

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2014

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

For the transition period from _____ to _____.

Commission File Number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

58-2301143

(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 NO

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if smaller reporting company)

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

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

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended September 30, 2014
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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

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

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

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

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

September 30, 2014 December 31, 2013

Assets		
Current Assets		
Cash and cash equivalents	\$ 35,050	\$ 11,105
Accounts receivable, net of \$8,100 and \$5,104 of allowances for chargebacks and other allowances at September 30, 2014 and December 31, 2013, respectively	14,570	12,513
Inventories, net	7,346	3,518
Prepaid expenses	599	580
Total Current Assets	57,565	27,716
Property, plant, and equipment, net	5,046	4,537
Intangible assets, net	43,188	10,409
Goodwill	1,838	1,838
Total Assets	\$ 107,637	\$ 44,500
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	\$ 3,059	\$ 1,429
Accrued expenses	3,888	1,326
Returned goods reserve	1,178	736
Deferred revenue	20	47
Total Current Liabilities	8,145	3,538
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, \$0.0001 par value, 33,333,334 shares authorized; 11,318,014 shares issued and outstanding at September 30, 2014; 9,629,174 shares issued and 9,619,941 shares outstanding at December 31, 2013	1	1
Class C Special Stock, \$0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	-	-
Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2014 and December 31, 2013, respectively	-	-
Treasury stock, 0 and 9,233 shares of common stock, at cost, at September 30, 2014 and December 31, 2013, respectively	-	(68)
Additional paid-in capital	140,221	89,501
Accumulated deficit	(40,730)	(48,472)
Total Stockholders' Equity	99,492	40,962
Total Liabilities and Stockholders' Equity	\$ 107,637	\$ 44,500

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

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

	<i>Three months ended September 30,</i>		<i>Nine months ended September 30,</i>	
	<u>2014</u>	<u>2013</u>	<u>2014</u>	<u>2013</u>
Net Revenues	\$ 17,387	\$ 7,836	\$ 34,933	\$ 19,550
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	3,061	2,710	7,800	7,290
Research and development	883	454	2,110	1,188
Selling, general and administrative	4,057	3,480	13,193	12,961
Depreciation and amortization	<u>1,187</u>	<u>382</u>	<u>2,596</u>	<u>673</u>
Total Operating Expenses	<u>9,188</u>	<u>7,026</u>	<u>25,699</u>	<u>22,112</u>
Operating Income/(Loss)	8,199	810	9,234	(2,562)
Other Income/(Expense)				
Interest income/(expense)	10	-	13	(467)
Other income/(expense)	<u>82</u>	<u>148</u>	<u>72</u>	<u>(336)</u>
Income/(Loss) Before Provision for Income Taxes	8,291	958	9,319	(3,365)
(Provision)/Benefit for Income Taxes	<u>(1,545)</u>	<u>83</u>	<u>(1,577)</u>	<u>83</u>
Net Income/(Loss) from Continuing Operations	6,746	1,041	7,742	(3,282)
Discontinued Operation				
Gain on discontinued operation, net of provision for income taxes	<u>-</u>	<u>150</u>	<u>-</u>	<u>150</u>
Net Income/(Loss)	<u>\$ 6,746</u>	<u>\$ 1,191</u>	<u>\$ 7,742</u>	<u>\$ (3,132)</u>
Computation of Income/(Loss) from Continuing Operations				
Attributable				
to Common Stockholders and Participating Securities:				
Net Income/(Loss) from Continuing Operations	\$ 6,746	\$ 1,041	\$ 7,742	\$ (3,282)
Preferred stock dividends	<u>-</u>	<u>-</u>	<u>-</u>	<u>(4,974)</u>
Income/(Loss) from Continuing Operations Attributable to Common Stockholders and Participating Securities	\$ 6,746	\$ 1,041	\$ 7,742	\$ (8,256)
Basic and Diluted Earnings/(Loss) Per Share:				
Continuing Operations	\$ 0.59	\$ 0.11	\$ 0.71	\$ (2.31)
Discontinued Operation	-	0.02	-	0.04
Basic Earnings/(Loss) Per Share	\$ 0.59	\$ 0.13	\$ 0.71	\$ (2.27)
Continuing Operations	\$ 0.59	\$ 0.11	\$ 0.70	\$ (2.31)
Discontinued Operation	-	0.02	-	0.04
Diluted Earnings/(Loss) Per Share	\$ 0.59	\$ 0.13	\$ 0.70	\$ (2.27)
Basic Weighted-Average Shares Outstanding	11,235	9,480	10,824	3,577
Diluted Weighted-Average Shares Outstanding	<u>11,302</u>	<u>9,480</u>	<u>10,865</u>	<u>3,577</u>

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

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

	<i>Nine months ended September 30,</i>	
	<u>2014</u>	<u>2013</u>
Cash Flows From Operating Activities		
Net income/(loss)	\$ 7,742	\$ (3,132)
Adjustments to reconcile net income to net cash and cash equivalents provided by/(used in) operating activities:		
Stock-based compensation	2,719	3
Depreciation and amortization	2,596	673
Non-cash interest relating to equity-linked securities and loan cost amortization	-	217
Non-cash compensation relating to business combination	-	4,418
Changes in operating assets and liabilities:		
Accounts receivable	(2,057)	(4,083)
Inventories	(3,296)	1
Prepaid expenses	(19)	(188)
Accounts payable	630	93
Accrued expenses, returned goods reserve and deferred revenue	2,977	(382)
	<u>11,292</u>	<u>(2,380)</u>
Net Cash and Cash Equivalents Provided by/(Used in) Continuing Operations	11,292	(2,380)
Net Cash and Cash Equivalents Used in Discontinued Operation	-	(239)
	<u>11,292</u>	<u>(2,619)</u>
Cash Flows From Investing Activities		
Cash acquired in business combination	-	18,198
Acquisition of product rights and other related assets	(34,634)	-
Acquisition of property and equipment	(782)	(162)
	<u>(35,416)</u>	<u>18,036</u>
Net Cash and Cash Equivalents (Used in)/Provided by Investing Activities	(35,416)	18,036
Cash Flows From Financing Activities		
Net proceeds from equity offering	46,680	-
Borrowings under line of credit, net	-	(4,065)
Treasury stock purchases	-	(433)
Proceeds from stock option exercises	777	-
Proceeds from warrant exercises	180	-
Excess tax benefit from share-based compensation awards	432	-
	<u>48,069</u>	<u>(4,498)</u>
Net Cash and Cash Equivalents Provided by/(Used in) Financing Activities	48,069	(4,498)
Change in Cash and Cash Equivalents	23,945	10,919
Cash and cash equivalents, beginning of period	<u>11,105</u>	<u>11</u>
Cash and cash equivalents, end of period	<u>\$ 35,050</u>	<u>\$ 10,930</u>
Supplemental disclosure for cash flow information:		
Cash paid for interest	\$ -	\$ 250
Cash paid for income taxes	\$ 137	\$ -
Supplemental non-cash investing and financing activities:		
Contingent payable for asset purchase	\$ 1,000	\$ -
Issuance of common stock in connection with business combination	\$ -	\$ 40,034
Cancellation of Series D, Series C, Series B, and Series A preferred stock	\$ -	\$ 53,726
Acquired non-cash net assets	\$ -	\$ 11,597
Preferred stock dividends accrued	\$ -	\$ 4,974

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

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

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

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

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

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations and cash flows. The condensed consolidated balance sheet at December 31, 2013, has been derived from audited financial statements of that date. The interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules and regulations prescribed by the United States Securities and Exchange Commission. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our annual report on Form 10-K for the year ended December 31, 2013. Certain prior period information has been reclassified to conform to the current period presentation.

Principles of Consolidation

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

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

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

Use of Estimates

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

Recent Accounting Pronouncements

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

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. The standard is effective for our reporting year beginning January 1, 2017 and early adoption is not permitted. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

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

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

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

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

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

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

Accruals for Chargebacks, Returns and Other Allowances

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

The following table summarizes activity in the balance sheet for accruals and allowances for the nine-month periods ended September 30, 2014 and 2013, respectively:

(in thousands)

	Accruals for Chargebacks, Returns and Other Allowances			
	Chargebacks	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2013	4,076	736	735	332
Accruals/Adjustments	27,431	996	3,690	1,243
Credits Taken Against Reserve	(24,722)	(554)	(3,394)	(1,152)
Balance at September 30, 2014	<u>\$ 6,785</u>	<u>\$ 1,178</u>	<u>\$ 1,031</u>	<u>\$ 423</u>
Balance at December 31, 2012	5,662	411	231	242
Accruals/Adjustments	20,133	1,155	1,436	752
Credits Taken Against Reserve	(19,735)	(1,108)	(980)	(668)
Balance at September 30, 2013	<u>\$ 6,060</u>	<u>\$ 458</u>	<u>\$ 687</u>	<u>\$ 326</u>

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

2. REVENUE RECOGNITION AND RELATED ALLOWANCES - continued

Credit Concentration

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

During the three month period ended September 30, 2014, three customers represented 26%, 23%, and 16% of net revenues. During the nine month period ended September 30, 2014, these same three customers represented 26%, 20%, and 16% of net revenues. As of September 30, 2014, net accounts receivable from these customers totaled \$9.6 million. During the three month period ended September 30, 2013, three customers represented 27%, 19%, and 6% of net revenues. During the nine month period ended September 30, 2013, these same three customers represented 28%, 18%, and 10% of net revenues.

3. BUSINESS COMBINATION

Summary

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

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

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

The results of operations of both companies are included in our consolidated financial statements for all periods after completion of the Merger.

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

3. BUSINESS COMBINATION – continued

Transaction Costs

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

<i>Transaction Costs</i>	<i>(in thousands)</i>
Category	(in thousands)
Legal fees	\$ 1,227
Accounting fees	122
Consulting fees	119
Monitoring and advisory fees	390
Transaction bonuses	4,801
Other	429
Total transaction costs	\$ 7,088

Of the total expenses, \$0.5 million and \$6.2 million was incurred and expensed in the three and nine months ended September 30, 2013, respectively. For the three months ended September 30, 2013, the entire \$0.5 million was recognized as selling, general and administrative expense. For the nine months ended September 30, 2013, \$5.5 million was recognized as selling, general and administrative expense, \$0.3 million as interest expense, and \$0.4 million as other expense. No transaction-related expenses were incurred in the three or nine months ended September 30, 2014.

Purchase Consideration and Net Assets Acquired

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

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

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

3. BUSINESS COMBINATION – continued

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

Pro Forma Condensed Combined Financial Information (unaudited)

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

(in thousands)	Three months ended		Nine months ended	
	September 30,		September 30,	
	2013		2013	
Net revenues	\$	7,836	\$	19,695
Net income/(loss)	\$	1,692	\$	(3,179)

4. EARNINGS/(LOSS) PER SHARE

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

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

(in thousands)	Three months ended		Nine months ended	
	September 30, 2014		September 30, 2014	
	Basic	Diluted	Basic	Diluted
Net income	\$ 6,746	\$ 6,746	\$ 7,742	\$ 7,742
Net income allocated to warrants	(38)	(37)	(43)	(42)
Net income allocated to restricted stock	(47)	(47)	(54)	(54)
Net income allocated to common shares	<u>\$ 6,661</u>	<u>\$ 6,662</u>	<u>\$ 7,645</u>	<u>\$ 7,646</u>

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

4. EARNINGS/(LOSS) PER SHARE - continued

The numerators for earnings per share from continuing operations and from the gain on discontinued operations for the three and nine months ended September 30, 2013 are calculated for basic and diluted earnings per share as follows:

(in thousands)	Three months ended		Nine months ended	
	September 30, 2013		September 30, 2013	
	Basic	Diluted	Basic	Diluted
Net income/(loss) from Continuing Operations	\$ 1,041	\$ 1,041	\$ (3,282)	\$ (3,282)
Preferred stock dividends	-	-	(4,974)	(4,974)
Net income allocated to warrants	(19)	(19)	-	-
Net income/(loss) from Continuing Operations allocated to common shares	\$ 1,022	\$ 1,022	\$ (8,256)	\$ (8,256)
Gain on discontinued operations	\$ 150	\$ 150	\$ 150	\$ 150
Net gain on discontinued operations allocated to warrants	(3)	(3)	(3)	(3)
Gain on discontinued operations allocated to common shares	\$ 147	\$ 147	\$ 147	\$ 147

For periods of net income, and when the effects are not anti-dilutive, we calculate diluted earnings per share by dividing net income available to common shareholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options, unvested restricted stock awards, and stock purchase warrants, using the treasury stock method. For periods of net income, anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, out-of-the-money warrants exercisable for common stock, and certain participating securities, if the effect of including both the income allocated to the participating security and the impact of the potential common shares would be anti-dilutive. Anti-dilutive shares have been excluded from the computation of diluted earnings per share.

For periods of net loss, diluted loss per share is calculated similarly to basic loss per share because the impact of all dilutive potential common shares is anti-dilutive. For periods of net loss, anti-dilutive shares consist of Class C Special stock, common stock options, unvested restricted stock awards, and warrants exercisable for common stock (and prior to the Merger, equity-linked securities, convertible preferred stock, and stock purchase warrants exercisable for preferred stock), and have been excluded from the computation of diluted loss per share. Prior to the Merger (Note 3), anti-dilutive shares included equity-linked securities, convertible preferred stock, and stock purchase warrants exercisable for preferred stock.

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings/(loss) per share, was 0.7 million and 0.9 million for the three month periods ended September 30, 2014 and 2013, respectively and 0.7 million and 3.7 million for the nine month periods ended September 30, 2014 and 2013, respectively.

As of September 30, 2014, we had 460 thousand options outstanding to purchase common stock, 79 thousand unvested restricted stock awards, and 469 thousand warrants to purchase common stock.

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5. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2014	December 31, 2013
Raw materials	\$ 4,455	\$ 1,480
Packaging materials	671	766
Work-in-progress	391	162
Finished goods	1,945	1,152
	<u>7,462</u>	<u>3,560</u>
Reserve for excess/obsolete inventories	(116)	(42)
Inventories, net	<u>\$ 7,346</u>	<u>\$ 3,518</u>

Vendor Concentration

We source the raw materials for our products, including active pharmaceutical ingredients (“API”), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. As a result, we are dependent upon our current vendors to supply reliably the API required for ongoing product manufacturing. During the three months ended September 30, 2014, we purchased approximately 49% of our inventory from two suppliers. During the nine months ended September 30, 2014, we purchased approximately 43% of our inventory from the same two suppliers. As of September 30, 2014, amounts payable to these suppliers was \$0.8 million. During the three months ended September 30, 2013, we purchased approximately 52% of our inventory from two suppliers. During the nine months ended September 30, 2013, we purchased approximately 32% of our inventory from two suppliers.

6. PROPERTY, PLANT, AND EQUIPMENT

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

(in thousands)	September 30, 2014	December 31, 2013
Land	\$ 87	\$ 87
Buildings	3,682	3,682
Machinery, furniture and equipment	4,478	3,736
Construction in progress	432	229
	<u>8,679</u>	<u>7,734</u>
Less: accumulated depreciation	(3,633)	(3,197)
Property, Plant and Equipment, net	<u>\$ 5,046</u>	<u>\$ 4,537</u>

Depreciation expense for the three month periods ended September 30, 2014 and 2013 totaled \$153 thousand and \$134 thousand, respectively. Depreciation expense for the nine month periods ended September 30, 2014 and 2013 totaled \$436 thousand and \$400 thousand, respectively. During the three and nine month periods ended September 30, 2014 and 2013, there was no material interest capitalized into construction in progress.

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7. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of the Merger (Note 3), we recorded goodwill of \$1.8 million in our one reporting unit. We assess the recoverability of the carrying value of goodwill as of October 31 of each year, and whenever events occur or circumstances changes that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value from the most recent assessment on October 31, 2013, through September 30, 2014. No impairment losses were recognized during the three and nine months ended September 30, 2014 or 2013.

Acquisition of Abbreviated New Drug Applications

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

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

Acquisition of Lithobid[®] Product Rights

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

Acquisition of Vancocin[®] Product Rights

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

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7. GOODWILL AND INTANGIBLE ASSETS – continued

Definite-Lived Intangible Assets

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

(in thousands)	<u>September 30, 2014</u>		<u>December 31, 2013</u>		<u>Amortization Period</u>
	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	<u>Gross Carrying Amount</u>	<u>Accumulated Amortization</u>	
Acquired ANDA intangible assets	\$ 12,577	\$ (999)	\$ 60	\$ (55)	3-10 years
Product rights	22,522	(573)	100	(100)	2-10 years
Teva license intangible asset	10,900	(1,239)	10,900	(496)	11 years
	<u>\$ 45,999</u>	<u>\$ (2,811)</u>	<u>\$ 11,060</u>	<u>\$ (651)</u>	

Our acquired ANDA intangible assets consist of the exclusive rights, including all of the applicable technical data and other relevant information, to produce certain pharmaceutical products that we acquired from various companies, including those acquired pursuant to the Teva Purchase Agreement. The product rights assets consist of the exclusive rights, including all of the applicable technical data and other relevant information, to produce certain branded pharmaceutical products that we acquired from various companies, including those acquired pursuant to the Lithobid Purchase Agreement and the Vancocin Purchase Agreement. The Teva license was acquired as part of the Merger (Note 3). Definite-lived intangible assets are stated at the lower of cost or fair value, net of amortization using the straight line method over the expected useful lives of the product rights. Amortization expense was \$1.0 million and \$0.2 million for the three months ended September 30, 2014 and 2013, respectively. Amortization expense was \$2.2 million and \$0.3 million for the nine months ended September 30, 2014 and 2013, respectively.

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

Expected future amortization expense is as follows:

(in thousands)	
2014 (remainder of the year)	\$ 1,122
2015	4,485
2016	4,485
2017	4,485
2018	4,485
2019 and thereafter	24,126
Total	<u>\$43,188</u>

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8. STOCK-BASED COMPENSATION

All stock options and restricted stock are granted under the ANI Pharmaceuticals, Inc. Fourth Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"). As of September 30, 2014, 628 thousand shares of our common stock remained available for issuance under the 2008 Plan.

On August 20, 2014, the Board of Directors approved a grant of options to purchase 25 thousand shares of common stock to one of our officers.

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

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

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

Total expense related to stock options for the three months ended September 30, 2014 was \$0.6 million. Total expense related to stock options for the nine months ended September 30, 2014 was \$2.5 million, \$1.3 million of which was a catch-up charge related to the 325 thousand stock options previously approved by the Board of Directors on July 12, 2013 and August 1, 2013 and granted at the May 22, 2014 annual meeting. Total expense related to restricted stock grants for the three and nine months ended September 30, 2014 was \$97 thousand and \$218 thousand, respectively. Total expense related to stock options was \$3 thousand for the three and nine months ended September 30, 2013. There was no expense related to restricted stock grants in the three and nine months ended September 30, 2013.

Options to purchase 5 thousand shares of common stock were exercised and 4 thousand options expired during the three months ended September 30, 2014. Options to purchase 36 thousand shares of common stock were exercised and 64 thousand options expired during the nine month period ended September 30, 2014. No options were exercised and no options expired during the three and nine months ended September 30, 2013. No restricted stock vested or was forfeited during the three and nine months ended September 30, 2014 or 2013.

9. STOCKHOLDER'S EQUITY

On March 10, 2014, we completed a follow-on public offering of 1.6 million shares of our common stock at a public offering price of \$31.00 per share (the "March 2014 Offering"). We received gross proceeds of \$50.0 million, or net proceeds of \$46.7 million after deducting costs of \$3.3 million, including the underwriters' fees and commissions, as well as expenses directly related to the March 2014 Offering. The number of shares sold in the March 2014 Offering includes the exercise in full by the underwriters of their option to purchase an additional 0.2 million shares of common stock.

In January 2014, warrants to purchase an aggregate of 20 thousand shares of common stock were exercised at \$9.00 per share. Warrants to purchase an aggregate of 67 thousand and 198 thousand shares of common stock expired unexercised during the three and nine months ended September 30, 2014, respectively.

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10. INCOME TAXES

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. Based upon historical losses and uncertainty of future taxable income, we have fully reserved for all net deferred tax assets as of September 30, 2014 and December 31, 2013. For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate expected for the entire year. We calculate income tax benefits related to stock-based compensation arrangements using the with and without method.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return, as well as guidance on derecognition, classification, interest and penalties and financial statement reporting disclosures. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the financial statements. We are subject to taxation in various jurisdictions and remain subject to examination by taxing jurisdictions for the years 1998 and all subsequent periods due to the availability of NOL carryforwards.

We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense. We did not have any amounts accrued relating to interest and penalties as of September 30, 2014 and December 31, 2013.

The effective tax rates for the three and nine months ended September 30, 2014 were 18.6% and 16.9% of pre-tax income reported in the period, respectively, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2014. The Company has elected to exclude the impacts from significant pre-tax non-recognized subsequent events from its estimated annual effective rate. Our estimated annual effective rate is primarily driven by our forecasted pre-tax income, estimated temporary and permanent differences, and the use of our existing NOLs. Changes in the estimated annual effective rate during the year are primarily driven by periodic changes to our forecasted pre-tax income. The utilization of our NOL carryforwards will be limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code. For the comparable three and nine month periods ended September 30, 2013, we did not have tax provisions due to the projected loss for the year, accumulated losses, which resulted in NOL carryforwards, and a full valuation allowance.

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

We lease equipment under operating leases that expire in May 2017. We also lease office space under operating leases that expire beginning in February 2016 through September 2018. Future minimum lease payments due under these leases total \$223 thousand as of September 30, 2014.

Rent expense for the three months ended September 30, 2014 and 2013 totaled \$17 thousand and \$11 thousand, respectively. Rent expense for the nine months ended September 30, 2014 and 2013 totaled \$53 thousand and \$26 thousand, respectively.

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11. COMMITMENTS AND CONTINGENCIES – continued

Government Regulation

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

Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone tablets (“EEMT”) and Opium Tincture, are marketed without approved New Drug Applications (“NDAs”) or ANDAs. In March 2014, we formally requested a pre-IND meeting with the FDA to discuss applying for an NDA for our Opium Tincture product. During the three months ended September 30, 2014 and 2013, net revenues for these products totaled \$8.9 million and \$4.4 million, respectively. During the nine months ended September 30, 2014 and 2013, net revenues for these products totaled \$19.4 million and \$7.7 million, respectively.

The FDA’s policy with respect to the continued marketing of unapproved products is stated in the FDA’s September 2011 compliance policy guide, *Marketed New Drugs without Approved NDAs or ANDAs*. Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. We believe that, so long as we comply with applicable manufacturing and labeling standards, the FDA will not take action against us under the current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for these unapproved products for the three months ended September 30, 2014 and 2013 were \$0.2 million and \$0.5 million, respectively. Our contract manufacturing revenues for these unapproved products for the nine months ended September 30, 2014 and 2013 were \$0.7 million and \$1.7 million, respectively.

We receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products for each of the three months ended September 30, 2014 and 2013 were \$0.1 million. Our royalties on the net sales of these unapproved products for each of the nine months ended September 30, 2014 and 2013 were \$0.2 million and \$0.3 million, respectively.

