ANI PHARMACEUTICALS INC
Form 10-Q
November 07, 2013

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 September 30, 2013

¨ **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 x

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 October 31, 2013, 9,480,206 shares of common stock and 10,868 shares of class C special stock of the registrant were outstanding.

ANI PHARMACEUTICALS, INC.
FORM 10-Q Quarterly Report
For the Quarterly Period Ended September 30, 2013
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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 under the Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about the potential benefits of the recent merger between BioSante Pharmaceuticals, Inc. and ANIP Acquisition Company (the "Merger"), the Company's plans, objectives, expectations and intentions with respect to future operations and products, the anticipated financial position, operating results and growth prospects of the Company 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 and the use of future dates. Forward-looking statements by their nature address matters that are, to different degrees, uncertain. Uncertainties and risks may cause the Company's actual results to be materially different than those expressed in or implied by such forward-looking statements. Uncertainties and risks include the risk that the Company may in the future be required to seek FDA approval for its unapproved products or withdraw such products from the market; the Company may fail to meet NASDAQ listing requirements; general business and economic conditions; the Company's need for and ability to obtain additional financing; the difficulty of developing pharmaceutical products, obtaining regulatory and other approvals and achieving market acceptance; and the marketing success of the Company's licensees or sublicensees. More detailed information on these and additional factors that could affect the Company's actual results are described in the Company's filings with the Securities and Exchange Commission, including its most recent annual report on Form 10-K and this quarterly report on Form 10-Q, as well as its proxy statement/prospectus, filed with the Securities and Exchange Commission on May 8, 2013. All forward-looking statements in this quarterly report speak only as of the date made and are based on the Company's current beliefs and expectations. The Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

ANI PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2013	December 31, 2012
Assets		
Current Assets		
Cash and cash equivalents	$ 10,929,806	$ 11,028
Restricted cash	2,260,100	-
Accounts receivable, net	9,515,096	5,432,401
Inventories, net	2,809,160	2,809,685
Prepaid expenses	580,597	313,193
Total Current Assets	26,094,759	8,566,307
Property and Equipment		
Land	86,949	86,949
Buildings	3,682,006	3,682,006
Machinery, furniture and equipment	3,736,484	3,564,948
Construction in progress	197,948	208,069
	7,703,387	7,541,972
Less: accumulated depreciation	3,062,900	2,662,799
Total Property and Equipment, net	4,640,487	4,879,173
Other Assets		
Intangible assets, net	10,712,273	85,000
Goodwill	1,838,309	-
Deferred loan costs, net	-	217,290
Total Other Assets	12,550,582	302,290
Total Assets	$ 43,285,828	$ 13,747,770

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

ANI PHARMACEUTICALS, INC.

Condensed Consolidated Balance Sheets

(Unaudited)

	September 30, 2013	December 31, 2012
Liabilities and Stockholders' Equity/(Deficit)		
Current Liabilities		
Accounts payable	$ 2,086,847	$ 1,993,567
Accrued expenses	1,338,215	555,635
Returned goods reserve	457,890	410,992
Deferred revenue	46,712	314,794
Borrowings under line of credit	-	4,065,307
Accrued compensation	2,535,746	21
Current liabilities, discontinued operation	131,613	370,766
Total Current Liabilities	6,597,023	7,711,082
Commitments and Contingencies (Note 10)		
Redeemable Convertible Preferred Stock		
10% Convertible Preferred Stock, Series A, $0.10 par value, stated value of $100 per share; no shares authorized, issued, or outstanding at September 30, 2013; 108,494 shares authorized, 102,774 shares issued and outstanding including cumulative dividends of $2,186,326 at December 31, 2012	-	11,579,126
10% Convertible Preferred Stock, Series B, $0.10 par value, stated value of $110 per share; no shares authorized, issued, or outstanding at September 30, 2013; 118,915 shares authorized, 78,491 shares issued and outstanding including cumulative dividends of $1,836,734 at December 31, 2012	-	10,560,082
12% Convertible Preferred Stock, Series C, $0.10 par value, stated value of $110 per share; no shares authorized, issued, or outstanding at September 30, 2013; 37,956 shares authorized, 34,810 shares issued and outstanding including cumulative dividends $994,471 at December 31, 2012	-	4,814,735
10% Convertible Preferred Stock, Series D, $0.10 par value, stated value of $30 per share; no shares authorized, issued, or outstanding at September 30, 2013; 3,400,000 shares authorized, 2,375,312 shares issued and outstanding including cumulative dividends of $4,184,858 at December 31, 2012	-	21,797,240
Total Redeemable Convertible Preferred Stock	-	48,751,183

Stockholders' Equity/(Deficit)		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 9,539,299 shares issued and 9,480,206 shares outstanding at September 30, 2013; 4,070,373 shares issued and outstanding at December 31, 2012	954	407
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,868 shares issued and outstanding at September 30, 2013 and December 31, 2012	-	-
Additional paid-in capital	89,024,878	1,083,431
Accumulated deficit	(51,904,465)	(43,798,333)
Treasury stock, 59,093 shares of common stock, at cost, on September 30, 2013	(432,562)	-
Total Stockholders' Equity/(Deficit)	36,688,805	(42,714,495)
Total Liabilities and Stockholders' Equity/(Deficit)	$ 43,285,828	$ 13,747,770

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

ANI PHARMACEUTICALS, INC.

Condensed Consolidated Statements of Operations

(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Net Revenues	$ 7,836,222	$ 5,036,024	$ 19,549,670	$ 15,049,619
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	2,629,119	2,321,773	7,066,195	6,292,377
Salaries and benefits	1,729,066	1,291,667	8,699,638	3,516,427
Freight	81,416	80,622	224,189	242,814
Research and development	453,897	148,650	1,187,461	636,726
Selling, general and administrative	1,750,734	1,256,754	4,261,182	2,961,649
Depreciation and amortization	381,699	143,959	672,828	425,238
Total Operating Expenses	7,025,931	5,243,425	22,111,493	14,075,231
Operating Income/(Loss) from Continuing Operations	810,291	(207,401)	(2,561,823)	974,388
Other Income/(Expense)				
Interest expense	-	(81,225)	(466,902)	(1,239,137)
Other income/(expense)	147,563	(91,205)	(336,393)	(190,605)
Net Income/(Loss) from Continuing Operations Before Income Tax Benefit	957,854	(379,831)	(3,365,118)	(455,354)
Income tax benefit	82,852	866	82,852	36,327
Net Income/(Loss) from Continuing Operations	1,040,706	(378,965)	(3,282,266)	(419,027)
Discontinued Operation				
Gain on discontinued operation, net of tax	150,337	1,617	150,337	67,793
Net Income/(Loss)	$ 1,191,043	$ (377,348)	$ (3,131,929)	$ (351,234)
Computation of Income/(Loss) from Continuing OperationsAttributable to Common Stockholders:				
Net Income/(Loss) from Continuing Operations	$ 1,040,706	$ (378,965)	$ (3,282,266)	$ (419,027)
Preferred stock dividends	-	(2,527,565)	(4,974,199)	(4,326,622)
Income/(Loss) from Continuing Operations Attributable to Common Stockholders	$ 1,040,706	$ (2,906,530)	$ (8,256,465)	$ (4,745,649)

Basic and Diluted Income/(Loss) Per Share:				
Continuing operations	$ 0.11	$ (1,295.82)	$ (2.31)	$ (4,689.38)
Discontinued operation	0.02	0.72	0.04	66.99
Basic and Diluted Income/(Loss) Per Share	$ 0.13	$ (1,295.10)	$ (2.27)	$ (4,622.39)
Basic and Diluted Weighted-Average Shares Outstanding	9,480,206	2,243	3,578,178	1,012

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

ANI PHARMACEUTICALS, INC.		
Condensed Consolidated Statements of Cash Flows		
(Unaudited)		
For the nine months ended September 30,	2013	2012
Cash Flows From Operating Activities		
Net loss from continuing operations	$ (3,282,266)	$ (419,027)
Adjustments to reconcile net loss to net cash and cash equivalents used in operating activities:		
Stock-based compensation	2,951	-
Depreciation and amortization	672,828	425,238
Non-cash interest relating to convertible debt and loan cost amortization	217,290	1,027,713
Non-cash compensation relating to business combination	4,418,524	-
Changes in operating assets and liabilities, net of those acquired in business combination:		
Accounts receivable	(4,082,695)	(518,429)
Inventories	525	(387,172)
Prepaid expenses	(188,143)	83,031
Accounts payable	93,280	87,897
Accrued expenses, returned goods reserve and deferred revenue	(382,858)	188,271
Net Cash and Cash Equivalents (Used in)/Provided by Continuing Operations	(2,530,564)	487,522
Net Cash Used in Discontinued Operation	(88,816)	(65,917)
Net Cash and Cash Equivalents (Used in)/Provided by Operating Activities	(2,619,380)	421,605
Cash Flows From Investing Activities		
Cash acquired in business combination	18,197,442	-
Acquisition of property and equipment, net of disposals	(161,415)	(76,888)
Net Cash and Cash Equivalents Provided by/(Used in) Investing Activities	18,036,027	(76,888)
Cash Flows From Financing Activities		
(Repayments)/borrowings under line of credit, net	(4,065,307)	364,362
Payment of debt issuance costs	-	(260,748)
Treasury stock purchases	(432,562)	-
Net Cash and Cash Equivalents Used in Continuing Operations	(4,497,869)	103,614
Net Cash Used in Discontinued Operation	-	(300,000)
Net Cash and Cash Equivalents Used in Financing Activities	(4,497,869)	(196,386)
Change in Cash and Cash Equivalents	10,918,778	148,331
Cash and cash equivalents, beginning of period	11,028	-
Cash and cash equivalents, end of period	$ 10,929,806	$ 148,331
Supplemental disclosure for cash flow information:		

Cash paid for interest	$	249,612	$	211,424
Supplemental non-cash investing and financing activities:				
Issuance of common stock in business combination	$	40,033,695	$	-
Cancellation of Series D, Series C, Series B, Series A, and common stock	$	57,296,106	$	-
Acquired intangibles	$	10,900,000	$	-
Acquired goodwill	$	1,838,309	$	-
Acquired restricted cash	$	2,260,100	$	-
Other acquired tangible assets	$	79,261	$	-
Assumed liabilities	$	3,479,979	$	-
Preferred stock dividends	$	4,974,199	$	4,326,622
Issuance of common and preferred stock upon cashless warrant exercise	$	-	$	4,984
Issuance of preferred stock upon convertible debt conversion	$	-	$	17,609,646

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

ANI PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Overview

ANI Pharmaceuticals, Inc. (the "Company") is a specialty pharmaceutical company, developing and marketing generic and branded prescription products. In two facilities located in Baudette, Minnesota, with combined manufacturing, packaging and laboratory capacity totaling 173,000 sq. ft., the Company manufactures oral solid dose products, as well as liquids and topicals, including those that must be manufactured in a fully contained environment due to their potency and/or toxicity. The Company also performs contract manufacturing for other pharmaceutical companies.

On June 19, 2013, BioSante Pharmaceuticals, Inc. ("BioSante") acquired ANIP Acquisition Company ("ANIP") in an all-stock, tax-free reorganization (Note 2), in which ANIP became a wholly-owned subsidiary of BioSante. BioSante was renamed ANI Pharmaceuticals, Inc. The Merger was accounted for as a reverse acquisition pursuant to which ANIP was considered the acquiring entity for accounting purposes. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. The results of operations of both companies are included in the Company's financial statements for all periods after completion of the Merger.

