June 30, 2016, we purchased 29% of our inventory from two suppliers. As of June 30, 2016, amounts payable to these two suppliers totaled \$0.2 million. In the six months ended June 30, 2015, we purchased 40% of our inventory from two suppliers.

In order to manufacture Opium Tincture, Oxycodone capsules, and Oxycodone oral solution, we must receive approval from the DEA for a quota to purchase the amount of opium and oxycodone needed to manufacture the respective products. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are dependent upon the DEA to approve quotas large enough to support our continued manufacture of Opium Tincture, Oxycodone capsules, and Oxycodone oral solution.

### Other Operating Expenses

(in thousands)	Six Months Ended June 30,				
	2016	2015	Change	% Change	
Research and development	\$ 1,730	\$ 1,398	\$ 332	23.7	%
Selling, general, and administrative	13,532	10,302	3,230	31.4	%
Depreciation and amortization	10,565	2,742	7,823	285.3	%
Total other operating expenses	\$ 25,827	\$ 14,442	\$ 11,385	78.8	%

For the six months ended June 30, 2016, other operating expenses increased to \$25.8 million from \$14.4 million for the same period in 2015, an increase of \$11.4 million, or 78.8%, primarily as a result of the following factors:

Research and development expenses increased from \$1.4 million to \$1.7 million, an increase of 23.7%, due to timing of work on development projects. Current projects include work on the ANDAs purchased in 2014 and 2015, as well as collaborations with partners. We anticipate that research and development costs will increase in 2016, in support of our strategy to expand our product portfolio.

Selling, general, and administrative expenses increased from \$10.3 million to \$13.5 million, an increase of 31.4%, primarily due to increased stock-based compensation expense and increases in personnel and related costs, including \$1.3 million of expenses related to the transition of our CFO in the second quarter of 2016. While all expense related to the transition was recognized in the second quarter of 2016, we anticipate that selling, general, and administrative expenses will continue to be greater in 2016 than in 2015 as we support anticipated additional revenue growth.

Depreciation and amortization increased from \$2.7 million to \$10.6 million, an increase of 285.3%, due primarily to the amortization of the NDAs for Corticotropin and Corticotropin-Zinc and the marketing and distribution rights acquired from H2-Pharma, LLC, both of which were acquired in January 2016, and the amortization of the rights, title, and interest in the NDA for Inderal LA, which was acquired in April 2016, as well as amortization of the ANDAs acquired in July 2015. We anticipate that depreciation and amortization expense will continue to be greater in 2016 than in 2015 as a result of our first and second quarter 2016 asset purchases.



**Other Expense, net**

(in thousands)	Six Months Ended June 30,			
	2016	2015	Change	% Change
Interest expense, net	\$ (5,612 )	\$ (5,474 )	\$ (138 )	2.5 %
Other (expense)/income, net	(10 )	68	(78 )	(114.7 )%
Total other expense	\$ (5,622 )	\$ (5,406 )	\$ (216 )	4.0 %

For the six months ended June 30, 2016, we recognized other expense of \$5.6 million, an increase of \$0.2 million from other expense of \$5.4 million for the same period in 2015. Interest expense, net for both periods consists primarily of interest expense on our convertible debt.

**Provision for Income Taxes**

Our provision for income taxes consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance.

(in thousands)	Six Months Ended June 30,			
	2016	2015	Change	% Change
Provision for income taxes	\$ (2,767 )	\$ (4,635 )	\$ 1,868	(40.3 )%

For the six months ended June 30, 2016, we recognized income tax expense of \$2.8 million, versus income tax expense of \$4.6 million for the same period in 2015, a decrease of \$1.8 million. Of the \$2.8 million of total tax expense, \$3.2 million is current expense and \$0.4 million is a net deferred benefit.

Our estimated annual effective tax rate was 53.4% of pre-tax income for the first quarter of 2016, was 52.2% of pre-tax income for the second quarter of 2016, and was 52.8% of pre-tax income for the six months ended June 30, 2016. The decrease in our estimated annual effective tax rate during the first half 2016 was primarily driven by the on-going revisions discussed above, and by the tax effect of discreet items, including changes in our estimated pre-tax income resulting from various asset acquisitions that occurred during the periods and associated changes to temporary differences arising from those asset acquisitions, as well as the impact of current period awards of stock-based compensation, stock option exercises, vesting of restricted stock, and disqualifying dispositions of incentive stock options, all of which impact the estimated annual effective rate in the period in which they occur. The effective tax rate for the six months ended June 30, 2015 was 36.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2015.