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

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11. COMMITMENTS AND CONTINGENCIES – continued

Shareholder Class Action and Derivative Lawsuits

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

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

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

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

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

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11. COMMITMENTS AND CONTINGENCIES – continued

Louisiana Medicaid Lawsuit

On September 11, 2013, the Attorney General of the State of Louisiana filed a lawsuit in Louisiana state court against numerous pharmaceutical companies, including us, under various state laws, alleging that each defendant caused the state's Medicaid agency to provide reimbursement for drug products that allegedly were not approved by the FDA and therefore allegedly not reimbursable under the federal Medicaid program. The lawsuit relates to three cough and cold prescription products manufactured and sold by our former Gulfport, Mississippi operation, which was sold in September 2010. Through its lawsuit, the state seeks unspecified damages, statutory fines, penalties, attorneys' fees and costs. On October 15, 2013, the defendants removed the lawsuit to the U.S. District Court. On November 14, 2013, the state filed a motion to remand the lawsuit to the Louisiana state court. On September 30, 2014, the U.S. District Court remanded the case from the federal to the state court. While we cannot predict the outcome of the lawsuit at this time, we could be subject to material damages, penalties and fines. We intend to vigorously defend against all claims in the lawsuit.

Other Commitments and Contingencies

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including us, are facing allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name Reglan prior to the FDA's February 2009 Black Box warning requirement. We have been named and served in 92 separate complaints, including three in Pennsylvania, nine in New Jersey, and 80 in California, covering 2,944 plaintiffs in total. In August 2012, we were dismissed with prejudice from all New Jersey cases. We consider our exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide manufactured by us prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) our market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once we received a request for change of labeling from the FDA, we submitted our proposed changes within 30 days, and such changes were subsequently approved by the FDA. At the present time, we are unable to assess the likely outcome of the remaining cases. Our insurance company has assumed the defense of this matter. In addition, our insurance company renewed our product liability insurance on September 1, 2012 and 2013 with absolute exclusions for claims related to Reglan and metoclopramide. We are unable to predict the outcome of these matters and the possible loss or range of loss, if any, associated with their resolution or any potential effect the legal action may have on our operations. Furthermore, we cannot provide assurances that the outcome of these matters will not have an adverse effect on our business, results of operations, financial condition, and cash flow. Like all pharmaceutical manufacturers, we in the future may be exposed to other product liability claims, which could harm our business, results of operations, financial condition, and cash flows.

12. FAIR VALUE DISCLOSURES

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, borrowings under line of credit, and other current liabilities) approximate their carrying values because of their short-term nature.

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12. FAIR VALUE DISCLOSURES – continued

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

Our CVRs, which were granted coincident with the Merger, are considered contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of our projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs, and the changes in such fair value, was immaterial as of and for the three and nine months ended September 30, 2013 and 2014.

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

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

(in thousands)

Description	Fair Value at September 30, 2014	Level 1	Level 2	Level 3
Liabilities				
CVRs	\$ -	\$ -	\$ -	\$ -

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

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

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

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

We measure our long-lived assets, including property, plant and equipment, intangible assets and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three and nine months ended September 30, 2014 and 2013.

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12. FAIR VALUE DISCLOSURES – continued

Acquired Non-Financial Assets Measured at Fair Value

In July 2014, we acquired from Noven the product rights associated with Lithobid, as well as a small amount of raw material inventory, for total consideration of \$12.0 million (Note 7). In addition, we capitalized \$45 thousand of legal costs directly related to the transaction. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the product rights, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The \$12.0 million of product rights will be amortized over their 10 year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three months ended September 30, 2014 and therefore no impairment loss was recognized in the three months ended September 30, 2014. We recorded \$86 thousand of inventory. The value of the raw material inventory was determined based on the most recent purchase price of the material.

In August 2014, we acquired from Shire the U.S. product rights associated with Vancocin, certain equipment, and inventory, for total consideration of \$11.0 million (Note 7). In addition, we capitalized \$0.1 million of legal costs directly related to the transaction. These assets were recorded at their relative fair values, which were determined based on Level 3 unobservable inputs. In order to determine the fair value of the product rights, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The \$10.5 million of product rights will be amortized over their 10 year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three months ended September 30, 2014 and therefore no impairment loss was recognized during the period from the date of acquisition to September 30, 2014. The value of the equipment was determined based on the amount for which we believe we would be able to sell the equipment. The \$0.2 million of equipment will be depreciated over its estimated 10 year useful life, and would be re-valued at the fair value if deemed to be other-than-temporarily impaired. We recorded \$0.4 million of inventory. The value of the raw material inventory was determined based on the most recent purchase price of the material. The value of the finished goods inventory was determined based on the estimated sales to be generated from the finished goods, less costs to sell, including a reasonable margin.

13. COLLABORATIVE ARRANGEMENTS

Sofgen Pharmaceuticals

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

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

We recognize the costs incurred with respect to the April 2014 Sofgen Agreement as expense and classify the expenses based on the nature of the costs. We have recorded \$27 and \$36 thousand of research and development expense related to the April 2014 Sofgen Agreement in the three months ended September 30, 2014 and since the inception of the agreement. No revenue has yet been recognized with respect to the April 2014 Sofgen Agreement.

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

13. COLLABORATIVE ARRANGEMENTS - continued

Dexcel Pharma Technologies Ltd

In June 2014, we entered into a collaboration agreement with Dexcel Pharma Technologies Ltd (“Dexcel”) to commercialize and sell a generic drug product (the “June 2014 Dexcel Agreement”). The product is subject to FDA approval of an ANDA filing. In general, Dexcel will be responsible for the manufacturing and regulatory submission of the product, including obtaining approval of the ANDA, and we will provide payments based on the completion of certain milestones. Upon approval, Dexcel will manufacture the drug and we will be responsible for the marketing and distribution, under our label, of the product in the United States, providing a percentage of profits from sales of the drug to Dexcel.

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

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

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this Form 10-Q quarterly report. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2013.

OVERVIEW

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

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

Generic Products

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

Branded Products

Cortenema[®]
Reglan[®] Tablets
Lithobid[®]
Vancocin[®]

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

- **Formulation Complexity.** Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that we intend to leverage in selecting products to develop or manufacture.
- **Patent Status.** We seek to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.
- **Market Size.** When determining whether to develop or acquire an individual product, we review the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. We endeavor to manufacture products with sufficient market size to enable us to enter the market with a strong likelihood of being able to price our products both competitively and at a profit.
- **Profit Potential.** We research the availability and cost of active pharmaceutical ingredients along with anticipated market share in determining which products to develop or acquire. In determining the potential profit of a product, our management forecasts our anticipated market share, pricing, which includes expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.
- **Manufacturing.** We generally seek to develop and manufacture products at our own manufacturing plants in order to maximize the capacity and utilization of our facilities, to ensure quality control in our products, and to maximize profit potential.
- **Competition.** When determining whether to develop or acquire an individual product, we research the existing and expected market share of generic competitors. We seek to develop products for which we can obtain a large market share, and may decline to develop a product if we anticipate that many generic competitors will be entering that product's market. Our highly specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies would be able to compete.

GENERAL

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net Revenues	\$ 17,387	\$ 7,836	\$ 34,933	\$ 19,550
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	3,061	2,710	7,800	7,290
Research and development	883	454	2,110	1,188
Selling, general and administrative	4,057	3,480	13,193	12,961
Depreciation and amortization	1,187	382	2,596	673
Operating Income/(Loss)	8,199	810	9,234	(2,562)
Interest income/(expense)	10	-	13	(467)
Other income/(expense)	82	148	72	(336)
Net Income/(Loss) Before (Provision)/Benefit for Income Taxes	8,291	958	9,319	(3,365)
(Provision)/Benefit for income taxes	(1,545)	83	(1,577)	83
Net Income/(Loss) from Continuing Operations	6,746	1,041	7,742	(3,282)
Gain on discontinued operation	-	150	-	150
Net Income/(Loss)	\$ 6,746	\$ 1,191	\$ 7,742	\$ (3,132)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2014	2013	2014	2013
Net Revenues	100.0%	100.0%	100.0%	100.0%
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	17.6%	34.6%	22.3%	37.3%
Research and development	5.1%	5.8%	6.0%	6.1%
Selling, general and administrative	23.3%	44.4%	37.8%	66.3%
Depreciation and amortization	6.8%	4.9%	7.4%	3.4%
Operating Income/(Loss)	47.2%	10.3%	26.5%	(13.1)%
Interest income/(expense)	0.1%	-%	-%	(2.4)%
Other income/(expense)	0.4%	1.9%	0.2%	(1.7)%
Net Income/(Loss) Before (Provision)/Benefit for Income Taxes	47.7%	12.2%	26.7%	(17.2)%
(Provision)/Benefit for income taxes	(8.9)%	1.1%	(4.6)%	0.4%
Net Income/(Loss) from Continuing Operations	38.8%	13.3%	22.2%	(16.8)%
Gain on discontinued operation	-%	1.9%	-%	0.8%
Net Income/(Loss)	38.8%	15.2%	22.2%	(16.0)%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2014 AND 2013

Net Revenues

(in thousands)	Three Months Ended September		Change	% Change
	2014	2013		
Generic pharmaceutical products	\$ 10,188	\$ 5,627	\$ 4,561	81.1%
Branded pharmaceutical products	4,806	745	4,061	545.1%
Contract manufacturing	1,350	1,326	24	1.8%
Contract services and other income	1,043	138	905	655.8%
Total net revenues	<u>\$ 17,387</u>	<u>\$ 7,836</u>	<u>\$ 9,551</u>	121.9%

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

Net revenues for the three months ended September 30, 2014 were \$17.4 million compared to \$7.8 million for the same period in 2013, an increase of \$9.6 million, or 121.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$10.2 million during the three months ended September 30, 2014, an increase of 81.1% compared to \$5.6 million for the same period in 2013. The primary reason for the increase was increased sales of Esterified Estrogen with Methyltestosterone tablets ("EEMT"), due to increases in prices per bottle. In addition, we experienced increased sales for our Fluvoxamine, HC Enema, and Opium Tincture products.

As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market EEMT and Opium Tincture without FDA-approved New Drug Applications ("NDAs"). The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing and labeling standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the three months ended September 30, 2014 and 2013 were \$8.9 million and \$4.4 million, respectively.

- Net revenues for branded pharmaceutical products were \$4.8 million during the three months ended September 30, 2014, an increase of 545.1% compared to \$0.7 million for the same period in 2013. The primary reasons for the increase were three months and two months of sales from our Lithobid and Vancocin products, respectively, the product rights to which were acquired during the third quarter of 2014, as well as higher unit sales of Reglan tablets.
- Contract manufacturing revenues were \$1.4 million during the three months ended September 30, 2014, a slight increase of 1.8% compared to \$1.3 million for the same period in 2013, due to timing of orders from contract manufacturing customers in the period. As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the three months ended September 30, 2014 and 2013 were \$0.2 million and \$0.5 million, respectively.

- Contract services and other income were \$1.0 million during the three months ended September 30, 2014, an increase of 655.8% from \$0.1 million for the same period in 2013, due primarily to royalties received on sales of the authorized generic of Vancocin, the product rights to which were acquired in the third quarter of 2014. As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products were \$0.1 million for each of the three month periods ended September 30, 2014 and 2013.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	<u>Three Months Ended September 30,</u>		<u>Change</u>	<u>% Change</u>
	<u>2014</u>	<u>2013</u>		
Cost of sales (excl. depreciation and amortization)	\$ 3,061	\$ 2,710	\$ 351	13.0%

Cost of sales consists of direct labor, including manufacturing and packaging, active and inactive pharmaceutical ingredients, freight costs, and packaging components. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on our condensed consolidated statements of operations.

For the three months ended September 30, 2014, cost of sales increased to \$3.1 million from \$2.7 million for the same period in 2013, an increase of \$0.4 million or 13.0%, primarily as a result of royalties due on proceeds from sales of Vancocin and its authorized generic. The contractual requirement to pay these royalties ends on December 31, 2014. Cost of sales as a percentage of net revenues decreased to 17.6% during the three months ended September 30, 2014, from 34.6% during same period in 2013, primarily as a result of price increases for EEMT and a favorable shift in product mix toward higher margin products, including our two new branded products, Lithobid and Vancocin.

We source the raw materials for our products, including active pharmaceutical ingredients (“API”), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA, which can take 18 months or longer. As a result, we are dependent upon our current vendors to reliably supply the API required for ongoing product manufacturing. In addition, certain of our APIs for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections. During the three months ended September 30, 2014, we purchased 49% of our inventory from two suppliers. As of September 30, 2014, amounts payable to these suppliers were \$0.8 million. In the three months ended September 30, 2013, we purchased 52% of our inventory from two suppliers.

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

Other Operating Expenses

(in thousands)	Three Months Ended September 30,			
	2014	2013	Change	% Change
Research and development	\$ 883	\$ 454	\$ 429	94.5%
Selling, general and administrative	4,057	3,480	577	16.6%
Depreciation and amortization	1,187	382	805	210.7%
Total other operating expenses	\$ 6,127	\$ 4,316	\$ 1,811	42.0%

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

For the three months ended September 30, 2014, other operating expenses increased to \$6.1 million from \$4.3 million for the same period in 2013, an increase of \$1.8 million, or 42.0%, primarily as a result of the following factors:

- Selling, general and administrative expenses increased from \$3.5 million to \$4.1 million, primarily due to increases in stock-based compensation expense in 2014.
- Research and development expenses increased from \$0.5 million to \$0.9 million, due to work on new development projects, including the ANDAs purchased from Teva Pharmaceuticals (“Teva”) in the first quarter of 2014, and new collaborations.
- Depreciation and amortization increased from \$0.4 million to \$1.2 million, an increase of 210.7%, due to amortization of the ANDAs purchased from Teva and amortization of product rights for Lithobid and Vancocin purchased during the third quarter.

Other Income

(in thousands)	Three Months Ended September 30,			
	2014	2013	Change	% Change
Interest income	\$ 10	\$ -	\$ 10	100.0%
Other income	82	148	(66)	(44.6)%
Total other income	\$ 92	\$ 148	\$ (56)	(37.8)%

For the three months ended September 30, 2014, we recognized other income of \$92 thousand versus \$148 thousand for the same period in 2013, a decrease of \$56 thousand, or 37.8%. This change resulted primarily from the following factors:

- Interest income increased to \$10 thousand as a result of interest earned on our cash balance in 2014.
- Other income decreased from \$148 thousand to \$82 thousand. Other income in the three months ended September 30, 2013 related to settling of older liabilities and other income in the three months ended September 30, 2014 related primarily to the receipt of an abatement for prior year property taxes resulting from a reassessment of the property value for our manufacturing facilities.

Gain on Discontinued Operation

(in thousands)

	<u>Three Months Ended September 30,</u>			
	<u>2014</u>	<u>2013</u>	<u>Change</u>	<u>% Change</u>
Gain on discontinued operation, net of tax	\$ -	\$ 150	\$ (150)	(100.0)%

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.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2014 AND 2013

Net Revenues

(in thousands)

	<u>Nine Months Ended September 30,</u>			
	<u>2014</u>	<u>2013</u>	<u>Change</u>	<u>% Change</u>
Generic pharmaceutical products	\$ 23,077	\$ 11,102	\$ 11,975	107.9%
Branded pharmaceutical products	6,149	2,742	3,407	124.3%
Contract manufacturing	4,121	4,876	(755)	(15.5)%
Contract services and other income	1,586	830	756	91.1%
Total net revenues	<u>\$ 34,933</u>	<u>\$ 19,550</u>	<u>\$ 15,383</u>	<u>78.7%</u>

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

Net revenues for the nine months ended September 30, 2014 were \$34.9 million compared to \$19.6 million for the same period in 2013, an increase of \$15.4 million, or 78.7%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$23.1 million during the nine months ended September 30, 2014, an increase of 107.9% compared to \$11.1 million for the same period in 2013. The primary reason for the increase was increased sales of EEMT, which was the result of increases in both market share and prices per bottle. In addition, we experienced increased sales for our Fluvoxamine, Opium Tincture, and HC Enema products. In the third quarter of 2013, a significant competitor stopped producing EEMT, which led to a material increase in our market share and enabled us to significantly increase the price we charge for the product. However, in the first half of 2014, the same competitor re-entered the market, which negatively impacted our EEMT unit sales and revenues during the period, which impact we expect will continue. Revenues for the nine months ended September 30, 2014 were reduced by \$3.9 million in charges related to price protection contract obligations for EEMT.

As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market EEMT and Opium Tincture without FDA-approved NDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing and labeling standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the nine months ended September 30, 2014 and 2013 were \$19.4 million and \$7.7 million, respectively.

- Net revenues for branded pharmaceutical products were \$6.1 million during the nine months ended September 30, 2014, an increase of 124.3% compared to \$2.7 million for the same period in 2013. The primary reasons for the increase was three months and two months of sales from our Lithobid and Vancocin products, respectively, the product rights to which were acquired during the third quarter of 2014. This increase was partially offset by lower unit sales of our Cortenema product and a slight decrease in unit sales of Reglan tablets.
- Contract manufacturing revenues were \$4.1 million during the nine months ended September 30, 2014, a decrease of 15.5% compared to \$4.9 million for the same period in 2013, due to decreased orders from contract manufacturing customers during the period. As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the nine months ended September 30, 2014 and 2013 were \$0.7 million and \$1.7 million, respectively.
- Contract services and other income were \$1.6 million during the nine months ended September 30, 2014, an increase of 91.1% from \$0.8 million for the same period in 2013, due primarily to royalties received on sales of the authorized generic of Vancocin, the product rights to which were acquired in the third quarter of 2014, partially offset by decreased contract services. As described in Note 11, *Commitments and Contingencies*, in the unaudited condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products for each of the nine month periods ended September 30, 2014 and 2013 were \$0.2 million and \$0.3 million.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	<u>Nine Months Ended September 30,</u>			% <u>Change</u>
	<u>2014</u>	<u>2013</u>	<u>Change</u>	
Cost of sales (excl. depreciation and amortization)	\$ 7,800	\$ 7,290	\$ 510	7.0%

Cost of sales consists of direct labor, including manufacturing and packaging, active and inactive pharmaceutical ingredients, freight costs, and packaging components. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on our condensed consolidated statements of operations.

For the nine months ended September 30, 2014, cost of sales increased to \$7.8 million from \$7.3 million for the same period in 2013, an increase of \$0.5 million or 7.0%, primarily as a result of an increase in sales of generic pharmaceutical products, as well as royalties due on proceeds from sales of Vancocin and its authorized generic. The contractual requirement to pay these royalties ends on December 31, 2014. Cost of sales as a percentage of net revenues decreased to 22.3% during the nine months ended September 30, 2014, from 37.3% during same period in 2013, primarily as a result of price increases for EEMT, a favorable shift in product mix toward higher margin products, including our two new branded products, Lithobid and Vancocin, as well as decreases in the cost of raw material for Opium Tincture.

We source the raw materials for our products, including API, from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA, which can take 18 months or longer. As a result, we are dependent upon our current vendors to reliably supply the API required for ongoing product manufacturing. In addition, certain of our APIs for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections. During the nine months ended September 30, 2014, we purchased 43% of our inventory from two suppliers. As of September 30, 2014, amounts payable to these suppliers were \$0.8 million. In the nine months ended September 30, 2013, we purchased 32% of our inventory from two suppliers.

Each year, we must submit a request to the DEA for a quota to purchase the amount of API needed to manufacture Opium Tincture. Without an approved quota from the DEA, we would not be able to purchase API from our supplier. As a result, we are dependent upon the DEA to annually approve a sufficient quota of API to support the continued manufacture of Opium Tincture.

Other Operating Expenses

(in thousands)	Nine Months Ended September 30,			
	2014	2013	Change	% Change
Research and development	\$ 2,110	\$ 1,188	\$ 922	77.6%
Selling, general and administrative	13,193	12,961	232	1.8%
Depreciation and amortization	2,596	673	1,923	285.7%
Total other operating expenses	\$ 17,899	\$ 14,822	\$ 3,077	20.8%

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

For the nine months ended September 30, 2014, other operating expenses increased to \$17.9 million from \$14.8 million for the same period in 2013, an increase of \$3.0 million, or 20.8%, primarily as a result of the following factors:

- Research and development expenses increased from \$1.1 million to \$2.1 million, due to work on new development projects, including the Teva products, new collaborations, and a filing fee for an ANDA submission of an anti-cancer drug.
- Selling, general and administrative expenses increased slightly, from \$13.0 million to \$13.2 million, primarily due to the increases in personnel and consulting, legal, and other fees related to becoming a public company, as well as increased stock-based compensation expense, including a \$1.3 million catch-up charge for non-cash stock-based compensation, which was recognized upon shareholder approval of an increase in shares available for issuance under our stock compensation plan. These increases were partially offset by the lack of \$5.0 million of Merger-related expenses incurred in the prior year period.
- Depreciation and amortization increased from \$0.7 million to \$2.6 million, an increase of 285.7%, due to amortization of the ANDAs purchased from Teva in the first quarter of 2014, amortization of product rights for Lithobid and Vancocin purchased during the third quarter of 2014, and a full nine months of amortization of the Teva license acquired in the Merger.

Other Income/(Expense)

(in thousands)	Nine Months Ended September 30,			
	2014	2013	Change	% Change
Interest income/(expense)	\$ 13	\$ (467)	\$ 480	(102.8)%
Other income/(expense)	72	(336)	408	(121.4)%
Total other income/(expense)	<u>\$ 85</u>	<u>\$ (803)</u>	<u>\$ 888</u>	<u>(110.6)%</u>

For the nine months ended September 30, 2014, we recognized other income of \$85 thousand versus other expense of \$803 thousand for the same period in 2013, a change of \$888 thousand, or 110.6%. This change resulted primarily from the following factors:

- Interest income/(expense) changed from \$467 thousand of expense to \$13 thousand of income as a result of interest earned on our cash balance in 2014, as well as paying down our revolving line of credit in the second quarter of 2013, in connection with the Merger. Interest expense in the nine months ended September 30, 2013 also included a termination fee and accelerated amortization of deferred loan costs.
- Other income/(expense) changed from \$336 thousand of other expense to \$72 thousand of other income, due primarily to the absence of payments of \$390 thousand to certain of our investors for monitoring and advisory fees in 2013. Upon completion of the Merger, our obligation to pay monitoring and advisory fees was terminated.

Gain on Discontinued Operation

(in thousands)	Three Months Ended September 30,			
	2014	2013	Change	% Change
Gain on discontinued operation, net of tax	\$ -	\$ 150	\$ (150)	(100.0)%

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 resulted from finalizing a portion of the remaining liabilities.

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	September 30, December 31,	
	2014	2013
Cash and cash equivalents	\$ 35,050	\$ 11,105
Accounts receivable, net	14,570	12,513
Inventories	7,346	3,518
Prepaid expenses	599	580
Total current assets	<u>\$ 57,565</u>	<u>\$ 27,716</u>
Accounts payable	\$ 3,059	\$ 1,429
Accrued expenses	3,888	1,326
Returned goods reserve	1,178	736
Deferred revenue	20	47
Total current liabilities	<u>\$ 8,145</u>	<u>\$ 3,538</u>

At September 30, 2014, we had \$35.1 million in unrestricted cash and cash equivalents. At December 31, 2013, we had \$11.1 million in unrestricted cash and cash equivalents. We received net proceeds of \$46.7 million from a follow-on public offering that closed on March 10, 2014 and generated \$11.3 million of cash from operations in the nine months ended September 30, 2014. In addition, in the first quarter of 2014, we acquired ANDAs related to 31 products for \$12.5 million from Teva. In the third quarter of 2014, we acquired the intellectual property rights and NDA associated with Lithobid, as well as raw material inventory, for \$11.0 million, not including the \$1.0 million contingency payment, and also acquired the U.S. intellectual property rights and NDA associated with Vancocin, two related ANDAs, and certain equipment and inventory for \$11.0 million.