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, lack of operating history and uncertainty of future profitability and possible fluctuations in financial results. The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations, and potential other funding sources, including cash on hand, to meet the Company's obligations as they become due. Management believes the going-concern basis is appropriate for the accompanying unaudited condensed consolidated financial statements based on its current operating plan through September 30, 2014.

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 ("US GAAP"). In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 31, 2012, 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 US GAAP have been omitted pursuant to instructions, rules and regulations prescribed by the instructions to Form 10-Q and Article 10 of Regulation S-X of the United States Securities and Exchange Commission. Management believes that the disclosures provided herein are adequate to make the information presented not misleading when these condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in the Company's annual report on Form 10-K for the year ended December 31, 2012 and proxy statement/prospectus filed on May 8, 2013. Certain prior period information has been reclassified to conform to the current period presentation.

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ANI PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES cont'd.

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.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires management 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, valuation of derivative liabilities, allowances for contingencies and litigation, deferred tax valuation allowance, and the depreciable lives of fixed assets. Actual results could differ from those estimates.

Credit Concentration

The Company's customers are primarily pharmaceutical companies, wholesale distributors, chain drug stores, and group purchasing organizations.

During the three month period ended September 30, 2013, two customers represented 27% and 19% of net revenues. During the three month period ended September 30, 2012, these same customers represented 24% and 25% of net revenues, respectively. As of September 30, 2013, accounts receivable from these customers totaled $6,105,271. During the nine month period ended September 30, 2013, four customers represented approximately 28%, 18%, 10%, and 5% of net revenues. During the nine month period ended September 30, 2012, these same four customers represented 24%, 21%, 8%, and 12% of net revenues, respectively.

Vendor Concentration

During the three month period ended September 30, 2013, the Company purchased approximately 54% of total costs of goods sold from two suppliers. As of September 30, 2013, amounts payable to these suppliers totaled $700,424. During the nine month period ended September 30, 2013, the Company purchased approximately 31% of total costs of goods sold from two suppliers. During the three month period ended September 30, 2012, the Company purchased approximately 43% of total costs of goods sold from two suppliers. During the nine month period ended September 30, 2012, the Company purchased approximately 55% of total costs of goods sold from three suppliers.

Revenue Recognition

Revenue is recognized for product sales upon passing of risk and title to the customer, when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured, and the Company has no further performance obligations.

These estimates reduce gross revenues to net revenues in the accompanying unaudited condensed consolidated statements of operations, and are presented as current liabilities or reductions in accounts receivable in the accompanying unaudited condensed consolidated balance sheets.

ANI PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES cont'd.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with original maturities of three months or less to be cash equivalents. All interest bearing and non-interest bearing accounts are guaranteed by the FDIC up to $250,000. The Company may maintain cash balances in excess of FDIC coverage. Management considers this to be a normal business risk.

In conjunction with the Merger, the Company acquired restricted cash, which will be paid out in satisfaction of certain severance liabilities assumed in the Merger (Note 2).

Accounts Receivable

The Company extends credit to customers on an unsecured basis. The Company uses the allowance method to provide for doubtful accounts based on management's evaluation of the collectability of accounts receivable, whereby the Company provides an allowance for doubtful accounts equal to the estimated uncollectible amounts. Management's estimate is based on historical collection experience and a review of the current status of trade accounts receivable. The Company determines trade receivables to be delinquent when they are greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. Management determined that no allowance for doubtful accounts was necessary as of September 30, 2013 and December 31, 2012.

Accruals for Chargebacks, Returns and Other Allowances

The Company's generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates and prompt payment discounts. The Company accrues for these items at the time of sale and continually monitors and re-evaluates the accruals as additional information becomes available. The Company makes adjustments to 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 nine month periods ended September 30, 2013 and 2012, respectively:

	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at January 1, 2013	$ 5,661,974	$ 410,992	$ 230,575	$ 241,840
Accruals/adjustments	20,132,724	1,154,726	1,435,996	751,993
Credits taken against reserve	(19,734,545)	(1,107,828)	(979,404)	(667,473)
Balance at September 30, 2013	$ 6,060,153	$ 457,890	$ 687,167	$ 326,360

	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts

Balance at January 1, 2012	$ 3,680,838	$ 252,045	$ 238,195	$ 166,439
Accruals/adjustments	15,996,550	486,844	925,488	522,812
Credits taken against reserve	(15,348,165)	(351,274)	(892,370)	(481,435)
Balance at September 30, 2012	$ 4,339,223	$ 387,615	$ 271,313	$ 207,816

ANI PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES cont'd.

Inventories

Inventories consist of raw materials, packaging materials, work-in-progress, and finished goods. Inventories are stated at the lower of cost or net realizable value. The Company values inventory at standard cost. The Company reviews and adjusts standard costs periodically and its inventory, as valued, approximates weighted average cost.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation is recorded on a straight-line basis over estimated useful lives as follows:

Buildings and improvements	20-40 years
Machinery, furniture and equipment	3-10 years

Construction in progress includes the cost of construction and other direct costs attributable to the construction, along with capitalized interest, if any. Depreciation is not recorded on construction in progress until such time as the assets are placed in service. During the nine month period ended September 30, 2013 and the year ended December 31, 2012, there was no material interest capitalized into construction in progress.

Depreciation expense for the three month periods ended September 30, 2013 and 2012 totaled $133,972 and $131,459, respectively. Depreciation expense for the nine month periods ended September 30, 2013 and 2012 totaled $400,101 and $387,738, respectively.

Management reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. Assets held for disposal are reportable at the lower of the carrying amount or fair value, less costs to sell. Management determined that no assets were impaired and no assets were held for disposal as of September 30, 2013 and December 31, 2012.

Income Taxes

The Company uses 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. For interim periods, the Company recognizes an income tax provision (benefit) based on its estimated annual effective tax rate expected for the entire year.

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ANI PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES cont'd.

Income Taxes cont'd.

Management uses 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. The Company has not identified any uncertain income tax positions that could have a material impact on the financial statements. The Company is subject to taxation in various jurisdictions and remains subject to examination by taxing jurisdictions for the years 1998 and all subsequent periods due to the availability of net operating loss carryforwards.

The Company recognizes interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense. The Company did not have any amounts accrued relating to interest and penalties as of September 30, 2013 and December 31, 2012.

The Company considers potential tax effects resulting from discontinued operations and records intra-period tax allocations, when those effects are deemed material.

Income/(Loss) per Share

Basic income/(loss) per share is calculated by dividing net income/(loss) less preferred stock dividends 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, diluted earnings per share is computed by dividing net income by the weighted-average number of shares of common stock outstanding plus the impact of all potential dilutive common shares, consisting primarily of stock purchase warrants and common stock options, using the treasury stock method.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive due to the net losses.

The number of anti-dilutive shares, consisting of Class C Special stock, common stock options, and warrants exercisable for common stock (and prior to the Merger, warrants exercisable for preferred stock, convertible debt, and convertible preferred stock), which have been excluded from the computation of diluted income/(loss) per share for the three month periods ended September 30, 2013 and 2012, were 909,792 and 242,247, respectively. The number of anti-dilutive shares, consisting of Class C Special stock, common stock options, and warrants exercisable for common stock, (and prior to the Merger, warrants exercisable for preferred stock, convertible debt, and convertible preferred stock), which have been excluded from the computation of diluted income/(loss) per share for the nine month periods ended September 30, 2013 and 2012, were 498,647 and 115,351, respectively.

As of September 30, 2013, the Company had 120,066 common stock options and 781,349 warrants exercisable for common stock outstanding.

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ANI PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(unaudited)

1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES cont'd.

Stock Splits

In July 2013, the Company's Board of Directors and stockholders approved a resolution to effect a one-for-six reverse stock split of the Company's common stock and Class C Special stock with no corresponding change to the par value. The number of authorized shares of common stock, Class C Special stock and blank check preferred stock was reduced proportionally. Common stock and Class C Special share numbers for all periods presented have been adjusted retrospectively to reflect the one-for-six reverse stock split.

Redeemable Convertible Preferred Stock

The carrying value of the Company's redeemable convertible preferred stock was increased by the accretion of any related discounts and accrued but unpaid dividends so that the carrying amount would equal the redemption amount at the dates the stock became redeemable. The Company's Series A, B, C and D preferred stock was redeemable at the option of the holders, subject to certain additional requirements. All of the Company's Series D preferred stock was exchanged for shares of BioSante common stock and all of the Company's Series A, B and C preferred stock were canceled in conjunction with the Merger (Note 2).

Segment Information

The Company currently operates in a single business segment.

Recent Accounting Pronouncements

The Company has evaluated all issued and unadopted Accounting Standards Updates and believes the adoption of these standards will not have a material impact on its results of operations, financial position, or cash flows.

2. BUSINESS COMBINATION

Summary

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

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

The Merger was accounted for as a reverse acquisition pursuant to which ANIP was considered the acquiring entity for accounting purposes. As such, ANIP's historical results of operations replace BioSante's historical results of operations for all periods prior to the Merger. BioSante, the accounting acquiree, was a pharmaceutical company

focused on developing high value, medically-needed products. ANIP entered into the Merger to secure additional capital and gain access to capital market opportunities as a public company.

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2. BUSINESS COMBINATION cont'd.

The results of operations of both companies are included in the Company's financial statements for all periods after completion of the Merger.

Transaction Costs

In conjunction with the Merger, the Company incurred approximately $7.1 million in transaction costs, which were expensed in the periods in which they were incurred. Costs incurred through September 30, 2013, include:

Category	
Legal fees	$1,226,535
Accounting fees	121,748
Consulting fees	119,194
Monitoring and advisory fees	390,000
Transaction bonuses	4,801,364
Other	428,992
Total transaction costs	$7,087,833

Of the total expenses, $928,695 was incurred and expensed in 2012 and $6,159,138 was incurred and expensed in the nine months ended September 30, 2013.

Purchase Consideration and Net Assets Acquired

The fair value of BioSante's common stock used in determining the purchase price was $1.22 per share, the closing price on June 19, 2013. The fair value of the vested BioSante stock options was not material. The following presents the preliminary allocation of the purchase consideration to the assets acquired and liabilities assumed on June 19, 2013:

Fair value of BioSante shares outstanding	$29,795,133
Estimated fair value of vested BioSante stock options	-
Total purchase consideration	$29,795,133
Assets acquired	
Cash and cash equivalents	$18,197,442
Restricted cash	2,260,100
Teva license intangible asset	10,900,000
Other tangible assets	79,261
Deferred tax assets, net	-
Goodwill	1,838,309
Total assets	33,275,112
Liabilities assumed	
Accrued severance	2,964,962
Other liabilities	515,017
Total liabilities	3,479,979

Total net assets acquired	$29,795,133

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2. BUSINESS COMBINATION cont'd.

The above allocation of the purchase price is based upon certain preliminary valuations and other analyses that have not been completed as of the date of this filing. Any changes in the estimated fair values of the net assets recorded for this business combination upon the finalization of more detailed analyses of the facts and circumstances that existed at the date of the transaction will change the allocation of the purchase price. As such, the purchase price allocations for this transaction are preliminary estimates, which are subject to change within the measurement period. Any subsequent changes to the purchase allocation that are material will be adjusted retrospectively during the measurement period.

