

ANI PHARMACEUTICALS INC
Form 10-Q
November 10, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2014

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

For the transition period from to .

Commission File Number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware **58-2301143**
(State or other jurisdiction of (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 ☒ 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 ☐ 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 ☐

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 ☒

As of November 3, 2014, there were 11,318,564 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.

FORM 10-Q — Quarterly Report

For the Quarterly Period Ended September 30, 2014

TABLE OF CONTENTS

	Page
PART I — FINANCIAL INFORMATION	
Item 1. Financial Statements (unaudited)	
<u>Condensed Consolidated Balance Sheets — As of September 30, 2014 and December 31, 2013</u>	4
<u>Condensed Consolidated Statements of Operations — For the Three and Nine Months Ended September 30, 2014 and 2013</u>	5
<u>Condensed Consolidated Statements of Cash Flows — For the Nine Months Ended September 30, 2014 and 2013</u>	6
<u>Notes to Condensed Consolidated Financial Statements</u>	7
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	25
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	35
Item 4. <u>Controls and Procedures</u>	35
PART II — OTHER INFORMATION	
Item 1. <u>Legal Proceedings</u>	36
Item 1A. <u>Risk Factors</u>	36
Item 2. <u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	36
Item 3. <u>Defaults upon Senior Securities</u>	36
Item 4. <u>Mine Safety Disclosures</u>	36
Item 5. <u>Other Information</u>	36
Item 6. <u>Exhibits</u>	37
<u>Signatures</u>	38

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

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

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

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2013, including the factors described in "Item 1A. Risk Factors," as well as our proxy statement, filed with the SEC on April 11, 2014. Other risks may be described from time to time in our filings made under the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

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

	September 30, 2014	December 31, 2013
Assets		
Current Assets		
Cash and cash equivalents	\$ 35,050	\$ 11,105
Accounts receivable, net of \$8,100 and \$5,104 of allowances for chargebacks and other allowances at September 30, 2014 and December 31, 2013, respectively	14,570	12,513
Inventories, net	7,346	3,518
Prepaid expenses	599	580
Total Current Assets	57,565	27,716
Property, plant, and equipment, net	5,046	4,537
Intangible assets, net	43,188	10,409
Goodwill	1,838	1,838
Total Assets	\$ 107,637	\$ 44,500
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 3,059	\$ 1,429
Accrued expenses	3,888	1,326
Returned goods reserve	1,178	736
Deferred revenue	20	47
Total Current Liabilities	8,145	3,538
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, \$0.0001 par value, 33,333,334 shares authorized; 11,318,014 shares issued and outstanding at September 30, 2014; 9,629,174 shares issued and 9,619,941 shares outstanding at December 31, 2013	1	1
Class C Special Stock, \$0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	-	-
	-	-

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Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively

Treasury stock, 0 and 9,233 shares of common stock, at cost, at September 30, 2014 and December 31, 2013, respectively	-	(68)
Additional paid-in capital	140,221	89,501	
Accumulated deficit	(40,730)	(48,472
Total Stockholders' Equity	99,492	40,962)
Total Liabilities and Stockholders' Equity	\$ 107,637	\$ 44,500	

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

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

	Three months ended September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Net Revenues	\$ 17,387	\$ 7,836	\$ 34,933	\$ 19,550
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	3,061	2,710	7,800	7,290
Research and development	883	454	2,110	1,188
Selling, general and administrative	4,057	3,480	13,193	12,961
Depreciation and amortization	1,187	382	2,596	673
Total Operating Expenses	9,188	7,026	25,699	22,112
Operating Income/(Loss)	8,199	810	9,234	(2,562)
Other Income/(Expense)				
Interest income/(expense)	10	-	13	(467)
Other income/(expense)	82	148	72	(336)
Income/(Loss) Before Provision for Income Taxes	8,291	958	9,319	(3,365)
(Provision)/Benefit for Income Taxes	(1,545)	83	(1,577)	83
Net Income/(Loss) from Continuing Operations	6,746	1,041	7,742	(3,282)
Discontinued Operation				
Gain on discontinued operation, net of provision for income taxes	-	150	-	150
Net Income/(Loss)	\$ 6,746	\$ 1,191	\$ 7,742	\$ (3,132)
Computation of Income/(Loss) from Continuing Operations Attributable to Common Stockholders and Participating Securities:				
Net Income/(Loss) from Continuing Operations	\$ 6,746	\$ 1,041	\$ 7,742	\$ (3,282)
Preferred stock dividends	-	-	-	(4,974)
	\$ 6,746	\$ 1,041	\$ 7,742	\$ (8,256)

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Income/(Loss) from Continuing Operations Attributable
to Common Stockholders and Participating Securities

Basic and Diluted Earnings/(Loss) Per Share:

Continuing Operations	\$ 0.59	\$ 0.11	\$ 0.71	\$ (2.31))
Discontinued Operation	-	0.02	-	0.04	
Basic Earnings/(Loss) Per Share	\$ 0.59	\$ 0.13	\$ 0.71	\$ (2.27))
Continuing Operations	\$ 0.59	\$ 0.11	\$ 0.70	\$ (2.31))
Discontinued Operation	-	0.02	-	0.04	
Diluted Earnings/(Loss) Per Share	\$ 0.59	\$ 0.13	\$ 0.70	\$ (2.27))
Basic Weighted-Average Shares Outstanding	11,235	9,480	10,824	3,577	
Diluted Weighted-Average Shares Outstanding	11,302	9,480	10,865	3,577	

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

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

	Nine months ended September 30,	
	2014	2013
Cash Flows From Operating Activities		
Net income/(loss)	\$ 7,742	\$ (3,132)
Adjustments to reconcile net income to net cash and cash equivalents provided by/(used in) operating activities:		
Stock-based compensation	2,719	3
Depreciation and amortization	2,596	673
Non-cash interest relating to equity-linked securities and loan cost amortization	-	217
Non-cash compensation relating to business combination	-	4,418
Changes in operating assets and liabilities:		
Accounts receivable	(2,057)	(4,083)
Inventories	(3,296)	1
Prepaid expenses	(19)	(188)
Accounts payable	630	93
Accrued expenses, returned goods reserve and deferred revenue	2,977	(382)
Net Cash and Cash Equivalents Provided by/(Used in) Continuing Operations	11,292	(2,380)
Net Cash and Cash Equivalents Used in Discontinued Operation	-	(239)
Net Cash and Cash Equivalents Provided by/(Used in) Operating Activities	11,292	(2,619)
Cash Flows From Investing Activities		
Cash acquired in business combination	-	18,198
Acquisition of product rights and other related assets	(34,634)	-
Acquisition of property and equipment	(782)	(162)
Net Cash and Cash Equivalents (Used in)/Provided by Investing Activities	(35,416)	18,036
Cash Flows From Financing Activities		
Net proceeds from equity offering	46,680	-
Borrowings under line of credit, net	-	(4,065)
Treasury stock purchases	-	(433)
Proceeds from stock option exercises	777	-
Proceeds from warrant exercises	180	-
Excess tax benefit from share-based compensation awards	432	-

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Net Cash and Cash Equivalents Provided by/(Used in) Financing Activities	48,069	(4,498)
Change in Cash and Cash Equivalents	23,945	10,919
Cash and cash equivalents, beginning of period	11,105	11
Cash and cash equivalents, end of period	\$ 35,050	\$ 10,930
Supplemental disclosure for cash flow information:		
Cash paid for interest	\$ -	\$ 250
Cash paid for income taxes	\$ 137	\$ -
Supplemental non-cash investing and financing activities:		
Contingent payable for asset purchase	\$ 1,000	\$ -
Issuance of common stock in connection with business combination	\$ -	\$ 40,034
Cancellation of Series D, Series C, Series B, and Series A preferred stock	\$ -	\$ 53,726
Acquired non-cash net assets	\$ -	\$ 11,597
Preferred stock dividends accrued	\$ -	\$ 4,974

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

ANI PHARMACEUTICALS, INC. and subsidiary

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and subsidiary, ANIP Acquisition Company (together, the “Company,” “we,” or “us”) is an integrated specialty pharmaceutical company developing, manufacturing, and marketing branded and generic prescription pharmaceuticals. Our targeted areas of product development currently include narcotics, oncology (anti-cancers), hormones and steroids, and complex formulations involving extended release and combination products. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota, which are capable of producing oral solid dose products, as well as liquids and topicals, narcotics, and potent products that must be manufactured in a fully-contained environment. Our strategy is to continue to use these manufacturing assets to develop, produce, and distribute niche generic pharmaceutical products.

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

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 31, 2013, has been derived from audited financial statements of that date. The interim condensed consolidated results of operations are not necessarily indicative of the

results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules and regulations prescribed by the United States Securities and Exchange Commission. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our annual report on Form 10-K for the year ended December 31, 2013. Certain prior period information has been reclassified to conform to the current period presentation.

Principles of Consolidation

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

ANI PHARMACEUTICALS, INC. and subsidiary

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

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

Use of Estimates

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

Recent Accounting Pronouncements

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

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the

transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

In August 2014, the FASB issued guidance requiring management to evaluate on a regular basis whether any conditions or events have arisen that could raise substantial doubt about the entity's ability to continue as a going concern. The guidance 1) provides a definition for the term "substantial doubt," 2) requires an evaluation every reporting period, interim periods included, 3) provides principles for considering the mitigating effect of management's plans to alleviate the substantial doubt, 4) requires certain disclosures if the substantial doubt is alleviated as a result of management's plans, 5) requires an express statement, as well as other disclosures, if the substantial doubt is not alleviated, and 6) requires an assessment period of one year from the date the financial statements are issued. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is permitted. We do not expect the adoption of this guidance to have a material impact 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.

ANI PHARMACEUTICALS, INC. and subsidiary

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, pri