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

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

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

(in thousands)	Nine Months ended September 30,	
	2014	2013
Operating Activities	\$ 11,292	\$ (2,619)
Investing Activities	\$ (35,416)	\$ 18,036
Financing Activities	\$ 48,069	\$ (4,498)

Net Cash Provided By/(Used In) Operations

Net cash provided by operating activities was \$11.3 million for the nine months ended September 30, 2014, compared to \$2.6 million used in operating activities during the same period in 2013, a change of \$13.9 million between the periods. This increase was due to changes in net income and changes in current assets and current liabilities. Net income from operations for the nine months ended September 30, 2014 increased by \$10.9 million from the same period in 2013, after adjusting for non-cash expenses. Changes in current assets and current liabilities for the nine months ended September 30, 2014 used \$1.8 million of cash compared to \$4.6 million for the same period in 2013, a decrease in use of cash of approximately \$2.8 million between the periods. Accounts receivable increased by \$2.1 million in the nine months ended September 30, 2014 as compared with an increase of \$4.1 million in the prior year period. Accrued expenses increased by \$3.0 million in the nine months ended September 30, 2014, as compared with a decrease of \$0.4 million in the prior year period. Accounts payable increased by \$0.6 million in the nine months ended September 30, 2014 as compared with \$0.1 million in the prior year period. These increases to cash provided were partially offset by an increase to inventory of \$3.3 million in the nine months ended September 30, 2014 as compared with a slight decrease of \$1 thousand in the prior year period.

Net Cash (Used In)/Provided By Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2014 was \$35.4 million, principally due to the \$12.5 million asset acquisition of the Teva ANDA products, \$11.0 million and \$11.0 million asset purchases related to Lithobid and Vancocin, respectively, in addition to \$0.9 million of capital expenditures during the period. Net cash provided by investing activities was \$18.0 million during the same period in 2013, relating primarily to the net cash acquired in the Merger, partially offset by capital expenditures.

Net Cash Provided By/(Used In) Financing Activities

Net cash provided by financing activities was \$48.1 million for the nine months ended September 30, 2014, resulting primarily from \$46.7 million of net proceeds received in our March 10, 2014 follow-on public offering. We also received \$0.8 million of cash from stock option exercises and \$0.2 million from warrant exercises during the nine months ended September 30, 2014. Net cash used in financing activities was \$4.5 million during the same period in 2013, resulting primarily from the repayment in September 2013 of our revolving line of credit in connection with the Merger.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

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

A summary of our significant accounting policies is included in Item 8. Consolidated Financial Statements, Note 1 — Description of Business and Summary of Significant Accounting Policies, in our Annual Report on Form 10-K for the year ended December 31, 2013. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Such policies are summarized in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2013.

RECENTLY ADOPTED ACCOUNTING PRONOUNCEMENTS

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

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2014 and December 31, 2013, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required due to Smaller Reporting Company status.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of September 30, 2014. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2014 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

In addition to the other information set forth in this report, please carefully consider the factors described in our most recent annual report on Form 10-K for the fiscal year ended December 31, 2013 under the heading “Part I — Item 1A. Risk Factors.” The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition and/or operating results. Other than as described below, there has been no material change to those risk factors.

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

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

Item 2. Unregistered Sales of Equity and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

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

SIGNATURES

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

ANI Pharmaceuticals, Inc. (Registrant)

Date: November 10, 2014

By: /s/ Arthur S. Przybyl
Arthur S. Przybyl
President and
Chief Executive Officer
(Principal Executive Officer)

Date: November 10, 2014

By: /s/ Charlotte C. Arnold
Charlotte C. Arnold
Vice President and
Chief Financial Officer
(Principal Financial Officer)

INDEX TO EXHIBITS

Exhibit No.	Description
10.1*	Asset Purchase Agreement between Noven Therapeutics, LLC and ANI Pharmaceuticals, Inc. Dated as of July 1, 2014
10.2*	Asset Purchase Agreement dated as of August 1, 2014 among ANI Pharmaceuticals, Inc. and Shire Viropharma Incorporated.
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

*Confidential treatment requested as to certain portions of this exhibit. Such portions have been redacted and filed separately with the Commission.

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [*]**

ASSET PURCHASE AGREEMENT

BETWEEN

NOVEN THERAPEUTICS, LLC

AND

ANI PHARMACEUTICALS, INC.

Dated as of July 1, 2014

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [*]**

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**Confidential Materials Omitted and Filed Separately with the Securities and Exchange
Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the
Securities Act of 1933, as amended. Confidential Portions are marked: [***]**

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EXHIBITS

Exhibit A	-	Form of Bill of Sale
Exhibit B	-	Form of Assignment and Assumption Agreement
Exhibit C	-	Form of Assignment of Trademark Rights
Exhibit D	-	Joint Public Statement
Exhibit E	-	Transfer Letter
Exhibit F	-	Supply Agreement Termination Letter
Exhibit G	-	Buyer's Acceptance Letter
Exhibit H	-	Customer Notification Letter

**Confidential Materials Omitted and Filed Separately with the Securities and Exchange
Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the
Securities Act of 1933, as amended. Confidential Portions are marked: [***]**

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this “Agreement”) is entered into as of July 1, 2014 (the “Closing Date”), by and between Noven Therapeutics, LLC, a Delaware limited liability company formerly known as JDS Pharmaceuticals, LLC (the “Seller”) and ANI Pharmaceuticals, Inc., a Delaware corporation (the “Buyer”). The Seller and the Buyer are referred to hereinafter individually as a “Party” and collectively as the “Parties.”

RECITALS

- A. The Seller is engaged in the promotion, distribution, marketing, and sale of the Lithobid Products (the “Business”).
- B. Pursuant to the terms of that certain Manufacturing and Supply Agreement, dated December 6, 2007, between Seller and ANIP Acquisition Company, a wholly owned subsidiary of Buyer (“ANIP Acquisition”), ANIP Acquisition is the current manufacturer of the Lithobid Products (the “Supply Agreement”).
- C. Buyer desires to purchase from Seller and Seller desires to sell to Buyer, the Purchased Assets for the Consideration and upon the terms and conditions set forth herein (the “Sale”), and the Board of Directors of each of the Seller and the Buyer has approved the consummation of the Sale and the transactions set forth herein.

In consideration of the mutual representations, warranties and covenants contained herein, the Parties hereto agree as follows:

SECTION 1 DEFINITIONS

- 1.1 “Act” means the Federal Food, Drug and Cosmetic Act, as amended, and the regulations promulgated thereunder from time to time.
- 1.2 “Additional Payment” has the meaning set forth in Section 2.2(b) below.
- 1.3 “Affiliate” means any person or legal entity controlling, controlled by or under common control with the person with respect to whom such status is at issue and shall include, without limitation, any corporation fifty percent (50%) or more of the voting power of which (or other comparable ownership interest for an entity other than a corporation) is owned, directly or indirectly, by the person with respect to whom such status is at issue or any corporation, person or entity which owns fifty percent (50%) or more of such voting power of the person with respect to whom such status is at issue.
- 1.4 “Agreement” has the meaning set forth in the preamble above.
- 1.5 “Allocation Schedule” has the meaning set forth in Section 2.2(c) below.
- 1.6 “AMP” has the meaning set forth in Section 3.11 below.
- 1.7 “Ancillary Agreements” has the meaning set forth in Section 2.3(a) below.
- 1.8 “ANIP Acquisition” has the meaning set forth in the recitals above.
- 1.9 “API” means the active pharmaceutical ingredient or pharmaceutically active compound Lithium Carbonate for use in the Lithobid Product.
-

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1.10 “Assumed Liabilities” has the meaning set forth in Section 2.1(c) below.

1.11 “Books and Records” means the Marketing Materials and Data, and all of the following, to the extent solely relating to the Lithobid Products or the Business and to the extent owned by Seller as of the Closing Date: all documents, if any, relating to the calculation of baseline AMP received by Seller from Solvay (but excluding any proprietary methodology documents created by Seller or any of Seller’s Affiliates with respect to the calculation of baseline AMP); all documents, if any, relating to NonFAMP-Eligible Transactions from October 1, 2013 through the Closing Date; vendor lists and audits; batch records; change control reports; all information relating to medical safety, including complaints and adverse drug event histories and files for the Lithobid Products; copies of all filings (and supporting documentation and correspondence) with Regulatory Authorities, including, but not limited to, the NDA for the Lithobid Products, as well as the Supplement; component and labeling purchasing specifications; quality assurance/control data; and customer lists (if any).

1.12 “Bulk Sales Laws” means the Laws of any jurisdiction relating to bulk sales that are applicable to the sale of the Purchased Assets by Seller hereunder.

1.13 “Business” has the meaning set forth in the recitals above.

1.14 “Business Day” means any day other than a Saturday, Sunday or another day on which commercial banks in New York, New York are authorized or required by law to close.

1.15 “Buyer” has the meaning set forth in the preamble above.

1.16 “Buyer Indemnified Party” has the meaning set forth in Section 8.1 below.

1.17 “Buyer’s Acceptance Letter” has the meaning set forth in Section 2.3(b)(iii) below.

1.18 “Cap” has the meaning set forth in Section 8.3(a) below.

1.19 “Closing” has the meaning set forth in Section 2.3 below.

1.20 “Closing Date” has the meaning set forth in the preamble.

1.21 “Closing Payment” has the meaning set forth in Section 2.3(b)(i) below.

1.22 “Confidential Information” has the meaning set forth in Section 9.1 below.

1.23 “Consideration” has the meaning set forth in Section 2.2(b) below.

1.24 “Disclosing Party” has the meaning set forth in Section 9.1 below.

1.25 “Dollar,” “Dollars” and the symbol “\$” each means lawful money of the United States of America.

1.26 “Excluded Assets” has the meaning set forth in Section 2.1(b) below.

1.27 “FDA” means the Food and Drug Administration or any successor agency thereof.

1.28 “FDA Review” means the FDA’s review of the Supplement.

1.29 “Finished Lithobid Product Inventory” has the meaning set forth in Section 2.1(b) below.

1.30 “Fundamental Representations” has the meaning set forth in Section 8.4(a) below.

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1.31 “Indemnified Parties” means (i) with respect to claims arising under Section 8.1, the Buyer Indemnified Parties, and (ii) with respect to claims arising under Section 8.2, the Seller Indemnified Parties.

1.32 “Indemnifying Party” means (i) with respect to claims arising under Section 8.1, the Seller, and (ii) with respect to claims arising under Section 8.2, the Buyer.

1.33 “Intellectual Property Rights” means any and all of the following intellectual property rights owned by the Seller or its Affiliates to the extent primarily used in the formulation, manufacture, packaging, promotion, distribution, marketing, and sale of the Lithobid Products: (i) patents, patent applications (filed and unified), invention disclosures and invention assignments; (ii) trademarks, trade names, trade dress, logos, slogans, rights of publicity, service marks and service names; (iii) copyrights and other works; (iv) worldwide web addresses and domain names; (v) Know-How; (vi) Trade Secrets; (vii) all applications, registrations, or common law or unregistered rights relating to any of the foregoing; and (viii) all rights to obtain renewals, continuations, divisions or other extensions of legal protections pertaining to any of the foregoing. For clarity and for all purposes under this Agreement, the name “Noven” and all trademarks and other intellectual property rights related thereto are not Intellectual Property Rights.

1.34 “Inventory” means all work-in-process, printed packaging components, raw materials, including API, and inventories of Finished Lithobid Product Inventory that is owned by Seller.

1.35 “Know-How” means all proprietary methods, processes, techniques, compositions, technology, information, data, results of tests, studies, statistical and other analyses and expertise, whether patented or unpatented, in each case to the extent related solely to the Lithobid Products, owned by the Seller or any Affiliate of the Seller which are, used solely in the formulation, manufacture or marketing of the Lithobid Products, including, without limitation, pharmacology, toxicology, drug stability, manufacturing and formulation methodologies and techniques, clinical and non-clinical safety and efficacy studies, marketing studies and absorption, excretion and metabolism studies, quality control and quality assurance processes, and shall include, without limitation, all tangible manifestations thereof.

1.36 “Knowledge” means, with respect to the Seller and with respect to any particular matter, the actual knowledge of Jeffrey Mihm, the Chief Administrative Officer and General Counsel of Seller or Bruce Friedman, Vice President of the Seller and the knowledge each has or would have after inquiry to his direct reports who have responsibility for and are likely to have knowledge of the matter in question.

1.37 “Law” means all applicable federal, state and local laws, statutes or ordinances, including, without limitation, (i) the Act and (ii) all regulations, rules, or published guidelines or pronouncements having the effect of law promulgated by any Regulatory Authority.

1.38 “Liability” means any liability (whether known or unknown, asserted or unasserted, absolute or contingent, accrued or unaccrued, liquidated or unliquidated, and due or to become due), including any liability for Taxes.

1.39 “Lithobid Marks” means the trademarks listed on Schedule II hereto.

1.40 “Lithobid Products” means the specific products listed on Schedule I hereto.

1.41 “Losses” has the meaning set forth in Section 8.1 below.

1.42 “Marketing Materials and Data” means all of the following, to the extent solely relating to the Lithobid Products and to the extent owned by Seller and in Seller’s possession: physician lists, customer lists, sales force training materials, market research materials, advertising and promotional materials and records of sales and cost data for the twelve (12) months ended April 30, 2014.

Confidential Materials Omitted and Filed Separately with the Securities and Exchange Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the Securities Act of 1933, as amended. Confidential Portions are marked: [*]**

1.43 “Material Adverse Effect” means (i) with respect to any Person, a material adverse effect on the assets, financial condition, or results of operations of such Person and its subsidiaries, taken as a whole, and (ii) with respect to the Business, a material adverse effect on the Business taken as a whole, provided that in no event will any of the following, individually or in the aggregate, be deemed to constitute, nor shall any of the following be taken into account in determining whether there has been, or will be, a Material Adverse Effect with respect to such Person, or with respect to the Business: (A) any change in general economic or financial market conditions, (B) any change in the general state of the industry in which such Person or the Business, as applicable, operates, (C) any act of terrorism or war, or (D) the announcement of the execution of this Agreement or the transactions contemplated hereby except to the extent any of the events in clauses (A) - (D) affects such Person or the Business in a disproportionate manner to other Persons or products in the industry.

1.44 “NDA” means New Drug Application 18-027.

1.45 “NDC” has the meaning set forth in Section 5.6 below.

1.46 “NonFAMP-Eligible Transactions” means those transactions relating to the Lithobid Products that are used to calculate the Non-Federal Average Manufacturer Price as defined by Veteran’s Health Care Act of 1992.

1.47 “Party” or “Parties” has the meaning set forth in the preamble above.

1.48 “Permitted Encumbrances” means (i) encumbrances for Taxes not yet due and payable or being contested in good faith for which adequate reserves have been established; and (ii) statutory and contractual encumbrances of landlords, carriers, warehousemen, mechanics, materialmen, suppliers and repairmen, and other like encumbrances, incurred in the ordinary course of business and not yet delinquent or being contested in good faith.

1.49 “Person” means an individual, a corporation, a general partnership, a limited partnership, a limited liability company, a limited liability partnership, an association, a trust or any other entity or organization, including a governmental authority.

1.50 “Product Approval” means with respect to each Lithobid Product, the NDA set forth opposite the name of such Lithobid Product on Schedule I hereto, together with the Supplement.

1.51 “Product Technology” means the Intellectual Property Rights, manufacturing technology, and trade secrets, including, but not limited to, the Know-How, that is owned or used by the Seller or its Affiliates and is necessary for the formulation, manufacture, packaging, release testing and stability and shelf life determination of the Lithobid Products, including, but not limited to, specifications and test methods, manufacturing and packaging instructions, master formula, validation reports (process, analytical methods and cleaning), stability data and analytical methods, but excluding any common industry practice, process or procedure used or usable in the manufacture of pharmaceutical products.

1.52 “Purchased Assets” has the meaning set forth in Section 2.1(a) below.

1.53 “Reasonable Commercial Efforts” means, with respect to a particular result, such efforts as a reasonably prudent Person desirous of achieving such result would use in similar circumstances; provided that the applicable Party shall be required to expend only such resources to achieve such result as are commercially reasonable in similar circumstances.

1.54 “Receiving Party” has the meaning set forth in Section 9.1 below.

1.55 “Regulatory Authority” means any governmental or regulatory body, court, agency, commission, official, or arbitrator, including, without limitation, the FDA.

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- 1.56 “Retained Liabilities” has the meaning set forth in Section 2.1(d) below.
- 1.57 “Sale” has the meaning set forth in the recitals above.
- 1.58 “Seller” has the meaning set forth in the preamble above.
- 1.59 “Seller Indemnified Party” has the meaning set forth in Section 8.2 below.
- 1.60 “Supplement” means the prior approval Supplement filed by Seller with the FDA relating to a change in particle size of the active pharmaceutical ingredients used in the Lithobid Products.
- 1.61 “Supply Agreement” has the meaning set forth in the recitals above.
- 1.62 “Supply Agreement Termination Letter” has the meaning set forth in Section 2.3(a)(iv) below.
- 1.63 “Tax Return” means any return, declaration, report, claim for refund, information return or statement or other document relating to Taxes, including any schedule or attachment thereto, and including any amendment thereof.
- 1.64 “Taxes” (and with correlative meanings, “Tax” and “Taxable”) means all taxes of any kind imposed by a federal, state, local or foreign governmental authority, including, but not limited to, those on, or measured by or referred to as, income, gross receipts, financial operation, sales, use, ad valorem, value added, franchise, profits, license, withholding, payroll (including all contributions or premiums pursuant to industry or governmental social security laws or pursuant to other laws and regulations), employment, excise, severance, stamp, occupation, premium, property, transfer or windfall profits taxes, customs, duties or similar fees, assessments or charges of any kind whatsoever, together with any interest, surcharges and penalties, additions to tax or additional amounts imposed by such governmental authority with respect to such amounts.
- 1.65 “Third Party” means any Person other than the Parties or any of their respective Affiliates.
- 1.66 “Threshold Amount” has the meaning set forth in Section 8.3(a) below.
- 1.67 “Trade Secrets” means information solely regarding the Lithobid Products, including technical and non-technical data, a formula, pattern, compilation, program device, method, technique, process or other information similar to any of the foregoing, that (i) derives economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other Persons who can derive economic value from its disclosure or use and (ii) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.
- 1.68 “Transfer Letter” has the meaning set forth in Section 2.3(a)(iii).

SECTION 2 THE SALE

2.1 Sale and Purchase: Assumption of Certain Liabilities.

(a) At the Closing, the Seller is selling, conveying, assigning, transferring, and, to the extent set forth in this Agreement, delivering to the Buyer, and the Buyer is purchasing and assuming from the Seller, all of the Seller’s right, title and interest in and to the following assets (collectively, the “Purchased Assets”):

- (i) the Books and Records;

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- (ii) the Inventory, except for the Finished Lithobid Product Inventory;
- (iii) the Product Approvals (to be effectuated as set forth in Section 2.4(b)); and
- (iv) all the Intellectual Property Rights, including, without limitation, the Lithobid Marks and worldwide web addresses and domain names listed on Schedule 2.1(a)(iv).

(b) Notwithstanding any other provision of this Agreement, the Purchased Assets do not include, and the Seller shall retain all rights, title and interest in and to, all assets, properties and rights of the Seller and its Affiliates, including all finished Lithobid Product Inventory bearing Seller's NDC code (" Finished Lithobid Product Inventory"), other than those assets specifically enumerated as Purchased Assets in Section 2.1(a) (collectively, the " Excluded Assets "). Without limiting the generality of the foregoing, the Parties agree and acknowledge that the Purchased Assets shall not include any property, plant or equipment, accounts receivable, cash, employees, or credit or refund of Taxes attributable to any period of time prior to the Closing Date. Buyer acknowledges and agrees that Seller may retain a copy of all or part of the documentation that it delivers to Buyer hereunder.

(c) At the Closing, as further consideration for the Purchased Assets, the Buyer shall only assume and agree to pay, perform and discharge (i) all Liabilities and obligations arising out of the conduct of the Business and/or the operation and/or use of the Purchased Assets by Buyer following the Closing, (ii) all product liability, product warranty and other Liabilities and obligations arising out of or relating to the manufacture, distribution and/or sale of any Lithobid Products sold using Buyer's NDC after the Closing Date or the use thereof; (iii) all regulatory responsibilities relating to the Lithobid Products arising after the Closing Date; (iv) notwithstanding any provision of this Agreement to the contrary, all Liabilities (including for product liability, breach of warranty or any other action or claim) for which Buyer, ANIP Acquisition or any of their respective Affiliates has Liability or in the future would have Liability pursuant to the Supply Agreement, including relating to voluntary and involuntary recalls and market withdrawals of the Lithobid Product); and (v) any Liabilities relating to any clinical study or any data associated therewith which arise from and after the Closing Date, if such clinical study was required or requested by any Regulatory Authority after the Closing Date (collectively, the " Assumed Liabilities ").

(d) All Liabilities of the Seller other than the Assumed Liabilities (the " Retained Liabilities ") shall be retained by and shall remain the sole responsibility of the Seller and its Affiliates, as applicable.

2.2 Consideration; Allocation of Consideration

(a) As consideration for the Purchased Assets, at the Closing, the Buyer is paying to Seller, the Closing Payment by wire transfer of readily available US dollars to an account specified by Seller in writing.

(b) In the event that on or prior to June 30, 2015 the FDA informs Buyer that the FDA Review has been completed and the proposed Supplement accepted without any additional requirement that Buyer conduct any further clinical trial in order to qualify or permit the requested change to the Lithobid Products specified in the Supplement, then, no later than ten (10) Business Days following the Buyer's receipt of the approval thereof from the FDA, the Buyer will make an additional payment to Seller of One Million Dollars (\$1,000,000), by wire transfer of immediately available funds (the " Additional Payment "). However, in the event that in connection with the FDA Review the FDA informs Buyer that any such further clinical trial is required or otherwise fails to approve the proposed Supplement on or prior to June 30, 2015, then no Additional Payment shall be made by Buyer to Seller hereunder. Each Party shall use (after Reasonable Commercial Efforts by Buyer to obtain such approval) Reasonable Commercial Efforts to obtain approval of the Supplement. The aggregate of the Closing Payment plus any Additional Payment and the Assumed Liabilities is referred to herein as the " Consideration ".

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(c) The Consideration shall be allocated in accordance with Schedule 2.2 (the “Allocation Schedule”). Each of the Parties agrees to (i) prepare and timely file all Tax Returns, in respect of all affected taxable periods (or portions thereof), in a manner consistent with the Allocation Schedule, and (ii) act in accordance with the Allocation Schedule for all Tax purposes, unless otherwise required by Law. Any unresolved disputes regarding the Allocation Schedule, including any amendments thereto, shall be promptly submitted to a jointly-retained third party accounting firm for determination, which shall be final and binding on the Parties. The cost and expenses of such third party accounting firm shall be borne equally by the Buyer and Seller.

(d) Any Taxes in the nature of a sales, transfer or use Tax payable on the sale or transfer of all or any portion of the Purchased Assets or the consummation of any other transaction contemplated hereby (but specifically excluding any income tax liabilities) shall be borne equally by the Seller and Buyer. The Buyer shall not be entitled to deduct and/or withhold from the Consideration otherwise payable to Seller pursuant to this Agreement under any provision of federal, state, local or foreign Tax Law.