The Teva license is being amortized on a straight-line basis over its estimated useful life of 11 years. Goodwill, which is not tax deductible since the transaction was structured as a tax-free exchange, is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition.

Former BioSante operations did not generate any revenue or expense from the acquisition date through September 30, 2013.

Pro Forma Condensed Combined Financial Information (unaudited)

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

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Net revenues	$ 7,836,222	$ 5,146,407	$ 19,694,710	$ 15,382,782
Net income/(loss)	$ 1,691,720	$ (6,246,057)	$ (3,178,713)	$ (23,066,678)

3. ACCOUNTS RECEIVABLE

Accounts receivable consist of the following as of:

	September 30, 2013	December 31, 2012
Accounts receivable, gross	$ 16,568,775	$ 11,556,510
Adjustments for chargebacks and other allowances	(7,053,679)	(6,124,109)
Accounts receivable, net	$ 9,515,096	$ 5,432,401

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4. INVENTORIES

Inventories consist of the following as of:

	September 30, 2013	December 31, 2012
Raw materials	$ 1,407,457	$ 974,967
Packaging materials	650,058	584,654
Work-in-progress	171,464	374,257
Finished goods	664,180	890,683
	2,893,159	2,824,561
Reserve for excess/obsolete inventories	(83,999)	(14,876)
Inventories, net	$ 2,809,160	$ 2,809,685

5. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of the Merger (Note 2), the Company recorded goodwill of $1,838,309. The Company conducts an impairment test of goodwill on an annual basis as of October 31 of each year. The Company also conduct tests if events occur or circumstances change that would, more likely than not, reduce the fair value of the Company below its carrying value. No such triggering events were identified during the period from the date of the Merger to September 30, 2013 and therefore no impairment loss was recognized as of September 30, 2013.

Intangible Assets

The components of net intangible assets are as follows:

	September 30, 2013		December 31, 2012		
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	Amortization Period
Acquired ANDA intangible asset	$ 60,000	$ -	$ 60,000	$ -	3 years
Reglan ® intangible asset	100,000	(100,000)	100,000	(75,000)	2 years
Teva license intangible asset	10,900,000	(247,727)	-	-	11 years
	$ 11,060,000	$ (347,727)	$ 160,000	$ (75,000)	

Intangible assets are stated at the lower of cost or fair value, net of amortization using the straight line method over the expected useful lives of the product rights, once the related products begin to sell. Amortization expense was $247,727 and $12,500 for the three month periods ended September 30, 2013 and 2012, respectively. Amortization expense was $272,727 and $37,500 for the nine month periods ended September 30, 2013 and 2012, respectively.

The Company tests 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 period from the date of the Merger to September 30, 2013 and therefore no impairment loss was recognized as of September 30, 2013.

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5. GOODWILL AND INTANGIBLE ASSETS cont'd.

Intangible Assets cont'd.

Expected future amortization expense is as follows:

2013 (remainder of year)	$247,728
2014	997,577
2015	1,010,910
2016	1,010,910
2017	1,004,243
2018 and thereafter	6,440,905
Total	$10,712,273

6. DISCONTINUED OPERATION

On September 17, 2010, the Company sold its operation in Gulfport, Mississippi to a third-party. The decision to sell the Gulfport operation was based on its historical underperformance and recurring losses and the anticipated need for continued financing from outside sources to maintain ongoing operations.

As of September 30, 2013 and December 31, 2012, total net liabilities associated with discontinued operation were $131,613 and $370,766, respectively, and consisted of balances due to various vendors of the discontinued operation and other remaining liabilities. These liabilities have been segregated from continuing operations in the accompanying unaudited condensed consolidated balance sheets.

The gains on discontinued operation totaled $150,337 and $1,617, net of $82,852 and $866 of income tax expense, respectively, for the three month periods ended September 30, 2013 and 2012, respectively. The gains on discontinued operation totaled $150,337 and $67,793, net of $82,852 and $36,327 of income tax expense, respectively, for the nine month periods ended September 30, 2013 and 2012, respectively and have been segregated from continuing operations in the accompanying unaudited condensed consolidated statements of operations. During the three and nine month periods ended September 30, 2013, the gain on discontinued operation was the result of finalizing a portion of the remaining liabilities. During the nine month period ended September 30, 2012, the gain on discontinued operation consisted of various vendor settlements.

7. LINE OF CREDIT

Prior to June 2012, the Company had borrowings under a line of credit agreement with a commercial lender. Under the terms of a forbearance agreement, amended in October 2011, the Company could borrow an amount equal to the lesser of the borrowing base, as defined, or $3.5 million. Interest accrued at an annual rate of the Base Rate, as defined, plus 6.0%. In addition, a usage fee equal to 0.75% per annum of the unused facility and a management fee equal to $9,000 per annum were assessed monthly. The line of credit was secured by substantially all of the Company's assets. The line of credit and amended forbearance agreement expired in June 2012 and all amounts borrowed were repaid in full at that time.

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7. LINE OF CREDIT cont'd.

In June 2012, the Company entered into a new revolver loan agreement with a commercial bank in the amount of $5,000,000. The revolver loan agreement bore interest daily at the greater of (i) LIBOR plus 5%, or (ii) 6%, and was secured by substantially all of the Company's assets. In addition, a usage fee equal to 0.375% per annum of the unused facility and a management fee equal to $18,000 per annum were assessed monthly. Under the agreement, the Company was required to maintain a minimum fixed charge coverage ratio of 1.1 to 1.0, calculated by dividing (a) (i) earnings before interest, taxes, depreciation and amortization (EBITDA) less (ii) unfinanced capital expenditures, by the sum of cash paid for (b) (i) interest and (ii) monitoring and advisory fees (Note 10). Also, the Company was required to generate at least $800,000 in EBITDA measured on a trailing four-quarter basis. Restrictive covenants applied to, among other things, research and development expenditures, additional liens, mergers or consolidations, and sales of assets. The Company was not in compliance with certain covenants as of December 31, 2012. The Company subsequently obtained a waiver from its lender, the loan covenants were revised, and the revolver loan limit was increased to $6.0 million.

Beginning in 2013, the Company was required to maintain a minimum fixed charge coverage ratio of 1.1 to 1.0. Also beginning in 2013, the Company was required to generate at least $225,000 in EBITDA during the three month period ending March 31, 2013, $450,000 in EBITDA during the six month period ending June 30, 2013, $675,000 in EBITDA during the nine month period ending September 30, 2013, and $900,000 in EBITDA for the year ended December 31, 2013 and for every quarterly period thereafter measured on a trailing four-quarter basis. Restrictive covenants applied to, among other things, additional liens, mergers or consolidations, and sales of assets. In the event of early termination, the Company was required to pay a prepayment fee of $180,000 if termination occurred in the first year, $120,000 if termination occurred in the second year, and $60,000 if termination occurred after the second year but prior to the last day of the term. As of December 31, 2012, $4,065,307 was outstanding on the revolver, at an effective interest rate of 6.0%. The revolver loan was repaid in full in June 2013.

8. STOCK-BASED COMPENSATION

All options are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"). As of September 30, 2013, 185,490 shares of the Company's common stock remained available for issuance under the 2008 Plan.

On July 12, 2013, the Company's Board of Directors approved grants of stock options to employees under the 2008 Plan, subject to shareholder approval of an increase in the total shares available for issuance under the 2008 Plan. As of September 30, 2013, the Company had 326,424 common stock options outstanding pending shareholder approval. Expense related to these stock options will begin to be recognized upon shareholder approval.

During the three and nine month periods ended September 30, 2013, the Company granted 20,832 options to board members under the 2008 Plan. Total expense related to these options was $2,951 during the three and nine month periods ended September 30, 2013. No options expired or were exercised during the three month periods ended September 30, 2013. Options to purchase an aggregate 67,093 shares of the Company's common stock expired and were cancelled during the nine month period ended September 30, 2013. No options were exercised during the nine month period ended September 30, 2013.

No warrants were granted or exercised during the three and nine month periods ended September 30, 2013. During the nine month period ended September 30, 2013, 8,333 warrants expired. No warrants expired during the three month

period ended September 30, 2013.

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9. INCOME TAXES

The Company has no current tax provision due to its current and accumulated losses, which result in net operating loss carryforwards. The utilization of the net operating loss carryforwards may be limited in future years as prescribed by Section 382 of the US Internal Revenue Code. Based upon the historical losses and uncertainty of future taxable income, management has fully reserved for the net operating loss carryforwards balance as of September 30, 2013 and December 31, 2012.

10. COMMITMENTS AND CONTINGENCIES

Operating Leases

The Company leases equipment under operating leases that expire in May 2017. The Company also leases office space under operating leases that expire in beginning in February 2014 through July 2018. Future minimum lease payments due under these leases total $478,169 as of September 30, 2013.

Rent expense for the three month periods ended September 30, 2013 and 2012 totaled $11,324 and $2,356, respectively. Rent expense for the nine month periods ended September 30, 2013 and 2012 totaled $25,721 and $6,987, respectively.

Monitoring and Advisory Fees

The Company was required to pay monitoring and advisory fees to two investors. A total of $0 and $50,000 of monitoring fees is included in other expense in the accompanying unaudited condensed consolidated statements of operations for the three month periods ended September 30, 2013 and 2012, respectively. A total of $483,956 and $150,000 is included in other expense in the accompanying unaudited condensed consolidated statements of operations for the nine month periods ended September 30, 2013 and 2012, respectively. These fees were paid quarterly in advance on the first business day of each calendar quarter.

Included in the amounts above and in conjunction with the Merger, the Company paid additional monitoring and advisory fees totaling $390,000 to the same two investors (Note 2). Upon completion of the Merger, the Company’s obligation to pay monitoring and advisory fees was terminated.

Government Regulation

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

Unapproved Products

Two of the Company’s products, Esterified Estrogen with Methyltestosterone tablets and Opium Tincture, are marketed without approved New Drug Applications (“NDA”) or Abbreviated New Drug Applications (“ANDA”). During the three month periods ended September 30, 2013 and 2012, net revenues for these products totaled $4,418,166 and $1,634,542, respectively. During the nine month periods ended September 30, 2013 and 2012, net revenues for these

products totaled $7,704,753 and $4,298,629, respectively.

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10. COMMITMENTS AND CONTINGENCIES cont'd.

Unapproved Products cont'd.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 compliance policy guide, *Marketed New Drugs without Approved NDAs or ANDAs*. Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. The Company believes that so long as it complies with applicable manufacturing and labeling standards, the FDA will not take action against it 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, the Company may be required to seek FDA approval for these products or withdraw such products from the market.

In addition, one group of products that the Company manufactures on behalf of a contract customer is 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. The Company's contract manufacturing revenues for the group of unapproved products for the three month periods ended September 30, 2013 and 2012 were $468,717 and $370,695, respectively. The Company's contract manufacturing revenues for the group of unapproved products for the nine month periods ended September 30, 2013 and 2012 were $1,692,921 and $774,653, respectively.

The Company receives royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract 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. The Company's royalties on the net sales of these unapproved products for the three month periods ended September 30, 2013 and 2012 were $134,745 and $88,502, respectively. The Company's royalties on the net sales of these unapproved products for the nine month periods ended September 30, 2013 and 2012 was $320,018 and $219,926, respectively.