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	June 30, 2016	December 31, 2015
Cash and cash equivalents	\$ 15,014	\$ 154,684
Accounts receivable, net	35,562	21,932
Inventories, net	25,052	13,387
Prepaid income taxes	150	1,127
Prepaid expenses and other current assets	4,046	1,453
Total current assets	\$ 79,824	\$ 192,583
Accounts payable	\$ 4,961	\$ 2,066
Accrued expenses and other	770	617
Accrued royalties	8,110	606
Accrued compensation and related expenses	1,071	1,188
Accrued Medicaid rebates	6,509	4,631
Returned goods reserve	3,309	2,648
Total current liabilities	\$ 24,730	\$ 11,756

At June 30, 2016, we had \$15.0 million in unrestricted cash and cash equivalents. At December 31, 2015, we had \$154.7 million in unrestricted cash and cash equivalents. We generated \$14.3 million of cash flows from operations in the six months ended June 30, 2016. In the first quarter of 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs for Corticotropin and Corticotropin-Zinc and the associated product rights and manufacturing licenses for \$75.0 million in cash and a percentage of future net sales of the products under the NDAs. In the first quarter of 2016 we purchased from H2-Pharma, LLC the rights to market, sell, and distribute two products for \$8.8 million in cash and the assumption of an accrued royalty of \$1.2 million, for a total of \$10.0 million in consideration. In the second quarter of 2016, we purchased from Cranford Pharmaceuticals, LLC the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods for \$60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA. In addition, at closing, we transferred \$5.0 million to an escrow account as security for future milestone payments.

In May 2016, we entered into a credit arrangement (the "Line of Credit") with Citizens Bank Capital, a division of Citizens Asset Finance, Inc. that provided for a \$30.0 million asset-based revolving credit loan facility. As of June 30, 2016, we had no outstanding balance on the Line of Credit, and our available borrowing base was \$30.0 million.

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

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue, and our revolving line of credit facility, will be sufficient to enable us to meet our working capital requirements for at least the next 12 months.

The following table summarizes the net cash and cash equivalents provided by/(used in) operating activities, investing activities, and financing activities for the periods indicated:

(in thousands)	Six Months Ended June 30,	
	2016	2015
Operating Activities	\$ 14,306	\$ 2,326
Investing Activities	\$ (151,583 )	\$ (4,810 )
Financing Activities	\$ (2,393 )	\$ 178

### Net Cash Provided By Operations

Net cash provided by operating activities was \$14.3 million for the six months ended June 30, 2016, compared to \$2.3 million provided by operating activities during the same period in 2015, an increase of \$12.0 million between the periods. This increase was principally due to increased sales volume and corresponding gross profit dollars, somewhat tempered by increased expenditures in support of the growth of the business.

### Net Cash Used In Investing Activities

Net cash used in investing activities for the six months ended June 30, 2016 was \$151.6 million, principally due to the January 2016 asset acquisition of the NDAs for Corticotropin and Corticotropin-Zinc for \$75.3 million, the January 2016 payment of \$8.8 million to H2-Pharma, LLC for marketing and distribution rights associated with two products, the April 2016 payment of \$60.0 million for the asset acquisition of the NDA for Inderal LA, an increase in restricted cash of \$5.0 million from the transfer of \$5.0 million to an escrow account as security for future milestone payments in relation to the Inderal LA asset acquisition, and \$2.1 million of capital expenditures during the period. Net cash used in investing activities was \$4.8 million during the same period in 2015, principally due to the \$4.5 million asset acquisition of the ANDA for Flecainide, in addition to \$0.3 million of capital expenditures during the period.

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

Net cash used in financing activities was \$2.4 million for the six months ended June 30, 2016, principally due to the \$2.5 million repurchase of the Company's common stock under our Stock Repurchase Program and \$0.3 million of debt issuance costs paid in relation to the Line of Credit, partially offset by \$0.5 million of proceeds from stock option exercises. Net cash provided by financing activities was \$0.2 million during the same period in 2015, resulting primarily from proceeds from stock option exercises and excess tax benefit from stock-based compensation awards.

## CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited interim condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our unaudited interim condensed consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, administrative fees and rebates, returns and other allowances, allowance for inventory obsolescence, accruals for contingent liabilities and litigation, fair value of long-lived assets, income tax provision, deferred taxes and valuation allowance, purchase price allocations, and the depreciable and amortizable lives of long-lived assets.

A summary of our significant accounting policies is included in Item 8. Consolidated Financial Statements, Note 1 — Description of Business and Summary of Significant Accounting Policies, in our Annual Report on Form 10-K for the year ended December 31, 2015. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Such policies are summarized in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2015.

## RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In March 2016, the Financial Accounting Standards Board ("FASB") issued guidance simplifying the accounting for and financial statement disclosure of stock-based compensation awards. Under the guidance, all excess tax benefits and tax deficiencies related to stock-based compensation awards are to be recognized as income tax expenses or benefits in the income statement and excess tax benefits should be classified along with other income tax cash flows in the operating activities section of the statement of cash flows. Under the guidance, companies can also elect to either estimate the number of awards that are expected to vest or account for forfeitures as they occur. In addition, the guidance amends some of the other stock-based compensation awards guidance to more clearly articulate the requirements and cash flow presentation for withholding shares for tax-withholding purposes. The guidance is effective for reporting periods beginning after December 15, 2016 and early adoption is permitted, though all amendments of the guidance must be adopted in the same period. The adoption of certain amendments of the guidance must be applied prospectively, and adoption of the remaining amendments must be applied either on a modified retrospective basis or retrospectively to all periods presented. We are currently evaluating the impact that this guidance will have on our consolidated financial statements.

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

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We are currently evaluating the impact that this guidance will have on our consolidated financial statements.



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

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

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

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

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. We are currently evaluating the impact, if any, that this guidance will have on our consolidated financial statements.

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

In addition to the specified contractual obligations set forth in the contractual obligations information provided in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2015, the following obligations were incurred or discharged during six months ending June 30, 2016:

In January 2016, we purchased from Merck Sharp & Dohme B.V. the NDAs for two previously marketed generic drug products for \$75.0 million in cash and a percentage of future net sales from product sales.

As of June 30, 2016 and December 31, 2015, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

Market risks include interest rate risk, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, only interest rate risk could have a significant impact on our results of operations.

As of June 30, 2016, our principal debt obligation was related to our Notes. In order to reduce the potential equity dilution that would result upon conversion of the Senior Convertible Notes issued in December 2014, we entered into note hedge transactions with a financial institution affiliated with one of the underwriters of the Senior Convertible Note offering. The note hedge transactions are expected generally, but not guaranteed, to reduce the potential dilution to our common stock and/or offset the cash payments we are required to make in excess of the principal amount upon any conversion of Senior Convertible Notes, in the event that the market price per share of our common stock, as measured under the terms of the Convertible Note Hedge Transactions, is greater than the conversion price of the Senior Convertible Notes, which is initially approximately \$69.48. In addition, in order to partially offset the cost of the note hedge transactions, we issued warrants to the hedge counterparty to purchase approximately 2.1 million shares of our common stock at a strike price of \$96.21. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock exceeds the strike price of the warrants. In addition, non-performance by the counterparties under the hedge transactions would potentially expose us to dilution of our common stock to the extent our stock price exceeds the conversion price.

Interest on the Notes accrues at a fixed rate of 3.0% on the outstanding principal amount of the Notes and is paid semi-annually every December 1st and June 1st until the Notes mature on December 1, 2019. Since the interest rate is fixed, we have no interest-rate market risk related to the Notes. However, if our stock price increases, the fair value of our Notes, and their likelihood of being converted, will increase accordingly.

On May 12, 2016, we entered into a credit agreement (the “Line of Credit”) with Citizens Business Capital, a division of Citizens Asset Finance, Inc. (the “Citizens Agreement”). The Citizens Agreement provides for a \$30.0 million asset-based revolving credit loan facility. Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.25%, 1.50%, or 1.75% per annum, depending upon availability under the Citizens Agreement or an alternative base rate plus either 0.25%, 0.50%, or 0.75% per annum, depending upon availability under the Citizens Agreement. We incur a commitment fee on undrawn amounts equal to 0.25% per annum. As of June 30, 2016, we had no outstanding balance on the Line of Credit.

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

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

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

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of June 30, 2016. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

##### *Changes in Internal Control over Financial Reporting*

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Part II — OTHER INFORMATION**

##### **Item 1. Legal Proceedings**

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

**Item 1A. Risk Factors**

In addition to the other information set forth in this report, please carefully consider the factors described in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2015 under the heading “Part I — Item 1A. Risk Factors.” The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition, and/or operating results. There have been no material changes to those risk factors since their disclosure in our most recent Annual Report on Form 10-K.

**Item 2. Unregistered Sales of Equity and Use of Proceeds**

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

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

42

**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 4, 2016 By: /s/ Arthur S. Przybyl  
Arthur S. Przybyl  
President and  
Chief Executive Officer  
(principal executive officer)

Date: August 4, 2016 By: /s/ Stephen P. Carey  
Stephen P. Carey  
Vice President and  
Chief Financial Officer  
(principal financial officer)



**INDEX TO EXHIBITS**

<b>Exhibit No.</b>	<b>Description</b>
10.1	Loan and Security Agreement between Citizens Business Capital and ANI Pharmaceuticals, Inc.
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