2.3 Closing. The closing (the “Closing”) of the Sale is taking place on the Closing Date, concurrently with the execution and delivery of this Agreement at the offices of Dentons US, LLP, located at 1221 Avenue of the Americas, New York, NY 10020. The effective time of the Closing shall be 12:01 am, Eastern Daylight Time on the Closing Date. The parties hereby agree that the Closing may take place by delivery of the documents to be delivered at the Closing by facsimile or other electronic transmission. All deliveries by one party to another party at Closing shall be deemed to have occurred simultaneously and none shall be effective until and unless all have occurred. At the Closing:

(a) The Seller shall deliver to the Buyer counterparts of the following documents, duly executed by the Seller (collectively referred to herein as the “Ancillary Agreements”):

(i) a Bill of Sale and Assignment and Assumption Agreement effecting the transfer of the Purchased Assets and the assignment and assumption of the Assumed Liabilities, in the form and substance of Exhibits A and B, respectively, hereto, executed by the Seller;

(ii) an assignment of the Lithobid Marks, in the form and substance of Exhibit C, executed by the Seller;

(iii) a letter of transfer from Seller to the FDA in the form of Exhibit E (the “Transfer Letter”);

(iv) a letter from Seller confirming that the Supply Agreement is terminated except for Section 2.9, Article III, Article V, Article VI, Article VII, Article VIII, Article XII and Article XIII (other than Section 13.9), in the form of Exhibit F (the “Supply Agreement Termination Letter”); and

(v) such other documents, instruments and certificates as the Seller and Buyer reasonably agree are necessary to effect the transactions herein described.

(b) The Buyer shall deliver to the Seller:

(i) the aggregate sum of Eleven Million Dollars (\$11,000,000) (the “Closing Payment”) by wire transfer of immediately available funds in accordance with Section 2.2(a);

(ii) counterparts of each of the Ancillary Agreements, duly executed by the Buyer as applicable;

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(iii) a letter from Buyer to the FDA notifying it of Buyer's acceptance of the transfer of the NDA referred to in the Transfer Letter in the form of Exhibit G (" Buyer's Acceptance Letter "); and

(iv) the Supply Agreement Termination Letter duly executed by ANIP Acquisition.

2.4 Transfer of Purchased Assets; Cooperation.

(a) On or as promptly as practicable after the Closing Date, the Seller shall (i) transfer (or implement arrangements reasonably satisfactory to Buyer for the transfer and delivery of physical possession of) all tangible assets included in the Purchased Assets to the Buyer or its designated representatives, and (ii) upon request of the Buyer, notify all of its agents that hold files or other tangible material included in the Purchased Assets that, effective as of the Closing, the Buyer owns such Purchased Assets, with directions to transfer such Purchased Assets to Buyer in accordance with the Buyer's instructions. Buyer shall pay for any costs or expenses associated with taking possession of the Purchased Assets. Notwithstanding the foregoing, to the extent not delivered at Closing, Seller shall deliver all of the non-electronic Books and Records related to the Product Approvals to Buyer no later than August 1, 2014, and on or before July 15, 2014, except as otherwise provided in Section 5.12(c). Seller shall provide to Buyer (1) all of the electronic Books and Records related to the Product Approvals, to the extent not previously delivered and (2) all case files since April 27, 2014, including readable .pdf copies of PADER listings and completed FDA form 3500As and source documents.

(b) Following the Closing, Seller shall file with the FDA all of the documents and the information required of a former owner, including, but not limited to, the Transfer Letter and Buyer shall file with the FDA the information required of a new owner or agent in respect thereof in the form of the Buyer's Acceptance Letter, in each case, at each Party's own expense. Seller may retain an archival copy of each Product Approval, including supplements and records that are required to be kept under 21 CFR §314.81.

(c) Notwithstanding anything to the contrary contained in this Agreement, if the sale, assignment, transfer, conveyance or delivery or attempted sale, assignment, transfer, conveyance or delivery to the Buyer of any asset that would be a Purchased Asset is (i) prohibited by any applicable Law or (ii) would require any authorization, approval, consent or waiver from a Third Party or Regulatory Authority and such authorization, approval, consent or waiver shall not have been obtained prior to the Closing, then nothing contained herein or in any Ancillary Agreement shall constitute or effect the sale, assignment, transfer, conveyance or delivery of any such asset. In such event, following the Closing, the Parties shall use their Reasonable Commercial Efforts, and cooperate with each other in good faith, to obtain promptly such authorization, approval, consent or waiver; provided, however, that the Buyer shall not be required to pay any consideration or fee or otherwise incur any expense (all such consideration, fees and expenses to be borne exclusively by the Seller) to obtain any such authorization, approval, consent or waiver. Pending such authorization, approval, consent or waiver, the Parties shall cooperate with each other in good faith in any reasonable and lawful arrangements that will provide to the Buyer the benefits of use of such asset, including any indemnities, that, in each case, it would have obtained had the asset been conveyed to the Buyer at the Closing. If authorization, approval, consent or waiver for the sale, assignment, transfer, conveyance or delivery of any such asset not sold, assigned, transferred, conveyed or delivered at the Closing is obtained, the Seller shall assign, transfer, convey and deliver such asset to the Buyer at no additional cost to the Buyer.

(d) Buyer shall be responsible for, and shall bear all costs associated with, completing the recordation of any trademark assignment for the Lithobid Marks with the appropriate Regulatory Authorities in each country in which the Lithobid Marks are registered; provided that Seller shall, for a period of three (3) years after the Closing, upon the reasonable request of Buyer, cooperate with Buyer to execute any additional documentation required to record and give effect to the assignment of the Lithobid Marks in any jurisdiction in accordance with this Agreement.

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SECTION 3 REPRESENTATIONS AND WARRANTIES OF THE SELLER

Except as otherwise disclosed to Buyer in the correspondingly numbered section of the disclosure schedules delivered to Buyer by the Seller on the date hereof, the Seller hereby represents and warrants to the Buyer as follows:

3.1 Organization. Seller is duly organized, validly existing and in good standing under the laws of Delaware.

3.2 Power and Authorization. The execution and delivery by the Seller of this Agreement and each Ancillary Agreement, and the performance of the Seller's obligations hereunder and thereunder and the consummation of the Sale are within the power and authority of the Seller and have been duly authorized by all necessary action on the part of the Seller. Each of this Agreement and each Ancillary Agreement (a) has been duly executed and delivered by a duly authorized representative of the Seller and (b) is a legal, valid and binding obligation of the Seller, enforceable against the Seller in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally.

3.3 Authorization of Governmental Authorities. Except for actions and filings disclosed on Schedule 3.3 and for the Transfer Letter and Buyer's Acceptance Letter (and FDA's acceptance thereof to the extent required), no action by or in respect of, or filing with, any Regulatory Authority is required by the Seller for, or in connection with, the valid and lawful (i) authorization, execution and delivery by the Seller of this Agreement and each Ancillary Agreement or (ii) the consummation of the Sale by the Seller.

3.4 Noncontravention.

(a) Except as disclosed on Schedule 3.4(a), the execution, delivery and performance by the Seller of this Agreement and the Ancillary Agreements do not (i) violate any Law or any decree or judgment of any court or other Regulatory Authority applicable to the Seller, the Business or any of the Purchased Assets; (ii) violate or conflict with, result in a breach of, constitute a default (or an event which, with or without notice or lapse of time or both, would constitute a default) under, permit cancellation of, or result in the creation of any encumbrance (other than Permitted Encumbrances) upon any of the Purchased Assets under, any contract to which the Seller is a party or by which it is bound (subject to Seller's obtaining the consents set forth on Schedule 3.4(b)); or (iii) violate or conflict with any provision of the Certificate of Incorporation or By-laws of the Seller.

(b) Except as set forth on Schedule 3.4(b) and for the Transfer Letter and Buyer's Acceptance Letter (and FDA's acceptance thereof to the extent required), no consents or approvals of, or filings or registrations by the Seller with any Regulatory Authority or any other Third Party are necessary in connection with the execution, delivery and performance of this Agreement or the Ancillary Agreements by the Seller.

3.5 Encumbrances. Except as disclosed on Schedule 3.5 and except for Permitted Encumbrances and/or Encumbrances created by or at the express direction of Buyer, there are no encumbrances on any of the Purchased Assets.

3.6 Purchased Assets. At Closing, the Seller shall convey to the Buyer good and marketable title to and/or an enforceable right to use, all of the Purchased Assets, subject to Encumbrances created by or at the express direction of Buyer.

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3.7 Intellectual Property.

(a) The current use by the Seller of the Intellectual Property Rights in the formulation, manufacture, packaging, promotion, distribution, marketing, and sale of the Lithobid Products does not interfere with, infringe upon, misappropriate, or otherwise conflict with any intellectual property rights of any Third Party. The Seller has not received any written charge, complaint, claim, demand, or notice since June 1, 2011 alleging any interference, infringement, misappropriation, or violation (including any claim that the Seller or any of its Affiliates must license or refrain from using any of the Intellectual Property Rights). To the Knowledge of the Seller, no Third Party (i) currently interferes or has since June 1, 2011 interfered with, (ii) currently infringes or has since June 1, 2011 infringed upon, or (iii) has since June 1, 2011 misappropriated any of the Intellectual Property Rights.

(b) Schedule 3.7(b) identifies all current and unexpired trademark and patent registrations that have been issued to the Seller or its predecessors that solely relate to the Lithobid Products. Each item identified in Schedule 3.7(b) is valid, subsisting and in full force and effect, and the Seller has taken all reasonable steps necessary to maintain such registrations, including the payment when due of all registration and maintenance fees and annuities and the filing of all necessary renewals, statements and certifications, and all necessary material documents and certificates in connection with such registered Intellectual Property Rights have been filed with the relevant patent, copyright or other governmental or Regulatory Authorities for the purposes of maintaining such registered Intellectual Property Rights.

(c) Section 3.6 (solely with respect to Product Approvals that constitute Intellectual Property Rights) and this Section 3.7 represent the sole and exclusive representations and warranties of the Seller regarding Intellectual Property Rights and no other representation and/or warranty in this Agreement shall apply to any Intellectual Property Rights.

3.8 Legal Compliance.

(a) Except as disclosed on Schedule 3.8(a), since June 1, 2009, the Seller has conducted its operations as they pertain to the Business in compliance, in all material respects, with all applicable Laws.

(b) Except as set forth on Schedule 3.8(b), the Seller has not received any written notice of a material violation of any applicable Law from any Regulatory Authority relating to the Purchased Assets or Business, including the promotion, distribution, marketing, and sale of the Lithobid Products since June 1, 2011.

(c) Except as set forth on Schedule 3.8(c), with respect to the Business, including the promotion, distribution, marketing, and sale of the Lithobid Products, the Seller has not received in writing since June 1, 2011, any warning letters or other correspondence from the FDA or any other Regulatory Authority in which the FDA or such other Regulatory Authority asserted that the promotion, distribution, marketing, or use and sale of any Lithobid Product was not in compliance with applicable Law. Except as disclosed on Schedule 3.8(b), with respect to the promotion, distribution, marketing, and sale of the Lithobid Products, there has not been, since June 1, 2011, any product recall, market withdrawal or replacement, or post-sale warning conducted by or on behalf of the Seller concerning the Lithobid Products or, to the Knowledge of the Seller, any product recall, market withdrawal or replacement conducted by or on behalf of any Third Party as a result of any alleged defect in the Lithobid Products.

(d) Seller has provided to Buyer readable .pdf copies of all PADERs or PADER listings from 2004 through April 27, 2014 and Medwatch forms for all expedited cases from 2009 through April 27, 2014. Since April 27, 2011, each PADER and annual report relating to the Lithobid Products was timely filed by the Seller with the FDA.

3.9 Litigation. Except as disclosed on Schedule 3.9, there is no lawsuit relating to the Purchased Assets of which Seller has Knowledge, or to the Knowledge of the Seller, threatened which would reasonably be expected to have a Material Adverse Effect on the Business. There is no lawsuit pending, or to the Knowledge of the Seller, threatened, which in any manner challenges or seeks the rescission of, or seeks to prevent, enjoin, alter or materially delay the consummation of, or otherwise relates to, this Agreement or the Sale. The Seller is not the plaintiff in and currently does not intend to initiate any lawsuit involving the Purchased Assets.

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3.10 Ordinary Course. As of June 30, 2014, the Finished Lithobid Product Inventory at the Company's three largest wholesalers in the aggregate is not more than 1600 units. Schedule 3.10 sets forth a summary, by week, of the shipments of Lithobid Products sold by or on behalf of the Seller to customers from April 1, 2014 through June 29, 2014.

3.11 AMP. Schedule 3.11 sets forth the baseline Average Manufacturers Price ("AMP") for the Lithobid Products as of March 31, 2014. As of the Closing Date, Seller has delivered to Buyer any and all Books and Records relating to the calculation of baseline AMP received by Seller from Solvay when Seller acquired the rights to Lithobid from Solvay (which for purposes of clarity excludes any proprietary methodology documents created by Seller or any of Seller's Affiliates with respect to the calculation of baseline AMP).

3.12 No Brokers. The Seller has no liability of any kind to, and is not subject to any claim of, any broker, finder or agent in connection with the Sale other than those which will be borne by the Seller.

3.13 Solvency. Immediately after giving effect to the Closing and the transactions contemplated by this Agreement, the Seller and each of its subsidiaries will be able to pay their respective debts as they become due and shall own property which has a fair saleable value greater than the amounts required to pay their respective debts (including a reasonable estimate of the amount of all contingent liabilities). Immediately after giving effect to the transactions contemplated by this Agreement, the Seller and each of its subsidiaries shall have adequate capital to carry on their respective businesses. No transfer of property is being made and no obligation is being incurred in connection with the transactions contemplated by this Agreement with the intent to hinder, delay or defraud either present or future creditors of the Seller or its subsidiaries.

3.14 No Other Representations or Warranties; Schedules.

(a) EXCEPT FOR THE REPRESENTATIONS AND WARRANTIES EXPRESSLY SET FORTH IN SECTION 3, THE SELLER DISCLAIMS ALL LIABILITY AND RESPONSIBILITY FOR ANY REPRESENTATION, WARRANTY, STATEMENT MADE OR INFORMATION COMMUNICATED (WHETHER ORALLY OR IN WRITING) TO BUYER, ITS AFFILIATES AND REPRESENTATIVES (INCLUDING ANY OPINION, INFORMATION OR ADVICE WHICH MAY HAVE BEEN PROVIDED TO BUYER, ITS AFFILIATES OR REPRESENTATIVES BY ANY DIRECTOR, OFFICER, EMPLOYEE, ACCOUNTING FIRM, LEGAL COUNSEL, OR OTHER AGENT, CONSULTANT, OR REPRESENTATIVE OF THE SELLER). ANY AND ALL STATEMENTS MADE OR INFORMATION COMMUNICATED BY THE SELLER OR ANY OF ITS REPRESENTATIVES OUTSIDE OF THIS AGREEMENT (INCLUDING BY WAY OF THE DOCUMENTS PROVIDED IN RESPONSE TO BUYER'S WRITTEN DILIGENCE REQUESTS AND ANY MANAGEMENT PRESENTATIONS PROVIDED), WHETHER VERBALLY OR IN WRITING, ARE DEEMED TO HAVE BEEN SUPERSEDED BY THIS AGREEMENT, IT BEING INTENDED THAT NO SUCH PRIOR OR CONTEMPORANEOUS STATEMENTS OR COMMUNICATIONS OUTSIDE OF THIS AGREEMENT, OR ANY WARRANTY OF MERCHANTABILITY OR WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, SHALL SURVIVE THE EXECUTION AND DELIVERY OF THIS AGREEMENT.

SECTION 4 REPRESENTATIONS AND WARRANTIES OF THE BUYER

The Buyer hereby represents and warrants to the Seller as of the date of this Agreement, as follows:

4.1 Organization. The Buyer is duly organized, validly existing and in good standing under the laws of Delaware.

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4.2 Power and Authorization. The execution, delivery and performance by the Buyer of this Agreement and each Ancillary Agreement and the consummation of the Sale are within the power and authority of the Buyer and have been duly authorized by all necessary action on the part of the Buyer. Each of this Agreement and each Ancillary Agreement (a) has been duly executed and delivered by a duly authorized representative of the Buyer and (b) is a legal, valid and binding obligation of the Buyer, enforceable against the Buyer in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws now or hereafter in effect relating to or affecting creditors' rights generally.

4.3 Authorization of Governmental Authorities. No action by or in respect of, or filing with, any governmental authority is required by the Buyer for, or in connection with, the valid and lawful (a) authorization, execution, delivery and performance by the Buyer of this Agreement and each Ancillary Agreement or (b) the consummation of the Sale by the Buyer.

4.4 No Brokers. The Buyer has no liability of any kind to, and is not subject to any claim of, any broker, finder or agent with respect to the Sale for which the Buyer will be liable.

4.5 Noncontravention.

(a) The execution, delivery and performance by the Buyer of this Agreement and the Ancillary Agreements to which the Buyer is a party do not and will not (i) violate any Law or any decree or judgment of any court or other Regulatory Authority applicable to the Buyer; (ii) violate or conflict with, result in a breach of, constitute a default (or an event which, with or without notice or lapse of time or both, would constitute a default) under, or permit cancellation of, any contract, agreement or obligation to which the Buyer is a party or by which it is bound; or (iii) violate or conflict with any provision of the Certificate of Incorporation or Bylaws of the Buyer.

(b) Except for any that have heretofore been obtained or made, no material consents or approvals of, or filings or registrations by the Buyer with, any Regulatory Authority or any other Third Party are necessary in connection with the execution, delivery and performance of this Agreement or the Ancillary Agreements by the Buyer.

4.6 Financial Capability. The Buyer has sufficient funds or credit resources to pay the Consideration and to perform and consummate the transactions contemplated by this Agreement, on the terms and subject to the conditions set forth herein.

4.7 Solvency. Immediately after giving effect to the Closing and the transactions contemplated by this Agreement, the Buyer and each of its subsidiaries will be able to pay their respective debts as they become due and shall own property which has a fair saleable value greater than the amounts required to pay their respective debts (including a reasonable estimate of the amount of all contingent liabilities). Immediately after giving effect to the transactions contemplated by this Agreement, the Buyer and each of its subsidiaries shall have adequate capital to carry on their respective businesses. No transfer of property is being made and no obligation is being incurred in connection with the transactions contemplated by this Agreement with the intent to hinder, delay or defraud either present or future creditors of the Buyer or its subsidiaries.

SECTION 5 COVENANTS AND AGREEMENTS

5.1 Expenses. Except to the extent otherwise expressly set forth in this Agreement, the Seller and the Buyer shall each bear their respective expenses incurred in connection with the preparation, execution and performance of this Agreement, including, without limitation, all fees and expenses of agents, representatives, counsel and accountants.

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5.2 Payment and Discharge of Liabilities. The Seller shall pay or otherwise satisfy in the ordinary course of business and as and when due, whether before or after the Closing Date, all of the Retained Liabilities in accordance with the terms thereof and in a manner consistent with their past practices in relation to the Business. The Buyer shall pay or otherwise satisfy in the ordinary course of business and as and when due, after the Closing Date, all of the Assumed Liabilities.

5.3 Further Assurances. Each Party shall exercise its Reasonable Commercial Efforts to execute such documents, further instruments of transfer and assignment and other papers and take such further actions as may be reasonably required to carry out the provisions hereof and the transactions contemplated hereby and by the Ancillary Agreements in accordance with the terms hereof and thereof.

5.4 Public Announcements. Exhibit D sets forth Seller's form of press release regarding the terms of this Agreement and the transactions set forth herein, and, except as set forth in Section 9, none of the Parties or their respective Affiliates or their respective directors, officers, employees and agents shall issue any press release or otherwise make any public statement in deviation or contravention of the contents of such press release without the approval of Buyer, in the case of any disclosure by Seller, or Seller in the case of a disclosure by Buyer.

5.5 Customer Notifications. As promptly as practicable after the Closing Date, the Buyer and Seller shall send the joint letter attached hereto as Exhibit H to all wholesale distributors, pharmacies and other customers of the Seller listed on Schedule 5.5.

5.6 NDC Numbers. Buyer has established new National Drug Code ("NDC") numbers for the Lithobid Products. The Buyer shall apply such new NDC numbers to all Lithobid Products manufactured or sold on or after the Closing Date.

5.7 Access After Closing.

(a) Following the Closing, for so long as such information is retained by the Buyer, the Buyer shall permit the Seller and its authorized representatives to have reasonable access to, and to make photocopies of, the Books and Records transferred to the Buyer that relate to the Purchased Assets with respect to the period prior to Closing, to the extent that such access may be required in connection with (i) the preparation of any accounting records or Tax returns or any audit involving the Lithobid Products or the Purchased Assets, (ii) any suit, claim, action, proceeding or investigation relating to the Purchased Assets, (iii) any regulatory filing or matter, or (iv) in connection with any other valid legal or business purpose of the Seller or its Affiliates. Such access shall be afforded during normal business hours and upon reasonable prior written notice from the Seller. The Buyer shall retain all Books and Records of the nature described above for a period of six (6) years following the Closing Date unless the Buyer gives the Seller notice of its intention to destroy any such records and affords the Seller a reasonable opportunity to take possession or make copies of any such records proposed to be destroyed.

(b) Subject to Section 2.4(c), following the Closing, for so long as such information is retained by the Seller, the Seller shall permit the Buyer and its authorized representatives to have reasonable access to, and to make photocopies of, the Books and Records retained by the Seller that relate to the Purchased Assets with respect to the period prior to Closing, to the extent that such access may be required in connection with (i) the preparation of any accounting records or Tax returns or any audit involving the Lithobid Products or the Purchased Assets, (ii) any suit, claim, action, proceeding or investigation relating to the Purchased Assets, (iii) any regulatory filing or matter or (iv) in connection with any other valid legal or business purpose of the Buyer or its Affiliates. Such access shall be afforded during normal business hours and upon reasonable prior written notice from the Buyer. The Seller shall retain all Books and Records of the nature described above for a period of six (6) years following the Closing Date unless the Seller gives the Buyer notice of its intention to destroy any such records and affords the Buyer a reasonable opportunity to take possession or make copies of any such records proposed to be destroyed.

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5.8 Inventory. Immediately following Closing, Seller and Buyer shall jointly notify Cardinal SPS in writing of the consummation of the Sale and Seller shall instruct Cardinal SPS to destroy the Finished Lithobid Product Inventory held by Cardinal SPS, and Buyer shall destroy any Finished Lithobid Product Inventory in its possession. Buyer shall pay or promptly reimburse Seller for any costs or expenses associated with Cardinal SPS's and/or Buyer's destruction of the Finished Lithobid Product Inventory. All accounts receivable and other amounts owed to Buyer or ANIP Acquisition or their respective Affiliates with respect to Inventory shall be deemed paid and satisfied in full by Seller. Buyer and Seller each agrees that in no event following the Closing Date will Buyer or Seller sell any Lithobid Products which are labeled with the Seller's name. Not in any way limiting any provision of this Agreement, Seller shall have no obligation to reimburse Buyer or ANIP Acquisition or their respective Affiliates for any Methylene Chloride purchased by Buyer or ANIP Acquisition or their respective Affiliates pursuant to the terms of the Supply Agreement or otherwise. Immediately following the Closing, Seller shall terminate its sample program with J. Knipper and Company and shall promptly cause any Finished Lithobid Product Inventory in the possession of J. Knipper and Company to be destroyed, at the sole cost and expense of Seller.

5.9 Regulatory Matters.

(a) Responsibility for the Lithobid Products. From and after the Closing Date, except as otherwise required by Law, the Buyer shall be solely responsible for all regulatory responsibilities under applicable Law, with respect to reporting and otherwise, in connection with the Lithobid Products, including (i) all regulatory responsibility with respect to the formulation, manufacture, packaging, promotion, distribution, marketing, use and sale of Lithobid Products; (ii) adverse drug experience reporting relating to the Lithobid Products, and (iii) NDAs with respect to the Lithobid Products (it being understood and agreed that nothing in this clause (a) shall in anyway be deemed to limit any right to indemnification Buyer and/or Seller may have under Section 8).