In October 2012, the Company received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of the Opium 10mg/mL Solution 118mL product ("Opium Tincture"), which is a non-NDA Product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research. Counsel to the Company sent a letter to the FDA on November 9, 2012 in support of the Company's position. Although the FDA confirmed receipt of this letter, the Company has received no further response thereto. If the FDA were to make a determination that the Company could not continue to sell Opium Tincture as an unapproved product, the Company would be required to seek FDA approval for such product or withdraw such product from the market. If the Company determined to withdraw the product from the market, the Company's net revenues for generic pharmaceutical products would decline materially, and if the Company decided to seek FDA approval, it would face increased expenses and might need to suspend sales of the product until such approval is obtained, and there are no assurances that the Company would receive such approval.

Shareholder Class Action and Derivative Lawsuits

On February 3, 2012, a purported class action lawsuit was filed in the United States District Court for the Northern District of Illinois under the caption Thomas Lauria, on behalf of himself and all others similarly situated v. BioSante Pharmaceuticals, Inc. and Stephen M. Simes naming the Company and its former President and Chief Executive Officer, Stephen M. Simes, as defendants. The complaint alleges that certain of the Company's disclosures relating to the efficacy of LibiGel® and its commercial potential were false and/or misleading and that such false and/or misleading statements had the effect of artificially inflating the price of the Company's securities resulting in violations of Section 10(b) of the Exchange Act, Rule 10b-5 and Section 20(a) of the Exchange Act. Although a substantially similar complaint was filed in the same court on February 21, 2012, such complaint was voluntarily dismissed by the plaintiff in April 2012. The plaintiff sought to represent a class of persons who purchased the Company's securities between February 12, 2010 and December 15, 2011, and sought unspecified compensatory damages, equitable and/or injunctive relief, and reasonable costs, expert fees and attorneys' fees on behalf of such purchasers. On November 6, 2012, the plaintiff filed a consolidated amended complaint. On December 28, 2012, the Company and Mr. Simes filed motions to dismiss the consolidated amended complaint. On September 11, 2013, the Illinois district court judge granted defendants' motions to dismiss, without prejudice, and gave plaintiffs 28 days to file an amended complaint. The plaintiffs did not file an amended complaint and the matter has been concluded.

On May 7, 2012, Jerome W. Weinstein, a purported stockholder of the Company, filed a shareholder derivative action in the United States District Court for the Northern District of Illinois under the caption Weinstein v. BioSante Pharmaceuticals, Inc. et al., naming the Company's directors as defendants and the Company as a nominal defendant. A substantially similar complaint was filed in the same court on May 22, 2012 and another substantially similar complaint was filed in the Circuit Court for Cook County, Illinois, County Department, Chancery Division, on June 27, 2012. The suits generally related to the same events that are the subject of the class action litigation described above. The complaints allege breaches of fiduciary duty, abuse of control, gross mismanagement and unjust enrichment as causes of action occurring from at least February 2010 through December 2011. The complaints seek unspecified damages, punitive damages, costs and disbursements and unspecified reform and improvements in the Company's corporate governance and internal control procedures.

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

On November 27, 2012, the plaintiff in the shareholder derivative action pending in Illinois state court filed an amended complaint. On January 18, 2013, the defendants filed a motion to dismiss the amended complaint. On July 1, 2013, the Illinois state court judge granted defendants' motions to dismiss, without prejudice, and gave plaintiffs until July 31, 2013 to file an amended complaint. On September 9, 2013, the Illinois state court judge granted defendants' motion to dismiss, with prejudice. On October 9, 2013, the plaintiffs filed a notice of appeal to Illinois state appellate court. The Company believes the state court complaint is without merit and will continue to defend the action vigorously.

Management is unable to predict the outcome of the remaining lawsuit and the possible loss or range of loss, if any, associated with its resolution or any potential effect the lawsuit may have on the Company's operations. Depending on the outcome or resolution of the remaining lawsuit, it could have a material effect on the Company's operations, including its financial condition, results of operations, or cash flows. No amounts have been accrued related to this lawsuit as of September 30, 2013.

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10. COMMITMENTS AND CONTINGENCIES cont'd.

Other Commitments and Contingencies

All manufacturers of the drug Reglan® and its generic equivalent metoclopramide, including the Company, are facing allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name Reglan® prior to the FDA's February 2009 Black Box warning requirement. The Company has been named and served in 85 separate complaints, including three in Pennsylvania, nine in New Jersey, and 73 in California, covering 2,934 plaintiffs in total. In August 2012, the Company was dismissed with prejudice from all New Jersey cases. Management considers the Company's exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide manufactured by the Company prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) the Company's market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once the Company received a request for change of labeling from the FDA, it submitted its proposed changes within 30 days, and such changes were subsequently approved by the FDA. At the present time, management is unable to assess the likely outcome of the remaining cases. The Company's insurance company has assumed the defense of this matter. In addition, the Company's insurance company renewed the Company's product liability insurance on September 1, 2011 and 2012 with absolute exclusions for claims related to Reglan® and metoclopramide. Management cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial condition and cash flow. Furthermore, like all pharmaceutical manufacturers, the Company in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

11. 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. US GAAP establishes a hierarchical disclosure framework which 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 the Company's funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, borrowings under line of credit, notes payable, and other current liabilities) approximate their carrying values because of their short-term nature.

The Company's CVRs (Note 2) are classified as liabilities and are measured at fair value using level 3 inputs. The fair value of CVRs was estimated using the present value of management's projection of the expected payments pursuant to the terms of the CVR agreement. The present value of the liability was calculated using a discount rate of 15%. The Company determined that the fair value of the CVRs, and the changes in such fair value, was not material as of September 30, 2013 and for the period from the date of the Merger to September 30, 2013.

ANIP's stock purchase warrants were classified as derivative liabilities and were measured at fair value using level 3 inputs. The fair value of stock purchase warrants was determined using a two-step process which included valuing ANIP's equity using both market and discounted cash flow methods, and then apportioning that value, using an equity allocation model, to each of ANIP's classes of stock. These models required the use of unobservable inputs such as fair

value of the ANIP's common and preferred stock, expected term, anticipated volatility, future interest and interest rates, expected cash flows and the number of outstanding common and preferred shares as of a future date. The Company determined that the fair value of the ANIP stock purchase warrants as of the date of the Merger, and the changes in such fair value for the period from December 31, 2012 to the date of the Merger, was not material. The ANIP stock purchase warrants were canceled in conjunction with the Merger (Note 2).

The Company has no other financial assets and liabilities that are measured at fair value. The Company has no nonfinancial assets or liabilities that are measured at fair value on a recurring basis.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this Form 10-Q quarterly report. This discussion contains forward-looking statements, based on current expectations and related to future events and the Company's future financial performance, that involve risks and uncertainties. The Company's 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 the Company's annual report on Form 10-K for the year ended December 31, 2012, and in Part II, Item 1.A. of this quarterly report.

OVERVIEW

ANI Pharmaceuticals, Inc. (the "Company") is an integrated specialty pharmaceutical company developing, manufacturing and marketing branded and generic prescription pharmaceuticals. In two facilities with combined manufacturing, packaging and laboratory capacity totaling 173,000 square feet, the Company manufactures oral solid dose products, as well as liquids and topicals, including narcotics and those that must be manufactured in a fully contained environment due to their potency and/or toxicity. The Company also performs contract manufacturing for other pharmaceutical companies.

The Company's established product portfolio consists of both branded and generic pharmaceuticals, including:

Generic Products	Branded Products
Opium Tincture	Cortenema®
Fluvoxamine Maleate Tablets	Reglan® Tablets
Esterified Estrogen with Methyltestosterone Tablets	
Hydrocortisone Enema	
Metoclopramide Syrup	

The Company's business strategy is to utilize its manufacturing assets to develop and market niche generic pharmaceuticals, focusing on products in pain management (narcotics), anti-cancer (oncolytics), women's health (hormones and steroids), as well as complex formulations, including extended release and combination products. These areas of focus reflect the Company's specialized manufacturing experience and capabilities and offer a large number of attractive niche generic product opportunities.

The Company considers 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 Difficulty.** Potent, extended release, combination and low dosage products.
- **Patent Status.** Existing patent protection, if any, time remaining to patent expiration, and existing patent challenges.
- **Market Size.** Current and expected market size at launch based on forecasted price erosion upon conversion from branded to generic pricing.
- **Profit Potential.** Availability and cost of active pharmaceutical ingredients combined with forecasted market share.
- **Manufacturing.** Ability of the Company to manufacture in its own facilities.
- **Competition.** Existing and expected competitors.

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GENERAL

The following table sets forth, for all periods indicated, items in the Company's unaudited condensed consolidated statements of operations as a percentage of net revenues:

	Three months ended September 30,				Nine months ended September 30,			
	2013		2012		2013		2012	
Net revenues	100.0	%	100.0	%	100.0	%	100.0	%
Operating Expenses								
Cost of sales (excluding depreciation and amortization)	33.6	%	46.1	%	36.1	%	41.8	%
Salaries and benefits	22.1	%	25.6	%	44.5	%	23.4	%
Freight	1.0	%	1.6	%	1.2	%	1.6	%
Research and development	5.8	%	2.9	%	6.1	%	4.2	%
Selling, general and administrative	22.3	%	25.0	%	21.8	%	19.7	%
Depreciation and amortization	4.9	%	2.9	%	3.4	%	2.8	%
Operating Income/(Loss) from Continuing Operations	10.3	%	-4.1	%	-13.1	%	6.5	%
Interest expense	-	%	-1.6	%	-2.4	%	-8.2	%
Other income/(expense)	1.9	%	-1.8	%	-1.7	%	-1.3	%
Income tax benefit	1.1	%	-	%	0.4	%	0.2	%
Net Income/(Loss) from Continuing Operations	13.3	%	-7.5	%	-16.8	%	-2.8	%
Gain on discontinued operations, net of tax	1.9	%	-	%	0.8	%	0.5	%
Net Income/(Loss)	15.2	%	-7.5	%	-16.0	%	-2.3	%

The following table summarizes the Company's results of operations for the periods indicated:

	Three months ended September 30,		Nine months ended September 30,	
	2013	2012	2013	2012
Net revenues	$ 7,836,222	$ 5,036,024	$ 19,549,670	$ 15,049,619
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	2,629,119	2,321,773	7,066,195	6,292,377
Salaries and benefits	1,729,066	1,291,667	8,699,638	3,516,427
Freight	81,416	80,622	224,189	242,814
Research and development	453, 897	148,650	1,187,461	636,726
Selling, general and administrative	1,750,734	1,256,754	4,261,182	2,961,649
Depreciation and amortization	381,699	143,959	672,828	425,238
Operating Income/(Loss) from Cont. Ops.	$ 810,291	$ (207,401)	$ (2,561,823)	$ 974,388
Interest expense	-	(81,225)	(466,902)	(1,239,137)
Other income/(expense)	147,563	(91,205)	(336,393)	(190,605)
Income tax benefit	82,852	866	82,852	36,327
Net Income/(Loss) from Cont. Ops	$ 1,040,706	$ (378,965)	$ (3,282,266)	$ (419,027)
Gain on discontinued operations, net of tax	150,337	1,617	150,337	67,793

Net Income/(Loss)	$ 1,191,043	$ (377,348)	$ (3,131,929)	$ (351,234)

RESULTS OF OPERATIONS FOR THREE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

Net Revenues

	Three months ended September 30, 2013	2012	Change	% Change	
Generic pharmaceutical products	$ 5,626,872	$ 2,834,478	$ 2,792,394	98.5	%
Branded pharmaceutical products	744,921	461,468	283,453	61.4	%
Contract manufacturing	1,326,036	1,533,832	(207,796)	-13.5	%
Contract services and other income	138,393	206,246	(67,853)	-32.9	%
Total Net Revenues	$ 7,836,222	$ 5,036,024	$ 2,800,198	55.6	%

The Company has historically derived substantially all of its revenues from sales of generic and branded pharmaceutical products, contract manufacturing, and contract services. Contract services includes product development services for potential contract customers, laboratory services for existing contract customers where those services are billed separately from contract manufacturing, and royalties on net sales of certain contract manufactured products.

