ANI PHARMACEUTICALS INC
Form 10-Q
May 05, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2015

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

For the transition period from to .

Commission File Number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

210 Main Street West

Baudette, Minnesota

(Address of principal executive offices)

(218) 634-3500

(Registrant’s telephone number including area code)

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

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

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

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨ (Do not check if smaller reporting company)	Smaller reporting company ¨

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

As of May 1, 2015, there were 11,414,517 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.

FORM 10-Q — Quarterly Report

For the Quarterly Period Ended March 31, 2015

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

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

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

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2014, including the factors described in "Item 1A. Risk Factors," as well as our proxy statement, filed with the SEC on April 24, 2015. Other risks may be described from time to time in our filings made under the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

NOTE REGARDING TRADEMARKS

Cortenema®, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)

(unaudited)

	March 31, 2015	December 31, 2014
Assets		
Current Assets		
Cash and cash equivalents	$ 165,563	$ 169,037
Accounts receivable, net of $8,096 and $8,708 of adjustments for chargebacks and other allowances at March 31, 2015 and December 31, 2014, respectively	17,371	17,297
Inventories, net	10,737	7,518
Deferred tax assets, net of valuation allowance	7,776	7,643
Prepaid expenses and other current assets	1,546	1,983
Total Current Assets	202,993	203,478
Property and equipment, net	5,281	5,223
Deferred financing costs, net	3,096	3,307
Deferred tax asset, net of valuation allowance	7,369	7,796
Intangible assets, net	45,408	42,067
Goodwill	1,838	1,838
Total Assets	$ 265,985	$ 263,709
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 2,288	$ 2,654
Accrued expenses and other	1,897	1,269
Accrued compensation and related expenses	513	1,348
Current income taxes payable	481	4,253
Accrued Medicaid rebates	2,077	2,264
Returned goods reserve	1,817	1,445
Total Current Liabilities	9,073	13,233
Long-term Liabilities		
Convertible notes, net of discount	112,172	110,691
Total Liabilities	$ 121,245	$ 123,924
Commitments and Contingencies (Note 11)		

Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 11,389,317 shares issued and 11,386,817 shares outstanding at March 31, 2015; 11,387,860 shares issued and outstanding at December 31, 2014	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	-	-
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at March 31, 2015 and December 31, 2014, respectively	-	-
Treasury stock, 2,500 shares of common stock, at cost, at March 31, 2015, 0 shares of common stock at December 31, 2014	-	-
Additional paid-in capital	160,095	159,509
Accumulated deficit	(15,356)	(19,725)
Total Stockholders' Equity	144,740	139,785
Total Liabilities and Stockholders' Equity	$ 265,985	$ 263,709

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

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

Condensed Consolidated Statements of Operations

(in thousands, except per share amounts)

(unaudited)

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

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

Condensed Consolidated Statements of Cash Flows

(in thousands)

(unaudited)

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

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

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

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ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

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

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 31, 2014, has been derived from audited financial statements of that date. The interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules and regulations prescribed by the United States Securities and Exchange Commission. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our annual report on Form 10-K for the year ended December 31, 2014. Certain prior period information has been reclassified to conform to the current period presentation.

Principles of Consolidation

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

Use of Estimates

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

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

Recent Accounting Pronouncements

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

In April 2015, the FASB issued guidance to simplify the balance sheet disclosure for debt issuance costs. Under the guidance, debt issuance costs related to a recognized debt liability will be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, in the same manner as debt discounts, rather than as an asset. The standard is effective for reporting periods beginning after December 15, 2015 and early adoption is permitted. We are currently evaluating the impact that this new accounting pronouncement will have on our financial statements.

We have evaluated all other issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our results of operations, financial position, or cash flows.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

2. REVENUE RECOGNITION AND RELATED ALLOWANCES - continued

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

Accruals for Chargebacks, Rebates, Returns and Other Allowances

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

The following table summarizes activity in the balance sheet for accruals and allowances for the three-month periods ended March 31, 2015 and 2014, respectively:

(in thousands)	Accruals for Chargebacks, Rebates, Returns and Other Allowances				
	Chargebacks	Medicaid Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2013	$ 4,076	$ 253	$ 736	$ 735	$ 332
Accruals/Adjustments	7,090	158	258	970	347
Credits Taken Against Reserve	(7,357)	(141)	(145)	(853)	(370)
Balance at March 31, 2014	$ 3,809	$ 270	$ 849	$ 852	$ 309

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

Credit Concentration

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

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARY

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

3. INDEBTEDNESS

Convertible Senior Notes

In December 2014, we issued $143.8 million of our Convertible Senior Note due 2019 (the "Notes") in a registered public offering. After deducting the underwriting discounts and commissions and other expenses (including the net cost of the bond hedge and warrant, discussed below), the net proceeds from the offering were approximately $122.6 million. The Notes pay 3.0% interest semi-annually in arrears on June 1 and December 1 of each year, starting on June 1, 2015 and are due December 1, 2019. The Notes are convertible into 2,068,793 shares of common stock, based on an initial conversion price of $69.48 per share.