(b) Communications with Regulatory Agencies. From and after the Closing Date, the Buyer shall have responsibility for all communication with the FDA with respect to the matters relating to the formulation, manufacture, packaging, promotion, distribution, marketing, use and sale of the Lithobid Products including without limitation, with respect to the Supplement and any clinical trials required following the FDA Review. To the extent any such communication relates to the Supplement, Buyer shall consult with Seller regarding the content of such communication and shall provide Seller with a copy of any material correspondence received from the FDA.

(c) Fee Obligations. From and after the Closing Date, Buyer shall assume all responsibility for any and all fee obligations for holders or owners of approved INDs, NDAs and Regulatory Approvals relating to the Lithobid Products after the Closing Date, including those defined under the Prescription Drug User Fee Act of 1992, as the same may be amended from time to time (it being understood and agreed that nothing in this clause (c) shall in anyway be deemed to limit any right to indemnification Buyer and/or Seller may have under Section 8).

5.10 Reporting of and Response to Adverse Drug Experience Reports, Medical Inquiries and Product Complaints. From and after the Closing Date, Buyer shall be responsible for responding to all adverse drug experience reports, complaints and medical inquiries with respect to the Lithobid Products in accordance with applicable Law and the Buyer's customary internal procedures for responding to such reports, complaints and inquiries. These adverse drug experience reports and Lithobid Product complaints and medical inquiries may arise from any sources such as (but not limited to) direct telephone calls, the filing of lawsuits, or written correspondence to either Party. Following the Closing, the Seller shall refer all reports of adverse drug experience and Lithobid Product complaints and medical inquiries that it receives to the Buyer within five (5) days after receipt thereof. As used herein, "adverse drug experience" shall have the meaning set forth in 21 CFR 314.80.

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5.11 Rebates; Returns.

(a) Each Party shall be responsible, at its own cost and expense, for the processing, payment, administration and support of any rebates, credits or allowances or other expenses for which it has contractual or other liability to any third party, regardless of when incurred, which relate to or arise out of sales of the Lithobid Product under its own NDC number.

(b) As of the Closing, each Party shall be operationally responsible for processing, acceptance and exchange/refund with respect to the return of all Lithobid Products bearing its NDC in accordance with its standard return terms and conditions. Financial responsibility for returns shall be as follows: (i) Buyer shall be financially responsible for returns related to Lithobid Product sold bearing its NDC number and (ii) Seller shall be financially responsible for returns related to Lithobid Products sold on or prior to the Closing Date under its NDC number. If any quantities of Lithobid Products are returned after the Closing Date to a Party that are properly allocated to the other Party as set forth above, the receiving Party shall inform the other Party as soon as practicable and, (1) if the Seller has received the return, Seller shall deliver to Buyer (at Buyer's expense if such return is allocated to Buyer) or destroy, at Buyer's election, such returned Lithobid Product, or (2) if the Buyer has received the return and if such return is allocated to the Seller, Buyer shall destroy or return, at Seller's election and expense, such returned Lithobid Product. Seller shall direct any requests to exchange returned Lithobid Product to Buyer for handling.

5.12 Post-Closing Cooperation. Following the Closing, the Parties agree to use Reasonable Commercial Efforts to transition the Business to the Buyer. In this regard:

(a) Seller shall send a copy of the Transfer Letter to the FDA immediately following the Closing, and Buyer will send a copy of Buyer's Acceptance Letter to the FDA immediately following the Closing;

(b) Seller and Buyer shall cooperate to effect a transfer of the pharmacovigilance relating to the Lithobid Products on the Closing Date and in this regard, Seller agrees to forward all customer inquiries, ADEs and customer questions received by it in respect of the Lithobid Products to the call center of Buyer previously identified to Seller;

(c) Seller and Buyer shall cooperate to effect the transfer, at Buyer's expense, of a copy of the Seller's safety database with respect to the Lithobid Products to Buyer (i.e., JDS files) no later than September 30, 2014; provided that such materials shall be provided in exclusively electronic form except for documents related to the pre-2004 period that are solely available in paper form;

(d) Seller shall promptly remove the Lithobid Products from the DailyMed website following the expiration of the last to expire lot of Lithobid Products sold by Seller under Seller's NDC code; and

(e) Seller shall provide Buyer with reasonable assistance with preparing any FDA sufficiency response, including with respect to any additional information which is in the possession of Seller and requested by the FDA in connection with the Supplement. Buyer shall draft any responses to deficiencies the FDA identifies with respect to the Supplement, and Seller shall use Reasonable Commercial Efforts to provide Buyer with information it needs to prepare and file with the FDA the regulatory filings required to be filed by Buyer for the manufacture, marketing and distribution of the Lithobid Products, including, without limitation, the applicable PADER and NDA annual report for 2015 (with applicable domestic distribution data). Each Party shall pay their own expenses incurred in connection with obtaining acceptance by the FDA of the Supplement; however, any third party costs, fees and/or other expenses associated with obtaining acceptance by the FDA of the Supplement shall be paid by Buyer.

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5.13 Buyer's Due Diligence Investigation.

(a) Buyer acknowledges and agrees that, for the purposes of this Agreement, none of the Seller, its Affiliates or representatives has made any representations or warranties regarding the Seller, the Business, the Purchased Assets or otherwise in connection with the transactions set forth herein or in the Ancillary Agreements, on which it relied other than the representations and warranties expressly made by the Seller in Section 3. Without limiting the generality of the foregoing, Buyer acknowledges and agrees that no projections, forecasts and predictions, other estimates, data, financial information, documents, reports, statements (oral or written), summaries, abstracts, descriptions, presentations (including any management presentation or facility tour), memoranda, or offering materials with respect to the Business or the Purchased Assets, is or shall be deemed to be a representation or warranty by the Seller or any of its Affiliates to Buyer, under this Agreement, or otherwise, and that Buyer has not relied thereon in determining to execute this Agreement and proceed with the transaction set forth herein. Buyer further acknowledges and agrees that to the extent materials it has received from the Seller and its agents and representatives include projections, forecasts and predictions relating to the Purchased Assets and the Business; that there are uncertainties inherent in attempting to make such projections, forecasts and predictions; that Buyer is familiar with such uncertainties and is taking full responsibility for making its own evaluation of the adequacy and accuracy of all projections, forecasts, predictions and information so furnished; that Buyer shall not have any claims against the Seller, its officers, directors, Affiliates or representatives, with respect thereto; and that Buyer has not relied thereon. Buyer acknowledges that no Person has been authorized by the Seller to make any representation or warranty regarding the Seller, the Business, the Purchased Assets, or the transactions set forth in this Agreement and in the Ancillary Agreements and, if made, such representation or warranty may not be relied upon as having been authorized by the Seller.

(b) Buyer acknowledges and agrees that it (i) has made its own inquiry and investigation into, and, based thereon and on the representations and warranties set forth in Section 3 and has formed an independent judgment concerning, the Purchased Assets and the Business, and (ii) has conducted such investigations of the Purchased Assets and the Business as Buyer deems necessary to satisfy itself as to the operations and conditions thereof, and will rely solely on such investigations and inquiries, and the express representations and warranties of the Seller set forth in Section 3. Buyer further acknowledges and agrees that it will not at any time assert any claim against the Seller or any of its present and former directors, officers, managers, partners, shareholders, employees, agents, Affiliates, consultants, investment bankers, attorneys, advisors or representatives, or attempt to hold any of such Persons liable, for any inaccuracies, misstatements or omissions with respect to the information furnished by such Persons concerning the Purchased Assets and/or the Business, other than any inaccuracies or misstatements in the representations and warranties expressly set forth in Section 3 (subject to the limitations and expiration set forth in Section 8).

(c) Further, without limiting any representation, warranty or covenant of the Seller expressly set forth herein, Buyer acknowledges that it has waived and hereby waives any further due diligence reviews, inspections or examinations with respect to the Seller, the Purchased Assets and the Business, including with respect to financial, operational, regulatory and legal compliance matters.

SECTION 6 INTENTIONALLY OMITTED

SECTION 7 INTENTIONALLY OMITTED

SECTION 8 INDEMNIFICATION

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8.1 Indemnification by the Seller. Subject to the limitations set forth in this Section 8, the Seller will indemnify and hold harmless the Buyer, its Affiliates and the Buyer's and its Affiliates' respective employees, officers, directors and representatives (each, a "Buyer Indemnified Party"), from, against and in respect of any and all actions, liabilities, governmental orders, encumbrances, losses, damages, bonds, dues, assessments, fines, penalties, Taxes, fees, costs, expenses (including reasonable legal fees, costs and/or expenses incurred in defending a Third Party claim) or amounts paid in settlement (which, except in respect of reasonable legal fees, costs and/or expenses incurred in defending a Third Party claim, shall be subject to the terms of Section 10.1(e)) (collectively, "Losses"), incurred or suffered by the Buyer Indemnified Parties or any of them as a result of, arising out of, or directly or indirectly relating to: (a) any breach of, or inaccuracy in, any representation or warranty made by the Seller in Section 3 of this Agreement; (b) any breach, nonperformance, or violation of any covenant or agreement of the Seller (including, without limitation, under this Section 8) contained in this Agreement or any Ancillary Agreement, or (c) any Retained Liability.

8.2 Indemnification by the Buyer. The Buyer will indemnify and hold harmless the Seller, its Affiliates and the Seller's and its Affiliates' respective employees, officers, directors and representatives (each, a "Seller Indemnified Party"), from, against and in respect of any and all Losses incurred or suffered by the Seller Indemnified Parties or any of them as a result of, arising out of, or directly or indirectly relating to: (a) any breach of, or inaccuracy in, any representation or warranty made by the Buyer in Section 4 of this Agreement; (b) any Assumed Liability asserted against any Seller Indemnified Party; or (c) any breach, nonperformance, or violation of any covenant or agreement of the Buyer (including, without limitation, under this Section 8) contained in this Agreement or any Ancillary Agreement.

8.3 Limits.

(a) The Buyer Indemnified Parties shall not be entitled to any indemnification in respect of Losses incurred by the Buyer Indemnified Parties pursuant to Section 8.1(a) for breaches of non-Fundamental Representations unless and until the aggregate amount of such Losses exceeds \$ [***] (the "Threshold Amount"), in which event if the aggregate amount of Losses exceeds the Threshold Amount, the Buyer Indemnified Parties may only recover the amount of such Losses in excess of the Threshold Amount. The maximum aggregate amount required to be paid by Seller to the Buyer Indemnified Parties pursuant to Section 8.1(a) for breaches of non-Fundamental Representations shall not exceed \$ [***] (the "Cap"). Not in any way limiting the provisions of this Section 8.3, the Seller will not have any obligation to indemnify the Buyer Indemnified Parties pursuant to this Section 8 to the extent that the aggregate amount of all such Losses incurred or suffered by such Indemnified Parties exceeds the Consideration paid by the Buyer. Notwithstanding the foregoing, the Threshold Amount and Cap shall not apply to Losses arising out of or resulting from actual (and not constructive) fraud committed by the Seller against the Buyer.

(b) Except as provided in this Section 8, nothing in this Agreement or any Ancillary Agreement shall impair, limit or otherwise affect any indemnification obligation of either Party to the other Party arising under any other agreement, including the Supply Agreement, between the Parties and any of their Affiliates. In this regard, it is understood and agreed that if any Losses for which Buyer would otherwise be entitled to indemnification under Section 8.1 are finally determined to have been caused by any occurrence for which Seller is otherwise entitled to indemnification under the Supply Agreement or any other act or omission by Buyer, ANIP Acquisition or any of their respective Affiliates, Seller shall have no obligation to indemnify Buyer to the extent thereof, and Buyer and its Affiliates shall indemnify Seller to the extent Seller is entitled to indemnification under the Supply Agreement and/or this Agreement.

(c) Buyer shall use Reasonable Commercial Efforts to avoid or mitigate any Loss which it or any Buyer Indemnified Party may suffer in consequence of any fact, matter or circumstance giving rise to a claim for indemnification under this Agreement or likely to give rise to a claim for indemnification under this Agreement.

(d) Where the Seller has made a payment to a Buyer Indemnified Party in relation to any claim and Buyer Indemnified Party is entitled to recover (whether by insurance, payment, discount, credit, relief or otherwise) from a Third Party a sum which indemnifies or compensates Buyer Indemnified Parties (in whole or in part) in respect of the Liability or Loss which is the subject of a claim, Buyer or its relevant Affiliates shall (i) promptly notify the Seller of the fact and provide such information as the Seller may reasonably require, (ii) take all Reasonable Commercial Efforts as the Seller may require to enforce such right and (iii) pay to the Seller, as soon as practicable after receipt, an amount equal to the amount recovered from the Third Party (net of taxation and less any reasonable costs of recovery).

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8.4 Time for Claims. No claim may be made or suit instituted seeking indemnification pursuant to this Section 8 unless a written notice describing the basis for such claim or suit in reasonable detail in light of the circumstances then known to the Indemnified Party is provided to the Indemnifying Party:

(a) at any time prior to the expiration of the applicable statute of limitations, in the case of any claim or suit based upon a breach or inaccuracy of the representations and warranties set forth in the first sentence and clause (a) of the second sentence of Section 3.2 (Power and Authorization), Section 3.6 (Purchased Assets), Section 3.12 (No Brokers), Section 4.2 (Power and Authorization) or Section 4.4 (No Brokers) (the “Fundamental Representations”);

(b) at any time, and without limitation as to time, for any claim arising from the Retained Liabilities, Assumed Liabilities or any covenant to be performed by either Party at or after the Closing (including with respect to the Additional Payment); or

(c) at any time prior to the twelve (12) month anniversary of the Closing Date, in the case of any claim or suit based upon a breach or inaccuracy of the non-Fundamental Representations.

(d) The representations and warranties made by the Parties under this Agreement shall survive the Closing for a period contemporaneous with the period during which the applicable Party may assert a claim in respect of a breach thereof, as set forth above in this Section 8.4.

8.5 Procedure. If any claim arises as to which a right of indemnification provided in this Section 8 may apply, the Indemnified Party shall promptly provide a written notice to the Indemnifying Party for its claims for indemnification, and, to the extent applicable, shall allow the Indemnifying Party and its insurers the opportunity to assume direction and control of the defense of such proceeding, at its sole expense, subject to the limitations set forth in this Section 8, including the settlement thereof at the sole option of the Indemnifying Party or its insurers; provided, however, that the Indemnifying Party may not enter into any compromise or settlement without the prior written consent of the Indemnified Party, which will not be unreasonably delayed, conditioned or withheld, unless such compromise or settlement is solely for monetary damages paid entirely by the Indemnifying Party and does not include any admission of legal wrongdoing on the part of the Indemnified Party and contains an unconditional release of the Indemnified Party, in which event no such consent shall be required. The Indemnified Party shall fully cooperate with the Indemnifying Party and its insurer in the disposition of any such matter and the Indemnified Party will have the right and option to participate in (but not control) the defense of any proceeding as to which this Section 8 applies, with separate counsel at its election and cost. If the Indemnifying Party fails to assume or declines to assume the defense of any such proceeding within fifteen (15) days after notice thereof, or fails to prosecute the defense of such claim in good faith and with reasonable diligence, or, in the opinion of counsel to the Indemnified Party there is a conflict of interest between the Indemnifying Party and the Indemnified Party, the Indemnified Party may assume the defense thereof for the account and at the risk of the Indemnifying Party (including with respect to reasonable attorney’s fees in connection therewith, but subject to the limitations set forth in this Section 8). The Indemnifying Party shall pay promptly to the Indemnified Party any Losses to which the Indemnified Party is entitled under this Section 8.

8.6 Exclusive Remedy; Release. The Parties (and, by their acceptance of the benefits under this Agreement, each Buyer Indemnified Party and Seller Indemnified Party) hereby agree that except as otherwise contemplated in Section 9.5, their sole and exclusive remedy after the Closing with respect to any and all claims relating to this Agreement and the Sale shall be pursuant to the indemnification provisions set forth in this Section 8. Notwithstanding the foregoing, this Section 8.6 shall not, and is in no way intended to, restrict any Party’s (a) rights or obligations under any Ancillary Agreement or (b) right to seek a temporary or permanent injunction and/or a decree for specific performance with respect to a breach or threatened breach of a covenant or agreement contained in this Agreement. Each of the Parties agrees that, to the fullest extent permitted by applicable Law, except to the extent of a breach of an express representation or warranty set forth in this Agreement in which case, the other Party may seek recourse subject to and in accordance with this Section 8 only against the other Party, the respective directors, officers, employees, affiliates, controlling persons, agents and representatives of the other Party shall not have any personal liability or responsibility whatsoever to the claiming Party or any of its directors, officers, employees, Affiliates, controlling persons, agents or representatives on any basis (including in contract or tort, under federal or state securities laws or otherwise) based upon any information provided or made available, or statements made (or any omissions therefrom), to the claiming Party or any of its directors, officers, employees, Affiliates, controlling persons, agents or representatives and each Party hereby releases the other Party and its Affiliates’ respective directors, officers, employees, affiliates, controlling persons, agents and representatives from any such liability or responsibility.

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8.7 Limits on Indemnification.

(a) In calculating amounts payable to an Indemnified Party, the amount of the Losses (i) shall not be duplicative of any other Loss for which an indemnification claim has been made, and (ii) shall be computed net of any amounts actually recovered by such Indemnified Party under any insurance policy with respect to such Loss, net of any reasonable out-of-pocket expenses actually incurred in collecting such amounts. The Indemnified Party will use Reasonable Commercial Efforts to collect any amounts available under such insurance coverage.

(b) Neither Party shall have any right to set off any Losses against any payments to be made by it or any of its Affiliates pursuant to this Agreement or any Ancillary Agreement.

(c) In any case where an Indemnified Party recovers from Third Parties any amount in respect of a matter with respect to which an Indemnifying Party has indemnified it pursuant to this Section 8, such Indemnified Party shall promptly pay over to the Indemnifying Party the amount so recovered (after deducting therefrom the full amount of the expenses incurred by it in procuring such recovery), but not in excess of the sum of (i) any amount previously so paid by the Indemnifying Party to or on behalf of the Indemnified Party in respect of such matter and (ii) any amount expended by the Indemnifying Party in pursuing or defending any claim arising out of such matter.

8.8 Treatment of Indemnification Payment by Seller. Any indemnification payment made by Seller hereunder shall be treated as a reduction of the Consideration for Tax purposes.

8.9 Consequential Damages. NOTWITHSTANDING ANYTHING TO THE CONTRARY CONTAINED HEREIN, NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY FOR SPECIAL, CONSEQUENTIAL, INDIRECT OR INCIDENTAL (INCLUDING WITHOUT LIMITATION LOST PROFITS), PUNITIVE OR ANY MEASURE OF DAMAGES BASED ON DIMINUTION OF VALUE OR ANY MULTIPLE OF EARNINGS, EBITDA, CASH FLOW OR SIMILAR CONCEPT UNDER THIS AGREEMENT EXCEPT TO THE EXTENT SUCH DAMAGES SHALL BE PAYABLE TO A THIRD PARTY.

SECTION 9 CONFIDENTIALITY

9.1 General. Pursuant to the terms of this Agreement, the Seller and the Buyer (in such capacity, the “Disclosing Party”) have each disclosed and will be disclosing to the other Party, and to its Affiliates and to their respective officers, directors, employees, agents and/or representatives (in such capacity, the “Receiving Party”) certain secret, confidential or proprietary data, Trade Secrets, Know-How, intellectual property, Product Technology and related information, including, without limitation, operating methods and procedures, marketing, manufacturing, distribution and sales methods and systems, sales figures, pricing policies and price lists and other business information (“Confidential Information”). For purposes of the preceding definition, Confidential Information included in the Purchased Assets shall be deemed Confidential Information of the Buyer from and after the Closing. The Receiving Party shall make no use of any Confidential Information of the Disclosing Party except in the exercise of its rights and the performance of its obligations set forth in this Agreement or the Ancillary Agreements. The Receiving Party (i) shall keep and hold as confidential, and shall cause its officers, directors, employees, agents and representatives to keep and hold as confidential, all Confidential Information of the Disclosing Party, and (ii) shall not disclose, and shall cause its officers, directors, employees, agents and representatives not to disclose, any Confidential Information of the Disclosing Party. Confidential Information disclosed by the Disclosing Party shall remain the sole and absolute property of the Disclosing Party, subject to the rights granted in this Agreement or the Ancillary Agreements.

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9.2 Exceptions. The above restrictions on the use and disclosure of Confidential Information shall not apply to any information which (i) is already known to the Receiving Party at the time of disclosure by the Disclosing Party (other than Confidential Information which forms a part of the Purchased Assets), as demonstrated by competent proof (other than as a result of prior disclosure under any agreement between the Parties with respect to confidentiality) or (ii) is or becomes generally available to the public other than through any act or omission of the Receiving Party in breach of this Agreement or the Ancillary Agreements. In addition, nothing in this Section 9 shall be interpreted to limit the ability of either Party to use or disclose its own Confidential Information in any manner or to any other Person.

9.3 Permitted Disclosures. It shall not be a breach of Section 9.1 if a Receiving Party discloses Confidential Information of a Disclosing Party (including any terms of this Agreement) (i) pursuant to a binding requirement of applicable Law or a Regulatory Authority, including obligations under securities Laws or rules or regulations of any securities exchange or market on which the Disclosing Party's or its Affiliates' stock is traded, or (ii) in a judicial, administrative or other legal proceeding to enforce or defend such Party's rights under this Agreement. In such event, the Receiving Party shall (A) provide the Disclosing Party with as much advance written notice as possible and as legally permissible of the required disclosure, (B) reasonably cooperate with the Disclosing Party in any attempt to prevent or limit the disclosure at the sole cost of the Disclosing Party, and (C) limit disclosure, if any, to the specific purpose at issue, or in the case of a disclosure under subsection (i) of this Section 9.3, to the extent required by such Law or Regulatory Authority. Without limiting the generality of the foregoing, if Buyer determines that it is required to file this Agreement as a material agreement under applicable securities laws, it shall use Reasonable Commercial Efforts to seek to incorporate the reasonable confidential treatment requests of Seller with respect to such disclosure, it being understood and agreed that neither the names of the Lithobid Products nor the Consideration paid will be the subject of any such confidential treatment request.

9.4 Confidential Terms. Each Party acknowledges and agrees that the terms and conditions of this Agreement shall be considered Confidential Information of each Party and shall be treated accordingly.

9.5 Equitable Remedies. Each Party specifically recognizes that any breach by it of this Section 9 may cause irreparable injury to the other Parties and that actual damages may be difficult to ascertain, and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each Party agrees that in the event of any such breach, notwithstanding the provisions of Section 8.6, the other Parties shall be entitled to seek, by way of private litigation in the first instance, injunctive relief and such other legal and equitable remedies as may be available.

SECTION 10 DISPUTE RESOLUTION

10.1 Jurisdiction; Venue; Service of Process.

(a) Each party, by its execution hereof, (a) hereby irrevocably attorns and submits to the exclusive jurisdiction of the state and federal courts of New York located in New York City, New York, for the purpose of any action between or among the parties (or any of them) arising in whole or in part under or in connection with this Agreement, (b) hereby waives and agrees not to assert, by way of motion, as a defense or otherwise, in any such action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such action brought in one of the above-named courts should be dismissed on grounds of forum non conveniens, should be transferred or removed to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court and (c) hereby agrees not to commence any such action (including for a declaratory judgment or the like) other than before one of the above-named courts.