Net revenue for the three month period ended September 30, 2013 was $7.8 million compared to $5.0 million for the same period in 2012, an increase of $2.8 million, or 55.6%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $5.6 million during the three month period ended September 30, 2013, an increase of 98.5% compared to $2.8 million for the same period in 2012. The primary reasons for the increase were increases in both market share and prices for Esterified Estrogen with Methyltestosterone tablets, resulting from a recent and significant decrease in competition, which the Company cannot be certain will continue, as well as market share gains on Fluvoxamine Maleate tablets. As described in Note 10 in the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, the Company markets Esterified Estrogen with Methyltestosterone tablets and Opium Tincture without FDA-approved New Drug Applications (“NDA”). The Company's combined net revenues for these products for the three month periods ended September 30, 2013 and 2012 were $4.4 million and $1.6 million, respectively.
- Net revenues for branded pharmaceutical products were $745,000 during the three month period ended September 30, 2013, an increase of 61.4% compared to $462,000 for the same period in 2012. The primary reason for the increase was higher unit sales of Reglan® tablets. This was partially offset by lower unit sales of Cortenema®.
- Contract manufacturing revenues were $1.3 million during the three month period ended September 30, 2013, a decrease of 13.5% compared to $1.5 million for the same period in 2012, due to decreased orders from contract manufacturing customers during the period. As described in Note 10 in the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, the Company contract manufactures a group of products on behalf of a customer, which are marketed by that customer without an FDA-approved NDA. The Company's contract manufacturing revenues for the group of unapproved products for the three month periods ended September 30, 2013 and 2012 were $469,000 and $371,000, respectively.
- Contract services and other income were $138,000 during the three month period ended September 30, 2013, a decrease of 32.9% from $206,000 for the same period in 2012, due to decreased fees charged to contract manufacturing customers. As described in Note 10, in the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, the Company receives royalties on the net sales of a group of contract-manufactured products, which are

marketed by the customer without an FDA-approved NDA. The Company's royalties on the net sales of these unapproved products for the three month periods ended September 30, 2013 and 2012 were $135,000 and $89,000, respectively.

Cost of Sales (Exclusive of Depreciation and Amortization)

	Three months ended September 30, 2013	2012	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 2,629,119	$ 2,321,773	$ 307,346	13.2 %

Cost of sales consists of direct labor, including manufacturing and packaging, active pharmaceutical ingredients ("API"), excipients and packaging components. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on the Company's statements of operations.

For the three month period ended September 30, 2013, cost of sales increased by $307,000 or 13.2% from the same period in 2012. Cost of sales as a percentage of net revenues decreased to 33.6% during the three month period ended September 30, 2013 from 46.1% during same period in 2012, primarily as a result of a price increase for Esterified Estrogen with Methyltestosterone tablets, a favorable shift in product mix toward higher margin products, as well as decreases in the costs of raw materials for Fluvoxamine Maleate tablets and Esterified Estrogen with Methyltestosterone tablets. These decreases in cost of sales were partially offset by an increase in the cost of raw material for Opium Tincture.

The Company sources the raw materials for its products, including APIs, from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA, which can take 18 months or longer. As a result, the Company is dependent upon its current vendors to reliably supply the APIs required for ongoing product manufacturing. During the three month period ended September 30, 2013, the Company purchased 54% of total costs of sales from two suppliers. As of September 30, 2013, amounts payable to these suppliers totaled $700,424.

Each year, the Company must submit a request to the Drug Enforcement Agency ("DEA") for a quota to purchase the amount of API needed to manufacture Opium Tincture. Without an approved quota from DEA, the Company would not be able to purchase API from its supplier. As a result, the Company is dependent upon the DEA to annually approve a sufficient quota of API to support the continued manufacture of Opium Tincture.

Other Operating Expenses

	Three months ended September 30, 2013	2012	Change	% Change
Salaries and benefits	$ 1,729,066	$ 1,291,667	$ 437,399	33.9 %
Freight	81,416	80,622	794	1.0 %
Research and development	453,897	148,650	305,247	205.3 %
General and administrative	1,750,734	1,256,754	493,980	39.3 %
Depreciation and amortization	381,699	143,959	237,740	165.1 %
Total Other Operating Expenses	$ 4,396,812	$ 2,921,652	$ 1,475,160	50.5 %

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

For the three month period ended September 30, 2013, other operating expenses increased to $4.4 million from $2.9 million for the same period in 2012, an increase of $1.5 million, or 50.5%, primarily as a result of the following

factors:

- Salaries and benefits increased from $1.3 million to $1.7 million, primarily as a result of one-time bonuses paid to certain officers after completion of the merger, and increases in personnel.
- Research and development expenses increased from $149,000 to $454,000, due to timing differences in product development schedules between the periods.
- Selling, general and administrative expenses increased from $1.3 million to $1.8 million, primarily as a result of expenses incurred relating to the Merger, as well as consulting, legal, and other fees related to becoming a public company.

- Depreciation and amortization increased from $144,000 to $382,000 during the three month period ended September 30, 2013, an increase of 165.1%, due to amortization of the Teva license acquired in the Merger.

Other Expenses

	Three months ended September 30, 2013	2012	Change	% Change
Interest expense	$ -	$ 81,225	$ (81,225)	-100.0 %
Other (income) expense	(147,563)	91,205	(238,768)	-261.8 %
Total Other Expenses	$ (147,563)	$ 172,430	$ (319,993)	-185.6 %

Other expenses consist of interest expense associated with the Company's revolving line of credit and secured subordinated convertible notes and other non-operating expenses including monitoring and advisory fees payable to certain of the Company's investors.

For the three month period ended September 30, 2013, the Company recognized other income of $148,000 versus other expense of $172,000 for the same period in 2012, a change of $320,000, or 185.6%. This change resulted primarily from the following factors, which are described in further detail in the Company’s proxy statement/prospectus filed with the SEC on May 8, 2013 under “Management of the Combined Company following the Merger Certain Relationships and Related Transactions” and “Executive Compensation Transaction Bonus Agreements and Related Agreements”:

- Interest expense decreased from $81,000 to $0 as a result of the Company paying down its revolving line of credit in the second quarter of 2013, in connection with the Merger.
- Other expense changed from expense of $91,000 to income of $148,000, which was the result of settling several aged liabilities. Other expense of $91,000 in the three months ended September 30, 2012 included $50,000 of monitoring fees paid to two investors. Upon completion of the Merger, the Company’s obligation to pay monitoring and advisory fees was terminated.

Gain on Discontinued Operation

	Three months ended September 30, 2013	2012	Change	% Change
Gain on discontinued operation, net of tax	$ 150,337	$ 1,617	$ 148,720	NM

Gain on discontinued operation consists of revenue and expenses associated with the Company's over-the-counter pharmaceutical products operation in Gulfport, Mississippi. This operation was sold in September 2010.

During the three month period ended September 30, 2013, the gain on discontinued operation resulted from finalizing a portion of the remaining liabilities. For the three month period ended September 30, 2012, the gain on discontinued operation consisted of various vendor settlements.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2013 AND 2012

Net Revenues

	Nine months ended September 30, 2013	2012	Change	% Change	
Generic pharmaceutical products	$ 11,101,556	$ 7,392,433	$ 3,709,123	50.2	%
Branded pharmaceutical products	2,742,473	1,329,049	1,413,424	106.3	%
Contract manufacturing	4,875,624	5,701,893	(826,269)	-14.5	%
Contract services and other income	830,017	626,244	203,773	32.5	%
Total Net Revenues	$ 19,549,670	$ 15,049,619	$ 4,500,051	29.9	%

Net revenue for the nine month period ended September 30, 2013 was $19.5 million compared to $15.0 million for the same period in 2012, an increase of $4.5 million, or 29.9%, compared to the same period in 2012, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $11.1 million during the nine month period ended September 30, 2013, an increase of 50.2% compared to $7.4 million for the same period in 2012. The primary reasons for the increase were increases in both market share and prices for Esterified Estrogen with Methyltestosterone tablets, resulting from a recent and significant decrease in competition, which the Company cannot be certain will continue, as well as market share gains on Opium Tincture and Fluvoxamine Maleate tablets. As described in Note 10 in the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, the Company markets Esterified Estrogen with Methyltestosterone tablets and Opium Tincture without FDA-approved NDAs. The Company's combined net revenues for these products for the nine month periods ended September 30, 2013 and 2012 were $7.7 million and $4.3 million, respectively.
- Net revenues for branded pharmaceutical products were $2.7 million during the nine month period ended September 30, 2013, an increase of 106.3% compared to $1.3 million for the same period in 2012. The primary reason for the increase was higher unit sales of Reglan® tablets. Higher unit sales of Cortenema® contributed to the increase to a lesser extent.
- Contract manufacturing revenues were $4.9 million during the nine month period ended September 30, 2013, a decrease of 14.5% compared to $5.7 million for the same period in 2012, due to decreased orders from contract manufacturing customers during the period. As described in Note 10 in the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, the Company contract manufactures a group of products on behalf of a customer, which are marketed by that customer without an FDA-approved NDA. The Company's contract manufacturing revenues for the group of unapproved products for the nine month periods ended September 30, 2013 and 2012 was $1.7 million and $775,000, respectively.
- Contract services and other income were $830,000 during the nine month period ended September 30, 2013, an increase of 32.5% from $626,000 for the same period in 2012, due to increased fees charged to contract manufacturing customers. As described in Note 10 in the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, the Company receives royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. The Company's royalties on the net sales of these unapproved products for the nine month periods ended September 30, 2013 and 2012 were $320,000 and $220,000, respectively.

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Cost of Sales (Exclusive of Depreciation and Amortization)

	Nine months ended September 30, 2013	2012	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 7,066,195	$ 6,292,377	$ 773,818	12.3 %

For the nine month period ended September 30, 2013, cost of sales increased by $774,000 or 12.3% from the same period in 2012. Cost of sales as a percentage of net revenues decreased to 36.1% during the nine month period ended September 30, 2013 from 41.8% during same period in 2012, primarily as a result of a price increase for Esterified Estrogen with Methyltestosterone tablets, a favorable shift in product mix toward higher margin products, as well as decreases in the costs of raw materials for Fluvoxamine Maleate tablets and Esterified Estrogen with Methyltestosterone tablets. These decreases in cost of sales were partially offset by an increase in the cost of raw material for Opium Tincture.

During the nine month period ended September 30, 2013, the Company purchased 31% of total costs of sales from two suppliers.