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(b) Each party agrees that for any action between the parties arising in whole or in part under or in connection with this Agreement, such party will bring actions only in the State of New York, in a state or federal court located in New York City, New York. Each party further waives any claim and will not assert that venue should properly lie in any other location within the selected jurisdiction.

(c) Each party hereby (a) consents to service of process in any action between the parties arising in whole or in part under or in connection with this Agreement in any manner permitted by the Laws of the State of New York, (b) agrees that service of process made in accordance with clause (a) or made by registered or certified mail, return receipt requested, at its address specified pursuant to Section 11.1, will constitute good and valid service of process in any such action and (c) waives and agrees not to assert (by way of motion, as a defense, or otherwise) in any such action any claim that service of process made in accordance with clause (a) or (b) does not constitute good and valid service of process.

(d) THE PARTIES HEREBY WAIVE, AND COVENANT THAT THEY WILL NOT ASSERT (WHETHER AS PLAINTIFF, DEFENDANT OR OTHERWISE), ANY RIGHT TO TRIAL BY JURY IN ANY ACTION ARISING IN WHOLE OR IN PART UNDER OR IN CONNECTION WITH THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREIN, WHETHER NOW EXISTING OR HEREAFTER ARISING, AND WHETHER SOUNDING IN CONTRACT, TORT OR OTHERWISE. THE PARTIES AGREE THAT ANY OF THEM MAY FILE A COPY OF THIS PARAGRAPH WITH ANY COURT AS WRITTEN EVIDENCE OF THE KNOWING, VOLUNTARY AND BARGAINED-FOR AGREEMENT AMONG THE PARTIES IRREVOCABLY TO WAIVE THEIR RIGHTS TO TRIAL BY JURY IN ANY ACTION WHATSOEVER BETWEEN OR AMONG THEM RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREIN, WHICH ACTION WILL INSTEAD BE TRIED IN A COURT OF COMPETENT JURISDICTION BY A JUDGE SITTING WITHOUT A JURY.

(e) In the event of litigation between the Parties arising from or regarding this Agreement, each Party shall bear its own costs and expenses incurred in connection with the litigation.

SECTION 11 MISCELLANEOUS

11.1 Notices. Any notice or other communication required or permitted hereunder shall be in writing and shall be deemed given when so delivered in person, by reputable overnight courier, by facsimile transmission (with receipt confirmed by automatic transmission report) or two (2) Business Days after being sent by registered or certified mail (postage prepaid, return receipt requested), as follows:

if to the Seller, to:

c/o Noven Pharmaceuticals
350 Fifth Avenue, 37th Floor
New York, NY 10118
Attn: General Counsel
Facsimile: 305-232-1836

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with a copy to:

Greenberg Traurig, P.A.
333 S.E. 2nd Avenue
Miami, Florida 33131
Attn: David A. Barkus, Esq.
Facsimile: (305) 961-5724

if to the Buyer, to:

ANI Pharmaceuticals, Inc.
210 Main Street Baudette, Minnesota 56623
Attn: Chief Executive Officer
Facsimile: 218-634-3540

with a copy to:

Dentons US LLP
1221 Avenue of the Americas
New York, NY 10020
Attn: Paul A Gajer, Esq.
Facsimile: 212-768-6800

Either Party may by notice given in accordance with this Section 11.1 to the other Parties designate another address or Person for receipt of notices hereunder.

11.2 Amendment; Waiver. This Agreement may not be amended except by an instrument signed by each of the Parties hereto. Any Party hereto may (a) extend the time for the performance of any of the obligations or other acts of another Party hereto or (b) waive compliance with any of the agreements of another Party or any conditions to its own obligations, in each case only to the extent such obligations, agreements, or conditions are intended for its benefit; provided, however, that any such extension or waiver shall be binding upon a Party only if such extension or waiver is set forth in a writing executed by such Party.

11.3 Entire Agreement. This Agreement and the Ancillary Agreements contain the entire agreement between the Parties with respect to the Sale and supersede all prior agreements, written or oral, between the Parties with respect thereto, including that certain Letter of Intent between the Seller and the Buyer, dated May 1, 2014, which is hereby deemed terminated and of no further force and effect, and, except for Section 2.9, Article III, Article V, Article VI, Article VII, Article VIII, Article XII and Article XIII (other than Section 13.9) of the Supply Agreement, the Supply Agreement (including all purchase orders thereunder) shall automatically terminate effective as of the Closing, and the Quality Assurance Agreement, dated July 1, 2008, shall automatically terminate effective as of the Closing.

11.4 Governing Law. This Agreement shall be governed by and construed exclusively in accordance with the internal laws of the State of New York.

11.5 Binding Effect; No Assignment; No Third-Party Beneficiaries.

(a) This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Neither the Seller nor the Buyer may assign any of its rights or delegate any of its liabilities or obligations hereunder without the prior written consent of the other; provided, that either Party may assign its rights and obligations under this Agreement without the other Party's prior written consent upon written notice to the other Party in connection with the transfer or sale of all or substantially all of the assets or business of such Party or any of its Affiliates or the merger or consolidation with another Person of such Party or any of its Affiliates; provided that no assignment or delegation hereunder shall limit or effect the assignor's obligations hereunder; and, provided further, that the Buyer may provide its lenders with a security interest in its rights under this Agreement in accordance with the terms of their security and collateral agreements in connection with any credit facility provided by such lenders to the Buyer and that such lenders may foreclose upon such security interest in accordance with the terms of such security and collateral agreements.

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Commission Pursuant to a Request for Confidential Treatment under Rule 406 under the
Securities Act of 1933, as amended. Confidential Portions are marked: [***]**

(b) Nothing in this Agreement, express or implied, is intended to or shall confer upon any Person other than the Parties and their respective successors and permitted assigns any right, benefit or remedy of any nature whatsoever under or by reason of this Agreement.

11.6 Section Headings; Construction; Interpretation. The headings of Sections in this Agreement are provided for convenience only and will not affect its construction or interpretation. All references to “Section” or “Sections” refer to the corresponding Section or Sections of this Agreement. All schedules and exhibits attached to this Agreement constitute an integral part of this Agreement and are incorporated herein. Unless the context of this Agreement clearly requires otherwise, (a) the singular shall include the plural and the plural shall include the singular wherever and as often as may be appropriate; (b) the masculine shall include the feminine and the feminine shall include the masculine wherever or as often as may be appropriate; (c) the words “include” and “including” shall mean “including without limitation”, and (d) the words “hereof,” “herein,” “hereunder,” and similar terms in this Agreement shall refer to this Agreement as a whole and not any particular Section or article in which such words appear.

11.7 Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, and all of which together shall constitute one and the same instrument.

11.8 Severability. If any provision of this Agreement is held invalid or unenforceable in any legal proceeding held pursuant to Section 10, the other provisions of this Agreement shall remain in full force and effect. Any provision of this Agreement held invalid or unenforceable only in part or degree will remain in full force and effect to the extent not held invalid or unenforceable. The Parties further agree to replace such invalid or unenforceable provision of this Agreement with a valid and enforceable provision that will achieve, to the extent possible, the economic, business and other purposes of such invalid or unenforceable provision.

11.9 Rules of Construction. The Parties hereto agree that they have been represented by counsel during the negotiation and execution of this Agreement and, therefore, waive the application of any law, regulation, holding or ruling of construction providing that ambiguities in an agreement or other document will be construed against the Party drafting such agreement or document.

11.10 Bulk Sales Laws. The Parties hereto waive compliance with the requirements of the applicable Bulk Sales Laws in connection with the consummation of the transactions contemplated hereby.

11.11 Independent Contractor. Neither the Seller nor the Buyer, together in each case with their respective employees or representatives, are under any circumstances to be considered as employees, agents, representatives, partners or joint venturers of the other by virtue of this Agreement, and neither shall have the authority or power to bind the other or contract in the other’s name.

11.12 No Implied Waivers. No failure on the part of the Seller or the Buyer to exercise and no delay in exercising any right, power, remedy or privilege under this Agreement, or provided by statute or at law or in equity or otherwise, including the right or power to terminate this Agreement, shall impair, prejudice or constitute a waiver of any such right, power, remedy or privilege or be construed as a waiver of any breach of this Agreement or as an acquiescence therein, nor shall any single or partial exercise of any such right, power, remedy or privilege preclude any other or further exercise thereof or the exercise of any other right, power, remedy or privilege.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the date first stated above.

NOVEN THERAPEUTICS, LLC

By: /s/ Jeffrey Eisenberg

Name: Jeffrey Eisenberg

Title: Authorized Representative

ANI PHARMACEUTICALS, INC.

By: /s/ Charlotte C. Arnold

Name: Charlotte C. Arnold

Title: Vice President & Chief Financial Officer

[Signature Page to Asset Purchase Agreement]

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Execution Version

ASSET PURCHASE AGREEMENT

dated as of

August 1, 2014

among

ANI PHARMACEUTICALS, INC.

and

SHIRE VIROPHARMA INCORPORATED

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EXHIBIT A: Form of Assignment and Assumption Agreement
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ASSET PURCHASE AGREEMENT

ASSET PURCHASE AGREEMENT (this “**Agreement**”) dated as of August 1, 2014 between ANI Pharmaceuticals, Inc., a Delaware corporation (“**Buyer**”), and Shire ViroPharma Incorporated, a Delaware corporation (the “**Seller**”).

WITNESSETH:

WHEREAS, Seller and its Subsidiaries hold the rights to manufacture, market, sell and distribute Vancocin® (the “**Product**”), an antibiotic containing vancomycin hydrochloride as the only active ingredient, for use in the treatment of both enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains) and *Clostridium difficile* -associated diarrhea or CDAD, in the oral capsule formulation in the Territory (the “**Business**”), as well as certain inactive Product Approvals (as defined below); and

WHEREAS, Buyer desires to purchase the Purchased Assets (as hereinafter defined) from Seller and assume the Assumed Liabilities (as hereinafter defined), and Seller desires to sell the Purchased Assets to Buyer, upon the terms and subject to the conditions hereinafter set forth.

NOW, THEREFORE, the parties hereto agree as follows:

ARTICLE 1 DEFINITIONS

Section 1.01. *Definitions.* (a) As used herein, the following terms have the following meanings:

“**Affiliate**” means, with respect to any Person, any other Person directly or indirectly controlling, controlled by or under common control with such other Person. For purposes of this definition, “control” when used with respect to any Person means the power to direct or cause the direction of the management and policies of such Person, directly or indirectly, whether through the ownership of voting securities, by contract or otherwise, and the terms “controlling” and “controlled” have correlative meanings.

“**Applicable Law**” means, with respect to any Person, any federal, state or local law (statutory, common or otherwise), rule, regulation, order, injunction, judgment, decree or ruling enacted, adopted, promulgated or applied by a Governmental Authority that is binding upon or applicable to such Person, as amended unless expressly specified otherwise.

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“ **Business Day** ” means a day, other than Saturday, Sunday or other day on which commercial banks in New York, New York are authorized or required by Applicable Law to close.

“ **Cardinal Health** ” has the meaning given to such term in the Exclusive Distribution Agreement included in the Excluded Contracts, dated as of January 14, 2005, between Seller and Cardinal Health PTS, LLC.

“ **Closing Date** ” means the date of the Closing.

“ **CMS** ” means Centers for Medicare & Medicaid Services.

“ **Excluded Contracts** ” means the Contracts set forth in Section 1.01(a)(1) of the Seller Disclosure Schedule.

“ **FDA Act** ” means the Food, Drug and Cosmetics Act of 1938.

“ **Distributor** ” means each of Cardinal Health, AmerisourceBergen Drug Corporation and McKesson Corporation.

“ **GAAP** ” means generally accepted accounting principles in the United States.

“ **Governmental Authority** ” means any transnational, domestic or foreign federal, state or local, governmental or regulatory authority, department, court, agency or official, including any political subdivision thereof.

“ **Intellectual Property Rights** ” means all: (i) trademarks, service marks, trade names, corporate names, logos, trade dress, slogans, Internet domain names and world wide web addresses, and all other source, origin or business identifiers, and all applications, registrations and renewals for, and goodwill associated with and symbolized by, any of the foregoing, whether registered or common law (collectively, “ **Marks** ”), (ii) patent disclosures, patent applications (filed and unfiled) and issued patents, and all registrations, continuations, continuations-in-part, divisionals, re-examinations, renewals, extensions, reissues and counterparts thereof, (iii) Trade Secrets, Know-How and other proprietary business information, (iv) works of authorship (whether or not copyrightable), moral rights, copyrights and registrations and applications therefor, and all renewals, extensions, restorations and reversions thereof, and (v) rights of publicity and privacy.

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“ **Know-How** ” means all proprietary methods, processes, techniques, compositions, information, data, results of tests, studies, statistical and other analyses and expertise, whether patented or unpatented, including pharmacology, toxicology, drug stability, manufacturing and formulation methodologies and techniques, clinical and non-clinical safety and efficacy studies, marketing studies and absorption, excretion and metabolism studies, quality control and quality assurance processes, and shall include all tangible manifestations thereof.

“ **knowledge of Seller** ,” “ **Seller’s knowledge** ” or any other similar knowledge qualification in this Agreement means to the actual knowledge as of the date hereof of the individuals specified in Section 1.01(a)(2) of the Seller Disclosure Schedule.

“ **Liability** ” means any debt, liability or obligation (whether direct or indirect, absolute or contingent, accrued or unaccrued, liquidated or unliquidated, known or unknown, or due or to become due), including any liability for Taxes, and including all costs and expenses relating thereto.

“ **Lien** ” means, with respect to any property or asset, any mortgage, lien, assessment, claim, title defect, pledge, charge, security interest or encumbrance in respect of such property or asset.

“ **NDC** ” means National Drug Code.

“ **NonFAMP Eligible Transactions** ” means those transactions relating to the Product that are used to calculate the Non-Federal Average Manufacturer Price as defined by Veteran’s Health Care Act of 1992.

“ **Packaging Materials** ” collectively means and includes any prescription information (including labeling and package inserts, indications and safety instructions), packaging (including any boxes or other containers) and similar materials relating to the packaging of the Product.

“ **Permitted Liens** ” means (i) Liens for Taxes, assessments or governmental charges or levies not yet due and payable, delinquent but payable without penalty or that are being contested in good faith and for which adequate reserves have been established in accordance with GAAP, (ii) Liens imposed by law, such as carriers’, warehousemen’s and mechanics’ Liens and other similar Liens arising or incurred in the ordinary course of business which secure payment of Liabilities not more than 30 days past due or which are being contested in good faith, (iii) any restrictions, limitations or conditions contained in the Contracts that are not the result of a breach thereof by Seller or any of its Affiliates, and (iv) the rights, if any, of third parties, appearing in product advertisements for the Product.

“ **Person** ” means an individual, corporation, partnership, limited liability company, association, trust or other entity or organization, including a Governmental Authority.

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“ **Pre-Closing Tax Period** ” means (i) any Tax period ending on or before the Closing Date and (ii) with respect to a Tax period that commences before but ends after the Closing Date, the portion of such period up to and including the Closing Date.

“ **Product Approvals** ” means with respect to the Product, the applicable New Drug Application and Abbreviated New Drug Applications set forth opposite the applicable Product formulation in Section 2.01(e) of the Seller Disclosure Schedule.

“ **Seller Disclosure Schedule** ” means the disclosure letter delivered by Seller to Buyer in connection with the execution and delivery of this Agreement.

“ **Subsidiary** ” means, with respect to any Person, any entity of which (i) securities or other ownership interests having ordinary voting power to elect a majority of the board of directors or other persons performing similar functions or (ii) 50% or more of the equity interests are at the time directly or indirectly owned by such Person.

“ **Tax** ” means any tax or other like assessment or charge of any kind whatsoever imposed by any Governmental Authority responsible for the imposition of any such tax (a “ **Taxing Authority** ”), together with any interest, penalty, addition to tax or additional amount, and any liability for any of the foregoing as a transferee or successor.

“ **Territory** ” means the United States and its territories.

“ **Trade Secrets** ” means Know-How that (i) derives economic value, actual or potential, as a result of being kept confidential, and not being readily ascertainable by third parties using proper means, and (ii) is the subject of efforts by its holder that are reasonable under the circumstances to maintain its confidentiality.

“ **Transaction Documents** ” means (i) this Agreement, (ii) the Assignment and Assumption Agreement, (iii) the assignment agreement transferring any Marks in accordance with Section 2.07(b)(i) and (iv) the Safety Data Transitional Agreement.

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(b) Each of the following terms is defined in the Section set forth opposite such term:

Term	Section
Agreed Allocation	2.08
Agreement	Preamble
AMP	3.11
Apportioned Obligations	6.02
Assignment and Assumption Agreement	2.07
Assumed Liabilities	2.03
Business	Recitals
Buyer	Preamble
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Seller	Preamble
Seller Fundamental Representations	7.01
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Shipped Products	2.04
Taxing Authority	1.01
Third Party Claim	7.03
Transfer Letter	2.07(d)
Transfer Taxes	6.02
Transferred Intellectual Property Rights	2.01
Transferred Product Registrations	2.01(e)
Transition Period	5.10(a)
Warranty Breach	7.02

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Section 1.02. *Other Definitional and Interpretative Provisions.* The words “hereof,” “herein” and “hereunder” and words of like import used in this Agreement shall refer to this Agreement as a whole and not to any particular provision of this Agreement. The captions herein are included for convenience of reference only and shall be ignored in the construction or interpretation hereof. References to Articles, Sections, Exhibits and Schedules are to Articles, Sections, Exhibits and Schedules of this Agreement unless otherwise specified. All Exhibits and Schedules annexed hereto or referred to herein are hereby incorporated in and made a part of this Agreement as if set forth in full herein. Any capitalized terms used in any Exhibit or Schedule but not otherwise defined therein shall have the meaning as defined in this Agreement. Any singular term in this Agreement shall be deemed to include the plural, and any plural term the singular. Whenever the words “include,” “includes” or “including” are used in this Agreement, they shall be deemed to be followed by the words “without limitation,” whether or not they are in fact followed by those words or words of like import. “Writing,” “written” and comparable terms refer to printing, typing and other means of reproducing words (including electronic media) in a visible form. References to any statute, rule or regulation shall be deemed to refer to such statute, rule or regulation as amended or supplemented from time to time, including through the promulgation of applicable rules or regulations. References to any agreement or contract are to that agreement or contract as amended, modified or supplemented from time to time in accordance with the terms hereof and thereof. References to any Person include the successors and permitted assigns of that Person. References from or through any date mean, unless otherwise specified, from and including or through and including, respectively. References to one gender include all genders.

ARTICLE 2
PURCHASE AND SALE

Section 2.01. *Purchase and Sale* . Except as otherwise provided below, upon the terms and subject to the conditions set forth in this Agreement, Buyer agrees to purchase from Seller, and Seller agrees to sell, convey, transfer, assign and deliver, or cause to be sold, conveyed, transferred, assigned and delivered, to Buyer at the Closing, free and clear of all Liens, other than Permitted Liens, all of Seller’s and each of its Subsidiaries’ right, title and interest in, to and under the following assets, as the same shall exist on the Closing Date (collectively, the “**Purchased Assets**”):

- (a) all Intellectual Property Rights that are owned by the Seller or any of its Subsidiaries and are exclusively used or held for use in the formulation, manufacture, packaging, promotion, distribution, marketing, and sale of the Product in the Territory, including those listed in Section 2.01(a) of the Seller Disclosure Schedule (the “**Transferred Intellectual Property Rights**”);

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(b) any Product inventory, Packaging Materials, active pharmaceutical ingredient, polyethylene glycol, work-in-process or finished goods to the extent held for use by or for the benefit of Seller or any of its Subsidiaries for the operation of the Business as currently conducted (the “ **Product Inventory and Supplies** ”);

(c) all of the personal property and equipment set forth in Section 2.01(c) of the Seller Disclosure Schedule;

(d) any and all regulatory files (including correspondence with regulatory authorities) owned by or in the possession or control of Seller or any of its Subsidiaries to the extent relating to the Purchased Assets or the operation of the Business (except for safety and adverse event data that shall be transferred in accordance with the Safety Data Transitional Agreement); *provided, however* , that the Seller and its Subsidiaries shall have the right to retain copies of any such regulatory files for their compliance records; *provided, further* , that with respect to any portions of such regulatory files that do not relate solely to the Purchased Assets or the Assumed Liabilities or are also required for the operation of the Excluded Assets or relate to the Excluded Liabilities, Seller may retain the originals of such regulatory files, and deliver, or cause to be delivered, copies thereof to Buyer and redact from any such regulatory files any information that is not related to the Purchased Assets or the Assumed Liabilities; and *provided, further* , (i) to the extent the delivery of any regulatory files is not reasonably practicable at the Closing, the Seller and its Subsidiaries will have up to 60 calendar days following the Closing to deliver such regulatory files to Buyer and (ii) Seller shall only have an obligation to deliver regulatory files that, to Seller’s knowledge, are in the possession or control of Seller;

(e) subject to Section 5.08, the registrations, applications, approvals, licenses and permits granted to Seller or its Subsidiaries by Governmental Authorities to develop and market the Product including the Product Approvals (the “ **Transferred Product Registrations** ”); *provided, however* , that Seller and its Affiliates shall have the right to retain copies for its compliance records of any such registrations, applications, approvals, licenses and permits;

(f) subject to Section 2.05 and except for the Excluded Contracts, all of the contracts and agreements listed in Schedule 2.01(f) of the Seller Disclosure Schedule (the “ **Contracts** ”);

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(g) all customer and sales information (including customer and supplier lists) and research data to the extent related to the Product and in the possession of Seller or any of its Subsidiaries; *provided, however*, that Seller and its Affiliates shall have the right to retain copies for its compliance records of any such information and data; *provided, further*, that with respect to any portions of such customer and sales information or research data that do not relate solely to the Purchased Assets or the Assumed Liabilities or are also required for the operation of the Excluded Assets or relate to the Excluded Liabilities, Seller may retain the originals of such information and data, and deliver, or cause to be delivered, copies thereof to Buyer and redact from any such information or data any information that is not related to the Purchased Assets or the Assumed Liabilities; and *provided, further*, (i) to the extent the delivery of any information or data is not reasonably practicable at the Closing, the Seller and its Subsidiaries will have up to 60 calendar days following the Closing to deliver such information or data to Buyer and (ii) Seller shall only have an obligation to deliver customer and sales information or research data that, to Seller's knowledge, are in the possession or control of Seller;

(h) subject to Section 2.02(c), copies of all books, records, files and papers, whether in hard copy or computer format, to the extent related to the Product (including with respect to research and development, medical safety or regulatory affairs), including (i) all documents, if any, relating to the calculation of baseline AMP (but excluding any proprietary methodology documents created by Seller or any of its Affiliates with respect to the calculation of baseline AMP) and (ii) an electronic version of the Vancocin Medical Information Inquiry Database; *provided* that Seller and its Affiliates shall have the right to retain the originals of any of the foregoing; *provided, further*, that with respect to any portions of such information and data that do not relate solely to the Purchased Assets or the Assumed Liabilities or are also required for the operation of the Excluded Assets or relate to the Excluded Liabilities, Seller may retain, the originals of the foregoing and deliver, or cause to be delivered, copies thereof to Buyer and redact from the copies of the foregoing provided to Buyer any information that is not related to the Purchased Assets or the Assumed Liabilities; and *provided, further*, (i) to the extent the delivery of the foregoing is not reasonably practicable at the Closing, the Seller and its Affiliates will have up to 60 calendar days following the Closing to deliver such copies to Buyer and (ii) Seller shall only have an obligation to deliver books, records, files and papers that, to Seller's knowledge, are in the possession or control of Seller;

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(i) subject to Section 2.02(c), copies of all books, records, files and papers, whether in hard copy or computer format, to the extent related to nonFAMP-Eligible Transactions from October 1, 2013 through the Closing Date; *provided* that Seller and its Affiliates shall have the right to retain the originals of any of the foregoing; *provided, further*, that with respect to any portions of such information and data that do not relate solely to the Purchased Assets or the Assumed Liabilities or are also required for the operation of the Excluded Assets or relate to the Excluded Liabilities, Seller may retain, the originals of the foregoing and deliver, or cause to be delivered, copies thereof to Buyer and redact from the copies of the foregoing provided to Buyer any information that is not related to the Purchased Assets or the Assumed Liabilities; and *provided, further*, (i) to the extent the delivery of the foregoing is not reasonably practicable at the Closing, the Seller and its Affiliates will have up to 60 calendar days following the Closing to deliver such copies to Buyer and (ii) Seller shall only have an obligation to deliver books, records, files and papers that, to Seller's knowledge, are in the possession or control of Seller; and

(j) all claims and contractual rights as against third parties held by or in favor of Seller or any of its Subsidiaries and relating exclusively to the Product.

Section 2.02. *Excluded Assets*. Nothing herein contained shall be deemed to sell, transfer, assign or convey the Excluded Assets to Buyer, and Seller and its Subsidiaries shall retain all right, title and interest to, in and under the Excluded Assets. The term “ **Excluded Assets** ” shall mean all assets, properties, interests and rights of Seller and any of its Affiliates other than the Purchased Assets, including the Excluded Contracts. For the avoidance of doubt, the Excluded Assets shall include (but are not limited to):

(a) all cash and cash equivalents on hand and in banks and investments held by Seller or any of its Affiliates;

(b) all other assets (including Intellectual Property Rights) owned by or licensed to Seller or its Affiliates, except for the Transferred Intellectual Property Rights;

(c) (i) all books, records, files and papers, whether in hard copy or computer format, (A) prepared in connection with this Agreement or any other Transaction Document or the transactions contemplated hereby or thereby, (B) prepared and maintained by any Seller or any of its Affiliates, including all regulatory files (including correspondence with regulatory authorities), market research data, and marketing data, to the extent such do not relate to the operation of the Business as currently conducted, (C) relating to employees of Seller or its Affiliates or (D) that are laboratory notebooks and (ii) all minute books and corporate records of Seller and its Affiliates;

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- (d) all materials, including any sales, promotional and marketing materials, advertising and display materials, Product literature, stationary, training materials in whatever medium (*e.g.* , audio, visual, print) and similar materials (other than Packaging Materials) relating to the marketing and promotion of the Product;
- (e) all accounts receivable, notes receivable or other indebtedness due and owing by any third party to Seller or any of its Affiliates, including any claims for refund of overpaid rebates for, and rebates from CMS relating to, Product shipped prior to the end of the Transition Period;
- (f) all rights of Seller or any of its Affiliates arising under this Agreement or any other Transaction Document or the transactions contemplated hereby or thereby;
- (g) all rights under the Seller's and their Affiliates' insurance policies or self-insurance that relate to the Business;
- (h) all accounting goodwill related to the Business; and
- (i) all privileged or confidential communications between Seller and any of its Affiliates and its and their respective attorneys, and any other privileged documents.

Section 2.03. *Assumed Liabilities* . (a) Upon the terms and subject to the conditions of this Agreement, Buyer agrees, effective from and after the Closing, to assume, pay, perform and discharge the following Liabilities of Seller and its Affiliates (the “ **Assumed Liabilities** ”):

- (i) all Liabilities arising under the Contracts (including Liabilities to customers under purchase orders made in the ordinary course of the sale and marketing of the Product consistent with past practice for any Product that has not been shipped prior to the Closing which shall be filled in accordance with Section 5.10), except for any Liabilities under a Contract arising from a breach of, or default under, such Contract by Seller or any of its Subsidiaries prior to the Closing;

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(ii) all Liabilities arising out of or relating to the return of, or rebates or chargebacks related to, any Product shipped after the end of the Transition Period; and

(iii) except to the extent that they constitute Excluded Liabilities, all other Liabilities arising out of or relating directly or indirectly to the Purchased Assets or the Business, or the ownership, sale or lease of any of the Purchased Assets, in each case only to the extent related to or arising out of any action, omission, occurrence or event on or after the Closing Date (including all Liabilities arising out of or relating to any product liability, breach of warranty or similar claim for injury to any Person or property that resulted from the use or misuse of the Product or otherwise related to the Product (including any action, suit, investigation or proceeding relating to any such Liabilities) shipped or sold after the Closing).

(b) Buyer and Seller hereby agree to reimburse one another, U.S. dollar for dollar, in the event that (i) any of Seller's or Buyer's customers, or their respective Affiliates' customers, offset against accounts payable by such customer to Seller or Buyer or their respective Affiliates, the cost of any Product returned by such customer, or (ii) Seller or Buyer or any of their respective Affiliates are required to issue a credit for the account of, or reimburse, any customer for returns, in each case which are the responsibility of the other party hereto pursuant to Section 2.03(a)(ii) and Section 2.04(a). Buyer and Seller hereby agree to, and to cause their respective Affiliates to, provide notice to one another of any such offset, issuance of credit or reimbursement for which such party or its Affiliate is entitled to be reimbursed pursuant to this Section 2.03(b). Payment shall be made promptly following receipt of notice of any such offset by or issuance of a credit to a customer (together with supporting documentation). Following the Closing, Buyer and Seller shall cooperate to ensure that a customer does not offset returns of any Product against both Seller (or any of its Affiliates) and Buyer (or any of its Affiliates).

(c) Buyer's obligations under this Section 2.03 shall not be subject to offset or reduction by reason of any actual or alleged breach of any representation, warranty or covenant contained in this Agreement or any document delivered in connection herewith or any right or alleged right to indemnification hereunder or thereunder.

Section 2.04. *Excluded Liabilities* . Notwithstanding any provision in this Agreement to the contrary, Buyer is assuming only the Assumed Liabilities and is not assuming any other Liability of Seller or any of its Affiliates of whatever nature, whether presently in existence or arising hereafter. All such other Liabilities shall be retained by and remain Liabilities of Seller or its Affiliates. The term "**Excluded Liabilities**" shall mean all Liabilities of Seller or any of its Affiliates other than the Assumed Liabilities. For the avoidance of doubt, the Excluded Liabilities shall include (but are not limited to):

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- (a) all Liabilities arising out of or relating to (i) the return of any Product bearing Seller's NDC (including Existing Inventory) shipped by Seller or its Subsidiaries to a third party prior to the end of the Transition Period (" **Shipped Products** ") or (ii) rebates or chargebacks related to any Shipped Products;
- (b) all Liabilities arising out of any action, suit, investigation or proceeding before any court or arbitrator or any other Governmental Authority to the extent arising out of actions, omissions or events occurring prior to the Closing Date relating to the Business or the Purchased Assets, including the matters set forth on Section 2.04(b) of the Seller Disclosure Schedule;
- (c) all Liabilities arising out of or relating to any product liability, breach of warranty or similar claim for injury to any Person or property that resulted from the use or misuse of the Product or otherwise related to the Product (including any action, suit, investigation or proceeding relating to any such Liabilities) shipped or sold before the Closing Date;
- (d) any Liability under Seller's or any of its Subsidiaries' employee benefits or compensation arrangements;
- (e) subject to Section 6.02(b) and Section 6.02(c), any and all Liabilities of Seller or any of its Subsidiaries for Taxes, including any Taxes arising as a result of the operation of the Business or the leasing, ownership, operation or use of the Purchased Assets prior to the Closing;
- (f) any Liability arising out of any Permitted Lien of the type set forth in clauses (i) and (ii) thereof; and
- (g) any Liability relating to an Excluded Asset.

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Section 2.05. *Assignment of Contracts and Rights* . Notwithstanding anything in this Agreement to the contrary, this Agreement shall not constitute an agreement to assign any Purchased Asset or any claim, right or benefit arising thereunder or resulting therefrom if an attempted assignment thereof, without the approval or consent of a third party, would constitute a breach thereof or in any way adversely affect the rights of Buyer or Seller or any of their respective Subsidiaries thereunder or be contrary to Applicable Law. Seller shall use its commercially reasonable efforts (which shall not require Seller to pay any money or other consideration to any Person or to initiate any claim or proceeding against any Person) (a) to obtain such approval or consent and (b) if such approval or consent cannot be obtained, to secure an arrangement reasonably satisfactory to Buyer ensuring that Buyer will receive the benefits under the Purchased Asset for which such consent is being sought and bear the burden of the Liabilities related to such Purchased Asset; *provided, however* , that (i) Seller shall have no obligation to obtain such consent or approval or to provide such an alternative arrangement other than the undertaking to use commercially reasonable efforts to obtain or provide the same as set forth in this Section 2.05, and (ii) Buyer shall have no remedy (including under Article 7) for failure of Seller to obtain any such consent or approval or to provide any such alternative arrangement (but, for the avoidance of doubt, Buyer may seek indemnification under Article 7 (subject to the limitations set forth therein) for a breach of Seller’s obligation to use commercially reasonable efforts as set forth in this Section 2.05). To the extent that, in connection with obtaining a third party’s consent under any Contract, one or more of the parties hereto enter into an agreement with such third party that provides for an allocation of Liability among the parties hereto with respect to such Contract that is inconsistent with the terms of this Agreement, the parties agree that, as among themselves, the provisions of this Agreement shall control.

Section 2.06. *Purchase Price* . The purchase price for the Purchased Assets (the “ **Purchase Price** ”) is \$11,000,000 in cash. The Purchase Price shall be paid as provided in Section 2.07 and allocated among the Purchased Assets as provided in Section 2.08.

Section 2.07. *Closing* . The closing (the “ **Closing** ”) of the purchase and sale of the Purchased Assets and the assumption of the Assumed Liabilities hereunder shall take place at 10:00 a.m. New York time at the offices of Dentons US LLP, 1221 Avenue of the Americas, New York, New York on the date hereof. At the Closing:

(a) Buyer shall deliver to Seller (or an Affiliate of Seller), on behalf of Seller and its Subsidiaries, the Purchase Price in immediately available funds by wire transfer to an account of Seller (or such Affiliate) designated by Seller, by notice to Buyer, not later than two Business Days prior to the Closing Date (and as promptly as practicable shall provide Seller a Fed reference number or *SWIFT* confirmation, as applicable);

(b) Seller and Buyer shall enter into (i) an Assignment and Assumption Agreement substantially in the form attached hereto as Exhibit A (the “ **Assignment and Assumption Agreement** ”) and an assignment agreement transferring any Marks set forth on Section 2.01(a) of the Seller Disclosure Schedule; and (ii) a Safety Data Transitional Agreement substantially in the form attached hereto as Exhibit B (the “ **Safety Data Transitional Agreement** ”);

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(c) (x) each party shall deliver or cause to be delivered to the other party such duly executed deeds, bills of sale, endorsements, consents, assignments and other good and sufficient instruments of conveyance and assignment as the parties and their respective counsel shall deem reasonably necessary to vest in Buyer all right, title and interest in, to and under the Purchased Assets and to evidence the assumption by Buyer of the Assumed Liabilities, in each case in accordance with the terms hereof and (y) Seller shall deliver or cause to be delivered to Buyer the FIRPTA certificate specified in Section 6.03;

(d) Seller shall deliver to Buyer a letter of transfer from Seller and its Affiliates to the FDA notifying it of the consummation of the purchase and sale hereunder substantially in the form of Exhibit C (the “**Transfer Letter**”); and

(e) Seller shall deliver to Buyer the sales data for the Product for the period from January 1, 2014 through June 30, 2014.

Section 2.08. *Purchase Price Allocation* . Seller and Buyer agree that, after Closing, they will negotiate in good faith to agree on a written allocation of the Purchase Price (increased to include, to the extent properly taken into account for Tax purposes, the Assumed Liabilities) among the Purchased Assets in accordance with Section 1060 of the Code (and any similar provision of state, local or foreign Tax law) (any such agreed allocation, the “**Agreed Allocation**”). Seller and Buyer agree to (i) be bound by any Agreed Allocation and (ii) act in accordance with any Agreed Allocation in the preparation, filing and audit of any Tax return (including filing IRS Form 8594), unless otherwise required by Applicable Law. Not later than 30 days prior to the filing of their respective IRS Forms 8594 relating to this transaction, each party shall deliver to the other party a copy of the IRS Form 8594 such party proposes to file.

Section 2.09. *Wrong Pocket Assets*. If at any time or from time to time after the Closing Date, Seller or any of its Affiliates, on the one hand, or Buyer or any of its Affiliates, on the other, shall receive or otherwise possess any asset (including cash) that should belong to Buyer, on the one hand, or Seller, on the other, pursuant to this Agreement, such Person shall promptly transfer, or cause to be transferred, such asset to the Person so entitled thereto. Prior to any such transfer in accordance with this Section 2.09, the Person receiving or possessing such asset shall hold such asset in trust for such other Person.

ARTICLE 3
REPRESENTATIONS AND WARRANTIES OF SELLER

Except as set forth in the Seller Disclosure Schedule, Seller represents and warrants to Buyer as of the date hereof that:

Section 3.01. *Existence and Power* . Seller is a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization and has all corporate power and all governmental licenses, authorizations, permits, consents and approvals required to carry on its business as now conducted, except for those licenses, authorizations, permits, consents and approvals the absence of which would not reasonably be expected to be material to the Business, the Purchased Assets and the Product, taken as a whole.

Section 3.02. *Authorization* . The execution, delivery and performance by Seller of this Agreement and each other Transaction Document, and the consummation of the transactions contemplated hereby and thereby, are within Seller's corporate powers and have been duly authorized by all necessary corporate action on the part of Seller. This Agreement constitutes, and upon the execution thereof each other Transaction Document shall constitute, a valid and binding agreement of Seller, enforceable against Seller in accordance with the terms hereof and thereof, subject to applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and other laws affecting creditors' rights generally and general principles of equity.

Section 3.03. *Governmental Authorization* . The execution, delivery and performance by Seller of this Agreement and each other Transaction Document, and the consummation of the transactions contemplated hereby and thereby, require no action by or in respect of, or filing with, any Governmental Authority other than (i) with respect to the transfer of the Product Approvals, the Transfer Letter and the related acceptance letter of Buyer to the FDA (and with respect to any other Transferred Product Registrations, similar letters), and (iii) any such action or filing as to which the failure to make or obtain would not reasonably be expected to be material to the Business, the Purchased Assets or the Product.

Section 3.04. *Noncontravention* . The execution, delivery and performance by Seller of this Agreement and each other Transaction Document, and the consummation of the transactions contemplated hereby and thereby, do not and will not (i) violate the certificate of incorporation, bylaws or comparable organizational documents of Seller or any of its Subsidiaries, (ii) assuming compliance with the matters referred to in Section 3.03, violate any Applicable Law, (iii) constitute a default under or give rise to any right of termination, cancellation or acceleration of any right or obligation or to a loss of any benefit relating to the Purchased Assets to which Seller or any of its Subsidiaries is entitled under any provision of any agreement or other instrument binding upon Seller or any of its Subsidiaries or (iv) result in the creation or imposition of any Lien on any Purchased Asset, except for Permitted Liens, with such exceptions, in the case of each of clauses (ii), (iii) and (iv), as would not reasonably be expected to be material to the Business, the Purchased Assets or the Product.

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Section 3.05. *Contracts* . (a) Except for the Contracts and the Excluded Contracts, neither Seller nor any of its Subsidiaries is a party to or bound by any contract, license, or agreement that is primarily used or held for use with respect to the Business or the Purchased Assets and that is material to the operation of the Business as currently conducted.

(b) None of the Contracts:

- (i) contain a covenant not to compete or other covenants that purport to limit or restrict the ability of Seller or any of its Subsidiaries to use the Purchased Assets or operate the Business;
- (ii) grant any option or preferential right to purchase any Purchased Asset (other than inventory in the ordinary course of business); or
- (iii) is for the benefit of any of Seller's Affiliates.

(c) Each Contract is a valid and binding agreement of Seller or its applicable Subsidiary and is in full force and effect, and none of Seller or its Subsidiaries or, to the knowledge of Seller, any other party thereto is in default or breach in any respect under the terms of any Contract, except for any such defaults or breaches that would not reasonably be expected to give rise to a right of cancellation of such Contract.

Section 3.06. *Litigation* . Except as set forth in Section 3.06 of the Seller Disclosure Schedule, there is no action, suit, investigation or proceeding pending against or, to the knowledge of Seller, threatened against, the Purchased Assets before any arbitrator or any Governmental Authority that would reasonably be expected to be material to the Business, the Purchased Assets and the Product, taken as a whole, or that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the transactions contemplated by this Agreement or the other Transaction Documents.

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Section 3.07. *Compliance with Laws* . (a) (i) Except as would not reasonably be expected to be material to the Business, the Purchased Assets or the Product, since January 24, 2014, and to the knowledge of Seller since January 1, 2012, Seller and each of its Subsidiaries have operated the Business in material compliance with all Applicable Law relating to the Business, including the FDA Act, (ii) all governmental licenses, permits, approvals and authorizations principally employed in, or necessary to the ongoing operation of the Business as currently conducted are in full force and effect and (iii) since January 24, 2014, and to the knowledge of Seller since January 1, 2012, no Governmental Authority has notified Seller or any of its Subsidiaries in writing that Seller or any of its Subsidiaries (with respect to the Product, the Purchased Assets or the operation of the Business) is in violation of any Applicable Law.

(b) Except as set forth in Section 3.07 of the Seller Disclosure Schedule, with respect to the Business, including the promotion, distribution, marketing, and sale of the Product, neither the Seller nor any of its Subsidiaries has received in writing since January 24, 2014, and to the knowledge of Seller since January 1, 2012, any warning letters or other correspondence from the FDA or any other analogous foreign Governmental Authority in which the FDA or such other analogous foreign Governmental Authority asserted that the promotion, distribution, marketing, or use and sale of the Product was not in compliance with Applicable Law. Except as set forth in Section 3.07 of the Seller Disclosure Schedule, with respect to the promotion, distribution, marketing, and sale of the Product, since January 24, 2014, and to the knowledge of Seller since January 1, 2012, there has not been any product recall, market withdrawal or post-sale warning conducted by or on behalf of the Seller or its Subsidiaries concerning the Product, or, to the knowledge of Seller, any product recall or market withdrawal conducted by or on behalf of any third party as a result of any alleged defect in the Product.

(c) Seller has provided to Buyer readable .pdf copies of all PADERs or PADER listings from 2004 through November 9, 2013 (including all Medwatch forms included therein). Since January 24, 2014, and to the knowledge of Seller since January 1, 2012, each PADER and annual report relating to the Product was timely filed with the FDA.

Section 3.08. *Title to Purchased Assets* . Seller or one of its Subsidiaries has good and marketable title to, or (if applicable) valid leaseholds in, all Purchased Assets, except where the failure to have such good and marketable title or valid leasehold interests would not reasonably be expected to be material to the Business, the Purchased Assets or the Product. No Purchased Asset is subject to any Lien, except for Permitted Liens and any other Liens that do not impede the ownership, operation or value of such Purchased Asset in any material respect.

Section 3.09. *Transferred Product Registrations* . (a) The Transferred Product Registrations constitute all material registrations, applications, approvals, licenses or permits granted by any Governmental Authority to develop and market the Product.

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(b) Except as set forth in Section 3.09 of the Seller Disclosure Schedule, the Product is manufactured and marketed in accordance with the specifications and standards contained in the Transferred Product Registrations, except where the failure to comply therewith would not reasonably be expected to be material to the Business, the Purchased Assets and the Product, taken as a whole.

(c) Except as set forth in Section 3.09 of the Seller Disclosure Schedule, prior to the transfer of any Transferred Product Registration in accordance with this Agreement, Seller or one of its Subsidiaries is the sole and exclusive owner of such Transferred Product Registration and has not granted any right of reference with respect thereto.

Section 3.10. *Intellectual Property*. (a) Section 2.01(a) of the Seller Disclosure Schedule sets forth a true and complete list of all issued and registered Intellectual Property Rights and applications for issuance or registration of Intellectual Property Rights, in each case, included in the Transferred Intellectual Property Rights. Except as would not reasonably be expected to be material to the Business, the Purchased Assets or the Product, to the knowledge of Seller, each item identified in Section 2.01(a) of the Seller Disclosure Schedule as registered is valid, subsisting and in full force and effect. The Seller or its Subsidiaries has taken all reasonable steps necessary to maintain such registrations, including the payment when due of all necessary registration and maintenance fees and annuities and the filing of all necessary renewals, statements and certifications, and all necessary material documents and certificates in connection with such registered Transferred Intellectual Property Rights have been filed with the relevant patent, copyright or other governmental or Regulatory Authorities for the purposes of maintaining such registered Transferred Intellectual Property Rights.

(b) Since January 24, 2014 and, to the knowledge of Seller, since January 1, 2012, neither the Seller nor any of its Subsidiaries has received any written charge, complaint, claim, demand, or notice alleging that the formulation, manufacture, packaging, promotion, distribution, marketing, or sale of the Product in the Territory interferes, infringes, misappropriates, or violates any third party's Intellectual Property Rights (including any written claim that the Seller or any of its Subsidiaries must license or refrain from using any third party's Intellectual Property Rights in connection with such activities). To the knowledge of Seller, no third party (i) currently infringes or has since January 24, 2012 infringed upon, or (ii) has since January 24, 2012 misappropriated any of the Transferred Intellectual Property Rights, in each case except as would not reasonably be expected to be material to the Business, the Purchased Assets or the Product.

(c) Except as set forth in Section 3.10 of the Seller Disclosure Schedule, neither Seller nor any of its Subsidiaries has made any pending claims or threatened to make any claim, in each case that a third party has infringed, misappropriated or otherwise violated any Transferred Intellectual Property Rights.

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Section 3.11. *AMP* . Section 3.11 of the Seller Disclosure Schedule sets forth the baseline Average Manufacturers Price (“ **AMP** ”) as calculated by Seller for the Product as of January 24, 2014.

Section 3.12. *Finders’ Fees* . There is no investment banker, broker, finder or other intermediary which has been retained by or is authorized to act on behalf of Seller who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

ARTICLE 4
REPRESENTATIONS AND WARRANTIES OF BUYER

Buyer represents and warrants to Seller as of the date hereof that:

Section 4.01. *Existence and Power* . Buyer is a corporation duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, and has all corporate powers and all governmental licenses, authorizations, permits, consents and approvals required to carry on its business as now conducted, except for those licenses, authorizations, permits, consents and approvals the absence of which would not reasonably be expected to prevent, materially delay or materially impair Buyer’s ability to consummate the transactions contemplated by this Agreement (a “ **Buyer Material Adverse Effect** ”).

Section 4.02. *Authorization* . The execution, delivery and performance by Buyer of this Agreement and each other Transaction Document to which it is a party, and the consummation of the transactions contemplated hereby and thereby, are within the corporate powers of Buyer and have been duly authorized by all necessary corporate action on the part of Buyer. This Agreement constitutes, and upon execution each other Transaction Document will constitute, a valid and binding agreement of Buyer, enforceable against Buyer in accordance with the terms hereof and thereof, subject to applicable bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium and other laws affecting creditors’ rights generally and general principles of equity.

Section 4.03. *Governmental Authorization* . The execution, delivery and performance by Buyer of this Agreement and each other Transaction Document, and the consummation of the transactions contemplated hereby and thereby, require no action by or in respect of, or filing with, any Governmental Authority other than any such action or filing as to which the failure to make would not reasonably be expected to have a Buyer Material Adverse Effect.