Other Operating Expenses

	Nine months ended September 30, 2013	2012	Change	% Change
Salaries and benefits	$ 8,699,638	$ 3,516,427	$ 5,183,211	147.4 %
Freight	224,189	242,814	(18,625)	-7.7 %
Research and development	1,187,461	636,726	550,735	86.5 %
General and administrative	4,261,182	2,961,649	1,299,533	43.9 %
Depreciation and amortization	672,828	425,238	247,590	58.2 %
Total Other Operating Expenses	$ 15,045,298	$ 7,782,854	$ 7,262,444	93.3 %

For the nine month period ended September 30, 2013, other operating expenses increased to $15.0 million from $7.8 million for the same period in 2012, an increase of $7.3 million, or 93.3%, primarily as a result of the following factors, which are described in further detail in the Company's proxy statement/prospectus filed with the SEC on May 8, 2013 under "Management of the Combined Company following the Merger Certain Relationships and Related Transactions" and "Executive Compensation Transaction Bonus Agreements and Related Agreements":

- Salaries and benefits increased from $3.5 million to $8.7 million, primarily as a result of non-cash transaction bonuses paid to the Company's executives upon completion of the Merger. The compensation expense resulting from these bonuses totaled $4.5 million. In addition, one-time bonuses paid to certain officers after completion of the merger and increases in personnel contributed to the increase in expense.
- Research and development expenses increased from $637,000 to $1,187,000, due to timing differences in product development schedules between the periods.
- Selling, general and administrative expenses increased from $3.0 million to $4.3 million primarily as a result of expenses incurred relating to the Merger.
- Depreciation and amortization increased from $425,000 to $673,000 during the nine month period ended September 30, 2013, an increase of 58.2%, due to amortization of the Teva license acquired in the Merger.

Other Expenses

	Nine months ended September 30, 2013	2012	Change	% Change	
Interest expense	$ 466,902	$ 1,239,137	$ (772,235)	-62.3	%
Other expense	366,393	190,605	175,788	92.2	%
Total Other Expenses	$ 833,295	$ 1,429,742	$ (596,447)	-41.7	%

For the nine month period ended September 30, 2013, other expenses decreased to $833,000 from $1.4 million for the same period in 2012, a decrease of $596,000, or 41.7%, primarily as a result of the following factors, which are described in further detail in the Company's proxy statement/prospectus filed with the SEC on May 8, 2013 under "Management of the Combined Company following the Merger Certain Relationships and Related Transactions" and "Executive Compensation Transaction Bonus Agreements and Related Agreements":

- Interest expense decreased from $1.2 million to $467,000. In June 2012, all of ANIP's subordinated debt was converted to Series D convertible preferred stock. In addition, the Company paid down its revolving line of credit in the second quarter of 2013, in connection with the Merger. The resulting reductions from both the subordinated debt conversion and repayment of the revolving line of credit were partially offset by an early termination fee and accelerated amortization of deferred loan costs incurred upon repayment of the line of credit.
- Other expense increased from $191,000 to $336,000 as a result of payments totaling $390,000 to certain of the Company's investors for overall management, deal structuring, financial advisory and due diligence services in connection with the Merger, partially offset by other income from the third quarter resulting from the settling of several aged liabilities.

Gain on Discontinued Operation

	Nine months ended September 30, 2013	2012	Change	% Change	
Gain on discontinued operation, net of tax	$ 150,337	$ 67,793	$ 82,544	121.8	%

Gain on discontinued operation consists of revenue and expenses associated with the Company's over-the-counter pharmaceutical products operation in Gulfport, Mississippi. This operation was sold in September 2010.

During the nine month period ended September 30, 2013, the gain on discontinued operation was the result of finalizing a portion of the remaining liabilities. For the nine month period ended September 30, 2012, the gain on discontinued operation consisted of various vendor settlements.

LIQUIDITY AND CAPITAL RESOURCES

The following table highlights selected liquidity and working capital information from the Company's balance sheets:

	September 30, 2013	December 31, 2012
Cash and cash equivalents	$ 10,929,806	$ 11,028
Restricted cash	2,260,100	-
Accounts receivable, net	9,515,096	5,432,401
Inventories	2,809,160	2,809,685

Prepaid expenses		580,597		313,193
Total Current Assets	$	26,094,759	$	8,566,307
Accounts payable	$	2,086,847	$	1,993,567
Accrued expenses		1,338,215		555,635
Returned goods reserve		457,890		410,992
Deferred revenue		46,712		314,794
Borrowings under line of credit		-		4,065,307
Accrued compensation		2,535, 746		21
Current liabilities of discontinued operations		131,613		370,766
Total Current Liabilities	$	6,597,023	$	7,711,082

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At September 30, 2013, the Company had $10.9 million in unrestricted cash and cash equivalents. At December 31, 2012, the Company had $11,000 in unrestricted cash and cash equivalents and unused availability of $935,000 under its then-existing line of credit.

The Company believes that its financial resources, consisting of current working capital and anticipated future operating revenue, will be sufficient to enable it to meet its 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:

	Nine months ended September 30,	
	2013	2012
Operating Activities	$ (2,619,380)	$ 421,605
Investing Activities	$ 18,036,027	$ (76,888)
Financing Activities	$ (4,497,869)	$ (196,386)

Net Cash Used In/Provided By Operations

Net cash used in operating activities was $2.6 million for the nine months ended September 30, 2013 compared to $422,000 provided by operating activities during the same period in 2012, an increase in the use of cash of $3.0 million between the periods. This increase was due to changes in current assets and current liabilities and changes in net loss. Increases in current assets and decreases in current liabilities (in each case a use of cash) for the nine month period ended September 30, 2013 totaled $4.6 million compared to $546,000 for the same period in 2012, an increase of approximately $4.0 million between the periods. Accounts receivable and prepaid expenses increased by $3.6 million and $271,000 more, respectively, in the nine month period ended September 30, 2013 than in the prior year period. Accrued expenses decreased by $571,000 more in the nine month period ended September 30, 2013 than in the prior year period. These increased uses of cash were partially offset by inventory changes, which decreased by $525 (providing cash) in the nine month period ended September 30, 2013 versus increasing by $387,000 (a use of cash) in the prior year period. This change in current assets and current liabilities was partially offset by the $995,000 increase between the periods in the Company's net loss from continuing operations, after adjusting for non-cash expenses.

Net Cash Used In/Provided By Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2013 was $18.0 million, principally due to cash acquired in the Merger, partially offset by capital expenditures during the period. Net cash used in investing activities was $77,000 during the same period in 2012.

Net Cash Used In/Provided By Financing Activities

Net cash used in financing activities was $4.5 million for the nine months ended September 30, 2013, resulting primarily from the repayment in June 2013 of the Company’s revolving line of credit in connection with the Merger. Net cash used in financing activities was $196,000 during the same period in 2012, resulting primarily from the repayment of notes due to a supplier of the Company’s discontinued operations and payments of debt issuance costs, partially offset by an increase in borrowings.

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CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on the Company's unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States (“US GAAP”). The preparation of these financial statements requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues and expenses. On an ongoing basis, management evaluates these estimates and assumptions, including those described below. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results and experiences may differ materially from these estimates.

Some of the estimates and assumptions management has to make under US GAAP require difficult, subjective and/or complex judgments about matters that are inherently uncertain and, as a result, actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding the Company's business operations, financial condition and results of operations.

Revenue Recognition

Revenue is recognized for product sales upon passing of risk and title to the customer, when estimates of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments are reasonably determinable, collection is reasonably assured, and the Company has no further performance obligations. These estimates reduce gross revenues to net revenues in the accompanying unaudited condensed consolidated statements of operations, and are presented as current liabilities or reductions in accounts receivable in the accompanying unaudited condensed consolidated balance sheets.

Accruals for Chargebacks, Returns and Other Allowances

The Company’s generic and branded product revenues are typically subject to agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates and prompt payment discounts. The Company accrues for these items at the time of sale based on the estimates and methodologies described below. In the aggregate, these gross-to-net accruals average 65% of generic and branded gross product sales, reduce gross revenues to net revenues in the accompanying statements of operations, and are presented as current liabilities or reductions in accounts receivable in the accompanying balance sheets. The Company continually monitors and re-evaluates the accruals as additional information becomes available, which includes, among other things, updates to trade inventory levels and customer product mix. The Company makes adjustments to the accruals at the end of each reporting period, to reflect any such updates to the relevant facts and circumstances.

Chargebacks

Chargebacks, primarily from wholesalers, are the most significant of the Company’s accruals. Chargebacks result from arrangements the Company has with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, the Company may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, the Company provides a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost (“WAC”).

Chargeback credits are calculated as follows:

Prior period chargebacks claimed by wholesalers are analyzed to determine the actual average selling price (“ASP”) for each product. This calculation is performed by product by wholesaler. ASPs can be affected by several factors such as:

- A change in customer mix;
- A change in negotiated terms with customers;
- A change in product sales mix;
- A change in the volume of off-contract purchases; and
- Changes in WAC.

As necessary, the Company adjusts ASPs based on anticipated changes in the factors above.

The difference between ASP and WAC is recorded at the same time the Company recognizes revenue from the product sale, as a reduction in both gross revenues and accounts receivable.

To evaluate the adequacy of its chargeback accruals, the Company obtains on-hand inventory counts from the wholesalers. The inventory counts are multiplied by the chargeback amount (the difference between ASP and WAC) to arrive at total expected future chargebacks, which is then compared to the chargeback accruals. The Company continually monitors chargeback activity and adjusts ASPs when it believes that actual selling prices will differ from current ASPs.

Returns

Consistent with industry practice, the Company maintains a return policy that allows customers to return product within a specified period prior to and subsequent to the product expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. The Company's product returns are settled through the issuance of a credit to the customer. Management’s estimate for returns is based upon its historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. Management continually monitors its estimates for returns and makes adjustments when it believes that actual product returns may differ from the established accruals.

Administrative Fees and Other Rebates

Administrative fees or rebates are offered to wholesalers, group purchasing organizations and indirect customers, consistent with pharmaceutical industry practice. The Company accrues for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of its administrative fee accruals, the Company obtains on-hand inventory counts from wholesalers. This inventory is multiplied by the ASPs to arrive at total expected future sales, which is then multiplied by contracted rates. The result is then compared to the administrative fee accruals. The Company continually monitors administrative fee activity and adjusts its accruals when it believes that actual administrative fees will differ from the accruals.

Prompt Payment Discounts

Sales discounts are granted for prompt payment. The reserve for sales discounts is based on invoices outstanding. The Company assumes that, based on past experience, 100% of available discounts will be taken.

The following table summarizes activity in the balance sheet for accruals and allowances for the nine month periods ended September 30, 2013 and 2012, respectively:

	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at January 1, 2013	$ 5,661,974	$ 410,992	$ 230,575	$ 241,840
Accruals/adjustments	20,132,724	1,154,726	1,435,996	751,993
Credits taken against reserve	(19,734,545)	(1,107,828)	(979,404)	(667,473)
Balance at September 30, 2013	$ 6,060,153	$ 457,890	$ 687,167	$ 326,360

	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at January 1, 2012	$ 3,680,838	$ 252,045	$ 238,195	$ 166,439
Accruals/adjustments	15,996,550	486,844	925,488	522,812
Credits taken against reserve	(15,348,165)	(351,274)	(892,370)	(481,435)
Balance at September 30, 2012	$ 4,339,223	$ 387,615	$ 271,313	$ 207,816

Accounts Receivable

The Company extends credit to customers on an unsecured basis. The Company uses the allowance method to provide for doubtful accounts based on management's evaluation of the collectability of accounts receivable whereby the Company provides an allowance for doubtful accounts equal to the estimated uncollectible amounts. Management's estimate is based on historical collection experience and a review of the current status of trade accounts receivable. The Company determines trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. Management determined that no allowance for doubtful accounts was necessary as of September 30, 2013 and December 31, 2012.

RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

In February 2013, the Financial Accounting Standards Board ("FASB") issued guidance related to additional reporting and disclosure of amounts reclassified out of accumulated other comprehensive income ("OCI"). Under this new guidance, companies will be required to disclose the amount of income or loss reclassified out of OCI to each respective line item on the income statement where net income is presented. The guidance allows companies to elect whether to disclose the reclassification either in the notes to the financial statements, or on the face of the income statement. This update is effective for annual and interim reporting periods for fiscal years beginning after December 15, 2012. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

In July 2012, the FASB issued accounting guidance to simplify the evaluation for impairment of indefinite-lived intangible assets. Under the updated guidance, an entity has the option of first performing a qualitative assessment to determine whether it is more likely than not that an indefinite-lived intangible asset is impaired before proceeding to the quantitative impairment test under which it would calculate the asset's fair value. When performing the qualitative assessment, the entity must evaluate events and circumstances that may affect the significant inputs used to determine the fair value of the indefinite-lived intangible asset. This guidance is effective for annual and interim impairment tests performed for fiscal years beginning after September 15, 2012. Early adoption is permitted. The adoption of this standard did not have a material impact on the Company's results of operations, cash flows or financial position.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2013 and 2012, the Company 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

At times the Company may invest in United States treasury notes, government asset backed securities and corporate bonds, all of which are exposed to interest rate fluctuations. The interest earned on these investments may vary based on fluctuations in the market interest rate.

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 the Company's 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 the Company's reports filed under the Exchange Act is accumulated and communicated to management, including the Company's

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

The management of the Company has carried out an evaluation, under the supervision and with the participation of the Company's principal executive officer and principal financial officer, of the effectiveness of the design and operation of the Company's disclosure controls and procedures, as of September 30, 2013. Based upon that evaluation, the Company's principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were effective. In designing and evaluating the Company's disclosure controls and procedures, management recognized 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
The Company is currently integrating BioSante's and ANIP's business processes and information systems, including internal controls. This work began immediately upon completion of the Merger and will continue throughout calendar year 2013.

There were no changes in the Company's internal control over financial reporting during the quarter ended September 30, 2013 that have materially affected, or are reasonably likely to materially affect, the Company's internal control over financial reporting.

Part II OTHER INFORMATION

Item 1. Legal Proceedings
Please refer to Note 10, *Commitments and Contingencies* and the subsection entitled "Shareholder Class Action and Derivative Lawsuits," in the notes to the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, which is incorporated into this item by reference.

Item 1A. Risk Factors
In addition to the other information set forth in this report, careful consideration should be taken of the factors described in the Company's most recent annual report on Form 10-K for the fiscal year ended December 31, 2012 under the heading "Part I Item 1A. Risk Factors." The risks described are not the only risks facing the Company. Additional risks and uncertainties not currently known to management, or that management currently deems to be immaterial, also may adversely affect its business, financial condition and/or operating results. Other than as described below, there has been no material change to those risk factors.

The Company has a history of losses and negative cash flow, expects losses and negative cash flow to continue for the foreseeable future and cannot offer any assurances that it will ever achieve profitability.

The Company has never been profitable, has an accumulated deficit of $51.9 million as of September 30, 2013, and has not generated positive cash flows from operations. To bridge the gap between revenues and operating and capital needs, the Company has been dependent on a variety of financing sources, including the issuance of equity securities and convertible notes, and revolving lines of credit.

The Company cannot guarantee that it will achieve sufficient revenues for profitability. Even if it achieves profitability, it cannot guarantee that it can sustain or increase profitability on a quarterly or annual basis in the future. If revenues grow more slowly than anticipated, or if operating expenses exceed the Company's expectations or cannot be adjusted accordingly, then the Company's business, results of operations, financial condition and cash flows will be materially and adversely affected.

Certain of the Company's generic products are marketed without approved New Drug Applications or Abbreviated New Drug Applications and the Company can offer no assurances that the FDA will not require the Company to seek approval for these products or withdraw them from the market. In either case, the Company's business, financial position and results of operations could be materially adversely affected.

Esterified Estrogen with Methyltestosterone tablets and Opium Tincture are marketed without approved New Drug Applications ("NDAs") or Abbreviated New Drug Applications ("ANDAs"). During the nine months ended September 30, 2013 and 2012, combined net revenues for these products were $7.7 million and $4.3 million, respectively. Due to a decrease in competition, the Company's market share and pricing has increased for Esterified Estrogen with Methyltestosterone tablets. As a result, the percentage of the Company's net revenues related to unapproved products has increased from 29% to 39% for the nine months ended September 30, 2013.

The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide, 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 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 with potential safety risks or that lack evidence of effectiveness. While the Company believes that so long as it complies with applicable manufacturing and labeling standards, the FDA will not take action against it under the current enforcement policy, it 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.

In October 2012, the Company received a telephone call requesting a meeting with the FDA representatives from the Minneapolis district of the FDA to discuss continued manufacturing and distribution of Opium Tincture, which is an unapproved product. That meeting was held on October 25, 2012 by conference telephone call and included FDA representatives from the Office of Compliance at the Center for Drug Evaluation and Research ("CDER"). Counsel to the Company sent a letter to the FDA on November 9, 2012 in support of the Company's position. Although the FDA confirmed receipt of this letter, the Company has received no further response thereto. If, as a result of such discussions or otherwise, the FDA were to make a determination that the Company could not continue to sell Opium Tincture as an unapproved product, the Company would be required to seek FDA approval for such product or withdraw such product from the market. If the Company determined to withdraw the product from the market, the Company's net revenues for generic pharmaceutical products would decline materially, and if the Company decided to seek FDA approval, it would face increased expenses and might need to suspend sales of the product until such approval is obtained, and there are no assurances that the Company would receive such approval.

In addition, one group of products that the Company manufactures on behalf of a contract customer, and based on the sale of which the Company receives royalties, is 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, which could materially adversely affect the Company's contract manufacturing and royalty revenue. The Company's contract manufacturing revenues from this group of unapproved products for the nine months ended September 30, 2013 and 2012 were $1,692,921 and $774,653, respectively. The Company's royalties on the net sales of these unapproved products for the nine months ended September 30, 2013 and 2012 were $320,018 and $219,926, respectively.

The Company's manufacture and distribution of drugs without approved NDAs or ANDAs could also result in legal actions by private parties, state governments or the federal government. These entities may allege that the Company has misrepresented the regulatory status of Esterified Estrogen with Methyltestosterone and Opium Tincture resulting in the submission of false claims to federal and state health care programs. Such legal actions could result in fines, penalties, reimbursement, and legal settlements that could bind the Company going forward and materially affect the Company's ability to market these products as well as the profitability of the Company's business, financial position and results of operations.

The Company's anticipated revenue growth and profitability, if achieved, is dependent upon the Company's ability to develop and/or license, or otherwise acquire, and introduce new products on a timely basis in relation to its competitors' product introductions, and to navigate the regulatory hurdles before, during and after the introduction of its new products. The Company's failure to do so successfully could have a material adverse effect on its business, financial position and results of operations.

The Company's future revenues and profitability will depend, to an extent, upon its ability to successfully develop, license or otherwise acquire, and commercialize, branded and generic pharmaceutical products in a timely manner. Product development is inherently risky and time-consuming. Likewise, product licensing involves inherent risks including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to the supply of product meeting specifications and terms such as license scope or termination rights. The development and commercialization process also requires substantial time, effort and financial resources. The Company may not be successful in commercializing products on a timely basis, if at all, which could adversely affect its business, financial position and results of operations.

Before any new prescription drug product can be marketed in the United States, marketing authorization approval is required by the United States Food and Drug Administration ("FDA"). The process of obtaining regulatory approval to manufacture and market branded and generic pharmaceutical products is rigorous, time consuming, costly and largely unpredictable. The Company may be unable to obtain requisite approvals on a timely basis for branded or generic products that it may develop, license or otherwise acquire. Moreover, if the Company obtains regulatory approval for

a drug, it may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which in turn could restrict its potential market for the drug. Also, for products pending approval, the Company may obtain raw materials or produce batches of inventory to be used in bioequivalence testing, as well as in anticipation of the product's launch. In the event that regulatory approval is denied or delayed, the Company could be exposed to the risk of this inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect the Company’s product introduction plans, business, financial position and results of operations.

The approval process for generic pharmaceutical products often results in the FDA granting simultaneous final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces a generic firm to face immediate competition when it introduces a generic product into the market. Additionally, further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to branded products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.

The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”), provides for a period of 180 days of generic marketing exclusivity for each abbreviated new drug application (“ANDA”) applicant that is first-to-file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to a reference drug product, commonly referred to as a Paragraph IV certification. During this exclusivity period, which under certain circumstances may be required to be shared with other applicable ANDA sponsors with Paragraph IV certifications, the FDA cannot grant final approval to other ANDA sponsors holding applications for the same generic equivalent. If an ANDA containing a Paragraph IV certification is successful and the applicant is awarded exclusivity, the applicant generally enjoys higher market share, net revenues and gross margin for that product than otherwise would be the case. However, an ANDA sponsor's ability to obtain 180 days of generic marketing exclusivity may be dependent upon its ability to obtain FDA approval or tentative approval within 30 months of the FDA's acceptance of its ANDA. If the Company is unable to obtain approval or tentative approval within that time period, it may risk forfeiture of such marketing exclusivity. Even if the Company obtains FDA approval for its generic drug products, if it is not the first ANDA applicant to challenge a listed patent for such a product, it may lose significant advantages to a competitor that filed its ANDA containing such a challenge. The same would be true in situations where the Company is required to share its exclusivity period with other ANDA sponsors with Paragraph IV certifications. Such situations could have a material adverse effect on the Company’s ability to market that product profitably and on its business, financial position and results of operations.

If the Company is unable to navigate its products through all of the regulatory hurdles it faces in a timely manner, its product introduction plans, business, financial position and results of operations could be materially adversely affected.

The FDA regulates and monitors all promotion and advertising of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require the company to change current practices and prevent unlawful activity in the future.

The Company's approved products may not achieve expected levels of market acceptance, which could have a material adverse effect on its profitability, business, financial position and results of operations.

Even if the Company is able to obtain regulatory approvals for its pharmaceutical products, the success of those products is dependent upon market acceptance. Levels of market acceptance for products could be impacted by several factors, including but not limited to:

- the availability of alternative products from the Company’s competitors;
- the price of the Company's products relative to that of the Company's competitors;
- the timing of the Company's market entry;

- the ability to market the Company's products effectively to the retail level; and
- the acceptance of the Company's products by government and private formularies.

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Some of these factors are not within the Company's control. Additionally, continuing studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety and efficacy of previously marketed products. In some cases, studies have resulted, and in the future may result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. These situations, should they occur, could have a material adverse effect on the Company's profitability, business, financial position and results of operations.

The Company began its own product development program in 2011 and expects to spend a significant amount of resources on research and development efforts that may not lead to successful product introductions. Failure to successfully introduce products into the market could have a material adverse effect on its business, financial position and results of operations.

The Company conducts research and development primarily to enable it to manufacture and market approved pharmaceuticals in accordance with applicable regulations. As the Company develops new products, its research expenses likely will increase. Because of the inherent risk associated with research and development efforts in the industry, the Company’s research and development expenditures may not result in the successful introduction of new pharmaceutical products approved by the FDA. Also, after the Company submits a marketing authorization application for a generic product, the FDA may change standards and/or request that the Company conduct additional studies and, as a result, the Company may incur total research and development costs to develop a particular product in excess of what it anticipated. Finally, the Company cannot be certain that any investment made in developing products will be recovered, even if it is successful in commercialization. To the extent that the Company spends significant resources on research and development efforts and is not able, ultimately, to introduce successful new products as a result of those efforts, its business, financial position and results of operations may be materially adversely affected.

The Company is entirely dependent on periodic approval by the Drug Enforcement Administration for the supply of the active pharmaceutical ingredient needed to make Opium Tincture and inability to obtain such approval would reduce or eliminate revenues from the sale of Opium Tincture. In addition, the Company is subject to strict regulation by the Drug Enforcement Administration and is subject to sanctions if it is unable to comply with related regulatory requirements.

The Drug Enforcement Administration (“DEA”) regulates certain drug products containing controlled substances, such as opium, pursuant to the US Controlled Substances Act (“CSA”). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, each year, the Company must submit a request to the DEA for a quota to purchase the amount of active pharmaceutical ingredient needed to manufacture Opium Tincture. Without an approved quota from DEA, the Company would not be able to purchase this ingredient from its supplier. As a result, the Company is entirely dependent upon the DEA to approve, on an annual basis, a quota of active pharmaceutical ingredient that is sufficiently large to support the continued manufacture of Opium Tincture at levels that would maximize the Company’s revenues or profits.

The Company does not own or license any material patents associated with its products, and its ability to protect and control unpatented trade secrets, know-how and other technological innovation is limited.

Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. The Company does not own or license any material patents associated with its products and therefore does not enjoy the same level of intellectual property protection with respect to such products as would a pharmaceutical manufacturer that markets a patented product. The Company has a limited ability to protect and control trade secrets, know-how and other technological innovation, all of which are unpatented. Others independently may develop similar or better proprietary information and techniques and disclose them publicly. Also, others may gain access to the Company's trade secrets, and the Company may not be able to meaningfully protect its rights to its unpatented trade secrets. In addition, confidentiality agreements and other measures may not provide meaningful protection for the Company's trade secrets in the event of unauthorized use or disclosure of such information. Failure to protect and control such trade secrets, know-how and innovation could harm the value of the Company's trade secrets, know-how and other technological innovation.

The use of legal, regulatory and legislative strategies by competitors, both branded and generic, including "authorized generics" and citizen's petitions, as well as the potential impact of proposed legislation, may increase the Company's costs associated with the introduction or marketing of the Company's generic products, could delay or prevent such introduction and/or could reduce significantly the Company's profit potential. These factors could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

The Company's competitors, both branded and generic, often pursue strategies to prevent or delay competition from generic alternatives to branded products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time generic competition initially enters the market;
- launching a generic version of their own branded product at the same time generic competition initially enters the market;
- filing citizen's petitions with the FDA or other regulatory bodies, including timing the filings so as to thwart generic competition by causing delays of the Company's product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or meet other approval requirements;
- initiating legislative and regulatory efforts to limit the substitution of generic versions of branded pharmaceuticals;
- filing suits for patent infringement that may delay regulatory approval of many generic products;
- introducing "next-generation" products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product for which the Company seeks regulatory approval;
- obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other potential methods;
- persuading regulatory bodies to withdraw the approval of branded name drugs for which the patents are about to expire, thus allowing the branded name company to obtain new patented products serving as substitutes for the products withdrawn; and
- seeking to obtain new patents on drugs for which patent protection is about to expire.

In the United States, some companies have lobbied Congress for amendments to the Hatch-Waxman Act that would give them additional advantages over generic competitors. For example, although the term of a company's drug patent can be extended to reflect a portion of the time an NDA is under regulatory review, some companies have proposed extending the patent term by the full amount of time spent in clinical trials rather than by only one half of the time that is currently permitted.

If proposals like these were to become effective, the Company's entry into the market and its ability to generate revenues associated with new products may be delayed, reduced or eliminated, which could have a material adverse effect on its business, financial position, results of operations and cash flows.

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The Company faces significant uncertainty with respect to the litigation brought against it and other manufacturers of metoclopramide and cannot provide assurances that the outcome of the matter will not have an adverse effect on its financial position, results of operations and/or cash flows from operations. In addition, the Company may be exposed to other product liability claims in the future.

All manufacturers of the drug Reglan® and its generic equivalent metoclopramide, including the Company, are facing allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name Reglan® prior to the FDA's February 2009 Black Box warning requirement. The Company has been named and served in 85 separate complaints, including three in Pennsylvania, nine in New Jersey, and 73 in California, covering 2,934 plaintiffs in total. In August 2012, the Company was dismissed with prejudice from all New Jersey cases. Management considers the Company's exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide manufactured by the Company prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) the Company's market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once the Company received a request for change of labeling from the FDA, it submitted its proposed changes within 30 days, and such changes were subsequently approved by the FDA. At the present time, management is unable to assess the likely outcome of the remaining cases. The Company's insurance company has assumed the defense of this matter. In addition, the Company's insurance company renewed the Company's product liability insurance on September 1, 2011 and 2012 with absolute exclusions for claims related to Reglan® and metoclopramide. Management cannot provide assurances that the outcome of these matters will not have an adverse effect on its business, results of operations, financial condition and cash flow. Furthermore, like all pharmaceutical manufacturers, the Company in the future may be exposed to other product liability claims, which could harm its business, results of operations, financial condition and cash flow.

The Company may experience declines in the sales volume and prices of its products as the result of the continuing trend toward consolidation of certain customer groups, such as the wholesale drug distribution and retail pharmacy industries, as well as the emergence of large buying groups. These developments could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

Consolidation among wholesale distributors, chain drug stores, and group purchasing organizations, has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. For example, the Company's net revenues are concentrated among two customers representing 27% and 19% of net revenues, respectively, during the three months ended September 30, 2013. As of September 30, 2013, accounts receivable from these two customers totaled $6.1 million, or approximately 64% of the Company's net accounts receivable. Drug wholesalers and retain pharmacy chains, which represent an essential part of the distribution chain of generic pharmaceutical products, have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing the Company's business. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to extract price discounts on the Company's products. The result of these developments may have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

The Company has a limited number of manufacturing facilities producing a substantial portion of its products. Production at any one of these facilities could be interrupted, which could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

A substantial portion of the Company's capacity as well as its current production is attributable to a limited number of manufacturing facilities and certain third party suppliers. During the three months ended September 30, 2013, the Company purchased approximately 54% of total costs of goods sold from two suppliers. A significant disruption at

any one of the facilities within the Company’s internal supply chain, even on a short-term basis, whether due to a labor strike, failure to reach acceptable agreement with labor and unions, adverse quality or compliance observation, act of God, civil or political unrest, or other events could impair the Company’s ability to produce and ship products to the market on a timely basis and, among other consequences, could subject the Company to exposure to claims from customers. Any of these events could have a material adverse effect on the Company’s business, financial position, results of operations and cash flows.

Virtually all contracts for the supply of pharmaceutical products by the Company to customers contain "failure to supply" clauses. Under these clauses, if the Company is unable to supply the requested quantity of product within a certain period after receipt of a customer's purchase order, the customer is entitled to procure a substitute product elsewhere and the Company must reimburse its customer for the difference between the Company’s contract price and the price the customer was forced to pay to procure the substitute product. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements, and can be far in excess of the revenue that the Company would otherwise have received on the sale of its own product. The ability to produce and ship a sufficient quantity of product is therefore critical to the Company.

The Company's depends on a limited number of suppliers for active pharmaceutical ingredients.

The Company's ability to manufacture and distribute drug products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the United States. Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect the Company's ability to manufacture and distribute drug product and could result in legal liabilities that could materially affect the Company's ability to realize profits or otherwise harm the Company's business, financial, and operating results. The Company sources the raw materials for its products, including active pharmaceutical ingredients ("API") from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. Changes in API suppliers must usually be approved through a Prior Approval Supplement by the FDA. As the API typically comprises the majority of a product's manufactured cost, and qualifying an alternative is costly and time-consuming, API suppliers must be selected carefully based on quality, reliability of supply and long-term financial stability.

As described above, virtually all contracts for the supply of pharmaceutical products by the Company to customers contain "failure to supply" clauses. The ability to source sufficient quantities of active pharmaceutical ingredients for manufacturing is therefore critical to the Company. For Opium Tincture, this ability to source adequate amounts of raw material is in turn dependent on the quota set by the DEA. See also, "The Company is entirely dependent on periodic approval by the DEA for the supply of the active pharmaceutical ingredient needed to make Opium Tincture and inability to obtain such approval would reduce or eliminate revenues from the sale of Opium Tincture. In addition, the Company is subject to strict regulation by the DEA and is subject to sanctions if it is unable to comply with related regulatory requirements."

Legislative or regulatory programs that may influence prices of pharmaceutical products could have a material adverse effect on the Company's business, financial position, results of operations and cash flows.

Current or future federal, state or foreign laws and regulations may influence the prices of drugs and, therefore, could adversely affect the prices that the Company receives for its products. For example, programs in existence in certain states in the United States seek to set prices of all drugs sold within those states through the regulation and administration of the sale of prescription drugs. Expansion of these programs, in particular state Medicaid programs, or changes required in the way in which Medicaid rebates are calculated under such programs, could adversely affect the prices the Company receives for its products and could have a material adverse effect on its business, financial position, results of operations and cash flows.

The Company is subject to federal, state and local laws and regulations, and complying with these may cause the Company to incur significant costs.

The pharmaceutical industry is subject to regulation by various federal authorities, including principally the FDA and, to a lesser extent, the DEA, and state governmental authorities. The U.S. Federal Food, Drug, and Cosmetic Act, the Controlled Substances Act of 1970 and other federal statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale and distribution of the Company's products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunction, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment and criminal prosecution.

The Company's research, product development and manufacturing activities have involved the controlled use of hazardous materials, and the Company may incur significant costs as a result of the need to comply with numerous

laws and regulations. The Company is subject to laws and regulations enforced by the FDA, the DEA, and other regulatory statutes including the Occupational Safety and Health Act (“OSHA”), the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local and foreign laws and regulations governing the use, manufacture, storage, handling and disposal of the Company’s products, materials used to develop and manufacture such products, and resulting waste products. For example, certain of the Company’s products, including Esterified Estrogen with Methyltestosterone, must be manufactured in a fully contained environment due to their potency and/or toxicity, and compliance with related OSHA requirements is costly.

The Company cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts, from these materials. In the event of an accident, the Company could be held liable for any damages that result, and any resulting liability could exceed its resources. The Company may also be required to incur significant costs to comply with environmental laws and regulations in the future. The Company is also subject to laws generally applicable to businesses, including but not limited to, federal, state and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to its business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm the Company’s business, results of operations, financial condition, cash flow and future prospects.

Item 2. Unregistered Sales of Equity and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

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

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ANI Pharmaceuticals, Inc.
(Registrant)

Date: November 7, 2013	By:	/s/ Arthur S. Przybyl
		Arthur S. Przybyl
		President and
		Chief Executive Officer
		(Principal Executive Officer)
Date: November 7, 2013	By:	/s/ Charlotte C. Arnold
		Charlotte C. Arnold
		Vice President and
		Chief Financial Officer
		(Principal Financial Officer)

INDEX TO EXHIBITS

Exhibit No.	Description
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