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Section 4.04. *Noncontravention* . The execution, delivery and performance by Buyer of this Agreement and each other Transaction Document, and the consummation of the transactions contemplated hereby and thereby, do not and will not (i) violate the certificate of incorporation or bylaws of Buyer, (ii) assuming compliance with the matters referred to in Section 4.03, violate any Applicable Law, (iii) require any consent or other action by any Person under, constitute a default under or give rise to any right of termination, cancellation or acceleration of any right or obligation or to a loss of any benefit to which Buyer is entitled under any provision of any agreement or other instrument binding upon Buyer or (iv) result in the creation or imposition of any material Lien on any asset of Buyer, with such exceptions, in the case of clauses (ii), (iii) and (iv) as would not reasonably be expected to have a Buyer Material Adverse Effect.

Section 4.05. *Litigation* . There is no action, suit, investigation or proceeding pending against or, to the knowledge of Buyer, threatened against or affecting Buyer before any arbitrator or any Governmental Authority that would reasonably be expected to have a Buyer Material Adverse Effect or that in any manner challenges or seeks to prevent, enjoin, alter or materially delay the transactions contemplated by this Agreement or the other Transaction Documents.

Section 4.06. *Financing* . Buyer has sufficient cash, available lines of credit or other sources of immediately available funds to enable it to make payment of the Purchase Price and any other amounts to be paid by it hereunder.

Section 4.07. *Finders' Fees* . There is no investment banker, broker, finder or other intermediary which has been retained by or is authorized to act on behalf of Buyer who might be entitled to any fee or commission in connection with the transactions contemplated by this Agreement.

Section 4.08. *Inspections; No Other Representations* . Buyer is an informed and sophisticated purchaser, and has engaged expert advisors, experienced in the evaluation and purchase of property and assets such as the Purchased Assets as contemplated hereunder. Buyer has undertaken such investigation and has been provided with and has evaluated such documents and information as it has deemed necessary to enable it to make an informed and intelligent decision with respect to the execution, delivery and performance of this Agreement. Except for the representations and warranties set forth in Article 3, Buyer (on behalf of itself and its Affiliates) acknowledges and agrees that no representation or warranty of any kind whatsoever, express or implied, at law or in equity, is made or shall be deemed to have been made by or on behalf of Seller or any of its Affiliates, and Seller hereby disclaims, and Buyer (on behalf of itself and its Affiliates) hereby disclaims any reliance upon, any such representation or warranty, notwithstanding the delivery or disclosure to Buyer or any of its representatives or Affiliates of any documentation or other information by the Seller or any of its representatives or Affiliates with respect to any one or more of the foregoing. Without limiting the generality of the foregoing, Buyer acknowledges that Seller makes no representation or warranty with respect to (i) the future performance of the Business or the Purchased Assets, including any projections, estimates or budgets delivered to or made available to Buyer of future revenues, future results of operations (or any component thereof), future cash flows or future financial condition (or any component thereof) with respect to the Purchased Assets, the Business or the Assumed Liabilities, or (ii) any other information or documents made available to Buyer or its counsel, accountants or advisors with respect to the Purchased Assets, the Business or the Assumed Liabilities, except, in each case, as expressly set forth in this Agreement.

ARTICLE 5
COVENANTS OF BUYER AND SELLER

Buyer and Seller agree that:

Section 5.01. *Further Assurances* . Seller and Buyer agree to execute and deliver such other documents, certificates, agreements, instruments of conveyance and transfer and other writings and to take such other actions as may be reasonably necessary or desirable in order to consummate or implement expeditiously the transactions contemplated by this Agreement.

Section 5.02. *Access to Information* . (a) On and after the Closing Date, Seller shall afford promptly to Buyer and its agents reasonable access to its books of account, financial and other records (including accountant's work papers), information, employees and auditors, in each case to the extent (i) related to the Purchased Assets or the Assumed Liabilities, (ii) not included in the Purchased Assets and (iii) reasonably necessary for Buyer in connection with any audit, investigation, dispute or litigation or any other reasonable business purpose relating to the Purchased Assets or the Assumed Liabilities, in each case arising on or before the Closing; *provided* that any such access by Buyer shall not unreasonably interfere with the conduct of the business of Seller or any of its Affiliates. Buyer shall bear all of the out-of-pocket costs and expenses (including attorneys' fees, but excluding reimbursement for general overhead, salaries and employee benefits) reasonably incurred by Seller and its Affiliates in connection with the foregoing. Notwithstanding the foregoing, Seller may redact any statements or other information in the portions of such information that do not relate to the Purchased Assets or the Assumed Liabilities or that relate to employees of Seller or any of its Affiliates. All requests for access to such books, records, information, employees and auditors shall be made to such representatives of Seller as Seller shall designate, which representatives shall be solely responsible for coordinating all such requests and all access permitted hereunder.

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(b) On and after the Closing Date, Buyer will afford promptly to Seller and its representatives reasonable access to its properties, books, records, employees and auditors to the extent reasonably necessary to enable Seller to determine any matter relating to its rights and Liabilities hereunder or to any period ending on or before the Closing Date; *provided* that any such access by Seller shall not unreasonably interfere with the conduct of the business of Buyer. All requests for access to such properties, books, records, information, employees and auditors shall be made to such representatives of Buyer as Buyer shall designate, which representatives shall be solely responsible for coordinating all such requests and all access permitted hereunder.

(c) Notwithstanding anything to the contrary contained herein, nothing in this Section 5.02 shall require (i) Seller or any of its Affiliates or Buyer or any of its Affiliates to violate any Applicable Law or a contract or obligation of confidentiality owed to a third party, to waive the protection of an attorney-client privilege, or to take any action that would result in the disclosure of any Trade Secrets (*provided* that, in the case of this clause (i), the disclosing party shall use commercially reasonable efforts to provide the other party, to the extent possible, with access to the relevant information in a manner that would not reasonably be expected to result in any such violation, waiver or disclosure) or (ii) the auditors and independent accountants of Seller or any of its Affiliates or of Buyer or any of its Affiliates to make any work papers available to any Person unless and until such Person has signed a customary confidentiality and hold harmless agreement relating to such access to work papers in form and substance reasonably acceptable to such auditors or independent accountants.

Section 5.03 . *Intellectual Property Matters.* (a) After the Closing, Buyer shall promptly, and in any event prior to the end of the Transition Period, complete the revision of all Packaging Materials existing as of the date hereof relating to the Product and/or used in the Business and not used in the sale of Products prior to the end of the Transition Period so as to not include any references to any Marks owned by or licensed to Seller or any of its Affiliates (excluding the Marks set forth on Section 2.01(a) of the Seller Disclosure Schedule, the “**Seller Marks**”) or any references to Seller’s or its Affiliates’ customer service address or phone number. Buyer shall not order any new Packaging Materials including references to the Seller Marks, except to the extent necessary to sell the Existing Inventory during the Transition Period. Without limiting the foregoing, in no event shall Buyer use any Seller Marks in any manner or for any purpose different from the use of such Seller Marks in connection with the Business during the 90-day period immediately preceding the Closing. Except as set forth in this Section 5.03(a), from and after the Closing, Buyer shall not have any right to use any of the Seller Marks. Any and all use of the Seller Marks by Buyer following the Closing until the complete phase-out of the Seller Marks as contemplated by this Section 5.03(a) shall (i) inure to the sole and exclusive benefit of the Seller and its Affiliates and (ii) be subject to Seller’s and its Affiliates’ quality control guidelines and procedures.

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(b) Effective as of and only upon the Closing, subject to the terms and conditions of this Agreement, Seller and its Subsidiaries hereby grant to Buyer a limited, non-exclusive, perpetual, irrevocable, non-sublicensable and, except to the extent this Agreement is permitted to be assigned by Buyer pursuant to Section 8.04, non-assignable, royalty-free, fully paid up, worldwide license, but solely in connection with the formulation, manufacture, packaging, promotion, distribution, marketing, and sale of the Product in the Territory, to use, reproduce, create derivative works of, distribute, make, have made, sale, offer for sale and import all Intellectual Property Rights (other than any Marks) that are owned and licensable by Seller or its Subsidiaries as of the Closing Date (without consent of or payment due to a third party or to Seller or any Subsidiary thereof) to the extent used in connection with the formulation, manufacture, packaging, promotion, distribution, marketing, and sale of the Product in the Territory as of the Closing Date.

Section 5.04. *Public Announcements* . Unless otherwise required by Applicable Law, by any listing agreement with any U.S. or U.K. securities exchange or share market or by any listing authority including the U.K. Listing Authority, subject to Section 5.07, Section 5.08 and Section 5.10, Seller and Buyer shall not, and cause their respective Affiliates not to, make any public announcement or disseminate any written communication to any supplier, customer, distributor or non-management employee of Seller or its Affiliates in respect of this Agreement or the transactions contemplated hereby, or otherwise communicate with any news media regarding this Agreement or the transactions contemplated hereby, without the prior written consent of Buyer and Seller (which consent shall not be unreasonably withheld, conditioned or delayed); *provided* that if any such announcement or communication is so required, Buyer and Seller shall consult with each other, to the extent reasonably practicable, in advance as to the contents and timing thereof; *provided, further*, that after the transactions contemplated by this Agreement have been announced, Seller and its Affiliates shall be entitled to respond to questions in the ordinary course or issue any press release or make any other public statement that, in each case, is not inconsistent with any public statement previously issued or made by it in accordance with the provisions of this Section 5.04. On the date hereof, Seller (and its Affiliates) and Buyer may issue a press release in substantially the form attached hereto as Exhibit D.

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Section 5.05. *Confidentiality.* (a) Effective as of the Closing, the Confidential Disclosure Agreement between Shire Human Genetic Therapies, Inc. and Buyer dated as of February 20, 2014 (the “**Confidentiality Agreement**”) shall terminate with respect to information to the extent relating to the Purchased Assets or the Assumed Liabilities; *provided, however*, that any and all other information provided to Buyer by Seller or its representatives concerning Seller or any of its Affiliates, and not otherwise constituting a Purchased Asset or an Assumed Liability, shall remain subject to the terms and conditions of the Confidentiality Agreement after the Closing.

(b) After the Closing, Seller and its Affiliates will hold, and will use their reasonable best efforts to cause their respective representatives to hold, in confidence all confidential documents and other information concerning the Purchased Assets or the Assumed Liabilities and information provided pursuant to Section 5.02(b). The obligation of Seller and its Affiliates to hold any such information in confidence shall not extend to any disclosure (i) that is required by Applicable Law, by any listing agreement with any U.S. or U.K. securities exchange or share market or by any listing authority including the U.K. Listing Authority, (ii) to the extent necessary to defend or prosecute any indemnification claim or any action, suit, investigation or proceeding, or (iii) except as a result of a disclosure in breach of this Agreement by Seller or its Affiliates after the Closing, of information generally available to the public or already known by a third party receiving such information from Seller or its Affiliates. The obligation of Seller and its Affiliates to hold any such information in confidence shall be deemed to be satisfied if they exercise the same care with respect to such information as they would take to preserve the confidentiality of their own similar information.

Section 5.06. *Return, Rebate and Chargeback Policies and Practices.* From and after the Closing, Buyer agrees that it will not take any action (i) with the intent to encourage, through the offering of incentives or changes in the return, rebate or chargeback policies or practices of the Business or otherwise (other than in the ordinary course of business consistent with the past practice of the Business prior to Closing), customers to return any Product shipped by Seller or any of its Affiliates prior to the end of the Transition Period, or to initiate any chargeback, rebate or similar request in respect of such Product, except as required by Applicable Law, or (ii) that would reasonably be expected to adversely affect Seller’s obligations to make rebate payments to, or entitlements to refunds for overpayments from (including in each case the amount thereof), CMS for Product shipped prior to the end of the Transition Period.

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Section 5.07. *Customer Notifications* . Promptly after the Closing Date, the parties shall notify all customers of the Business in writing, in a form agreed by the parties prior to the date hereof, (i) of the transfer of the Purchased Assets to Buyer and (ii) that all purchase orders for the Product received by Seller or any of its Affiliates prior to the Closing Date but not filled as of such date will be filled in the ordinary course (*provided* that Seller and Buyer shall cooperate with each other to ensure that such purchase orders as well as any additional purchase orders received between the Closing Date and the end of the Transition Period are filled in accordance with the provisions of Section 5.10). All purchase orders for the Product received by Seller after the end of the Transition Period shall be forwarded by Seller to Buyer or Buyer's distributor at the address to be provided by Buyer prior to the end of the Transition Period.

Section 5.08. *Transfer of Purchased Assets; Maintenance of Transferred Product Registrations; Cooperation* . (a) On or as promptly as reasonably practicable after the Closing Date, the Seller shall and shall cause its Subsidiaries to (i) transfer (or implement arrangements reasonably satisfactory to Buyer for the transfer and delivery of physical possession of) all tangible assets included in the Purchased Assets to the Buyer or its designated representatives, and (ii) upon reasonable request of the Buyer, notify all of its agents that hold files or other tangible material included in the Purchased Assets that, effective as of the Closing, the Buyer owns such Purchased Assets, with directions to transfer such Purchased Assets to Buyer in accordance with the Buyer's reasonable instructions. Buyer shall pay for any costs or expenses associated with the delivery of the Purchased Assets to Buyer or any of its designees. Notwithstanding the foregoing, to the extent the following are included in the Purchased Assets and are not delivered at the Closing, Seller shall deliver and cause its Subsidiaries to deliver (1) all of the books and records (in electronic and non-electronic form) related to the Product Approvals and (2) all case files since May 1, 2014, including readable .pdf copies of PADER listings and completed FDA form 3500As, to Buyer no later than 60 calendar days after the Closing Date; *provided* that Seller shall only have an obligation to deliver such books, records and files that, to Seller's knowledge, are in the possession or control of Seller.

(b) As promptly as reasonably practicable following the Closing, Seller shall file with the FDA all of the documents and the information reasonably required of a former owner, including the Transfer Letter, and Buyer shall file with the FDA the information required of a new owner or agent in respect thereof, including an acceptance letter to the FDA. Seller may retain an archival copy of each Product Approval, including supplements and records that are required to be kept under 21 CFR §314.81.

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(c) Buyer shall be responsible for, and shall bear all costs associated with, completing the recordation of any trademark assignment for the Marks set forth on Section 2.01(a) of the Seller Disclosure Schedule with the appropriate Regulatory Authorities in each country in which such Marks are registered; *provided* that Seller shall, for a period of two (2) years after the Closing and at Buyer's sole cost and expense, upon the reasonable request of Buyer, cooperate and cause its Subsidiaries to cooperate with Buyer to execute any additional documentation required to record and give effect to the assignment of such Marks in any jurisdiction in accordance with this Agreement.

(d) Until the completion of the transfer of the Transferred Product Registrations to Buyer: (i) Seller shall use commercially reasonable efforts to maintain the Transferred Product Registrations, (ii) if and to the extent reasonably requested by Buyer, Seller shall use commercially reasonable efforts to pursue, in such manner as may be reasonably directed by Buyer, those ongoing variations, amendments and renewals which are pending at the Closing Date and shall not withdraw them, and (iii) Seller shall not be required to initiate any new variations or amendments, except to the extent that they are necessary (in Buyer's reasonable, good faith opinion) for the continuation of the Business and then only upon Buyer's written request and direction. Neither Seller nor any of its Affiliates shall have any Liability or obligation to indemnify Buyer (A) if any or all of the Transferred Product Registrations are not transferred by any Governmental Authority, or such transfer is delayed, for any reason, except to the extent directly resulting from Seller's or any of its Subsidiaries' gross negligence or willful misconduct or a breach of Section 5.08(a) by Seller or (B) for taking any action requested or directed by Buyer pursuant to Section 5.08(d)(ii) or Section 5.08(d)(iii).

(e) For the avoidance of doubt, Seller does not warrant, and shall not be responsible for, the successful maintenance or renewal of any Transferred Product Registration after the Closing Date, except to the extent that a Governmental Authority cancels such Transferred Product Registration or refuses its renewal solely as a result of Seller's or any of its Subsidiaries' gross negligence or willful misconduct. In addition, Buyer acknowledges that Buyer shall be solely responsible for perfecting Buyer's title to the Transferred Intellectual Property Rights after the Closing Date, including recording the change in title.

(f) Buyer shall, and shall cause its Affiliates to, cooperate with Seller to deliver Seller any additional documentation and materials that may be reasonably requested by Seller to effect the transfer of the Transferred Product Registrations to Buyer. Buyer shall bear the cost of (i) all fees levied by the relevant Governmental Authority in connection with the transfer of the Transferred Product Registrations pursuant to this Section 5.08 and (ii) all costs and expenses arising from the maintenance of the Transferred Product Registrations after the Closing and any variations, amendment and renewals undertaken pursuant to Section 5.08(d)(ii) or Section 5.08(d)(iii).

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(g) Notwithstanding that any Packaging Materials may include Seller Marks or that Seller may remain the holder of any Transferred Product Registrations (but without limiting Seller's obligations under the Safety Data Transitional Agreement or Buyer's obligations under Section 5.03(a)), Buyer shall be responsible for (i) complying with Applicable Law after the Closing with respect to the Business, the Product and the Packaging Materials and (ii) any Liabilities arising from or relating to the marketing and sale of any Product after the Closing or the conduct of the Business after the Closing (all of which Liabilities shall be deemed Assumed Liabilities for purposes hereof). Until such time as the relevant Transferred Product Registrations are transferred to Buyer, Buyer shall not make any changes to the Packaging Materials (other than to the extent required by Applicable Law or Section 5.03(a), and only to such extent) without the consent of Seller, which consent shall not be unreasonably withheld, conditioned or delayed; *provided* that if Seller consents to any such requested change or such change is required by Applicable Law, Seller shall reasonably cooperate with Buyer, and shall provide such reasonable assistance as may be necessary, in implementing any such change. Any reasonable direct costs and expenses incurred from or as a consequence of any such change shall be fully borne by Buyer.

(h) Following the Closing, the parties agree to use commercially reasonable efforts to transition the Business to the Buyer. In this regard:

(i) Seller shall send a copy of the Transfer Letter to the FDA immediately following the Closing;

(ii) Seller shall as soon as reasonably practicable remove the Product from the DailyMed website following the expiration of the last to expire lot of Product sold by Seller under Seller's NDC;

(iii) Seller shall use commercially reasonable efforts, at Buyer's expense, to provide Buyer with reasonable assistance and information necessary to prepare and file with the FDA the applicable PADER and NDA annual report for 2015 (with applicable domestic distribution data).

Section 5.09 . *Buyer Insurance* . Promptly following the Closing, Buyer shall obtain and, maintain product liability insurance coverage with respect to the Product from a financially sound and reputable insurance company or companies, that is customary in scope and amount of coverage. Upon Seller's written request, Buyer shall promptly provide Seller with a copy of a certificate of insurance evidencing such insurance in form reasonably acceptable to Seller.

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Section 5.10. *Sales of Inventory Existing at Closing* . (a) Immediately following the Closing and until the earlier of (i) [***] and (ii) the date specified in a written notice from Buyer to Seller that it will be able to commence commercial sales of the Product using its own NDC (the period from the Closing Date until the earlier of (i) and (ii), the “ **Transition Period** ”), Seller shall act as a distributor for Buyer and, in this regard, direct each of the Distributors to continue to sell existing inventory of Product bearing Seller’s NDC (Product inventory bearing Seller’s NDC existing at the Closing, the “ **Existing Inventory** ”), and Seller’s existing Packaging Materials and to otherwise operate under their applicable Excluded Contract, in each case in the ordinary course of business throughout the Transition Period for the account of Buyer, and direct Cardinal Health to: (A) continue during the Transition Period to (1) process purchase orders and ship Existing Inventory, (2) process returns of Existing Inventory and (3) process rebates and chargebacks relating to Existing Inventory, each in the ordinary course of business, and (B) deliver a copy of any ordinary course reports provided to Seller regarding the foregoing to Seller and Buyer. Notwithstanding the foregoing, the Transition Period shall terminate if Buyer is in breach of its obligations under Section 5.10(c) and fails to cure such breach within five Business Days after having been notified of such breach in writing by Seller.

(b) Seller shall remit to Buyer or instruct Cardinal Health to remit to Buyer, as applicable, within 30 days after the end of each calendar month, (i) \$[***] and (ii) \$[***] of Existing Inventory sold during the Transition Period, out of the proceeds received by Seller in such month in respect of such sales, in accordance with wire instructions provided to Seller prior to the date hereof, less a fee equal to \$[***] of the Product sold, to be retained by Seller in consideration of the services rendered by it to Buyer under this Section 5.10.

(c) Buyer shall (i) use reasonable best efforts to obtain its own NDC and to enable itself to commence commercial sales of the Product using its own NDC (including by causing to be manufactured Product bearing Buyer’s NDC) as promptly as practicable after Closing, (ii) promptly inform Seller in writing upon receipt of its NDC, (iii) reasonably cooperate, and cause its Affiliates to reasonably cooperate, with Seller, in providing any information or assistance reasonably requested by Seller in connection with this Section 5.10, including any information Buyer possesses in respect of sales of Existing Inventory as Seller may require to include in any regulatory filings to be made in respect of the Product sold bearing Seller’s NDC.

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(d) Without Buyer's prior written consent (in the event of a material breach by a Distributor, not to be unreasonably withheld, conditioned or delayed), Seller shall not terminate the Excluded Contracts with the Distributors with respect to the Product with effect prior to the end of the Transition Period except in accordance with this Section 5.10(d). Upon receipt of written instructions from Buyer, but in no event later than the earlier to occur of (i) October 1, 2014 and (ii) two Business Days following the last day of the Transition Period, Seller shall provide notice to the Distributors of the termination of their respective Excluded Contracts with respect to the Product (which termination shall be effective in accordance with the terms of the applicable Excluded Contract) and instruct Cardinal Health to follow the written directions of Buyer with respect to the disposition of any remaining Existing Inventory.

(e) Seller and its Affiliates shall have no Liability to Buyer or any of its Affiliates in connection with its provision of services under this Section 5.10, except to the extent caused by Seller's fraud or intentional misconduct and except to the extent such Liability constitutes an Excluded Liability pursuant to Section 2.04(a). Notwithstanding anything in this Agreement to the contrary (other than Section 2.05), but subject to this Section 5.10, unfilled purchase orders for Product issued by customers, including pursuant to an Excluded Contract, shall be deemed to be a Purchased Asset hereunder, and all Liabilities arising under such purchase orders shall be Assumed Liabilities hereunder.

Section 5.11 . *Non-Compete* . For a period of three (3) years from Closing Date, neither Seller nor any of its Subsidiaries shall market or sell, or license to any other party the right to market or sell, the Product, or any "AB-rated" generic thereof, in the Territory (a "**Competing Business**"); *provided* that, notwithstanding the foregoing, neither Seller nor any of its Subsidiaries shall be restricted from:

(a) collectively owning less than five percent (5%) of any class of securities of any publicly traded company conducting a Competing Business if such securities are held as a passive investment; or

(b) acquiring one or more Persons or businesses that include within its business a Competing Business, so long as (1) the Competing Business comprises no more than 25% of the acquired business and (2) Seller or its Subsidiaries, as applicable, completes the sale of the Competing Business within six months of the acquisition; *provided, however* , that if such sale is subject to regulatory approval, then such six-month period shall be extended until five Business Days after all regulatory approvals have been received, but only to the extent that the parties to such sale are using commercially reasonable efforts to obtain any such approvals.

ARTICLE 6
TAX MATTERS

Section 6.01 . *Tax Matters*. Except as set forth in the Seller Disclosure Schedule, Seller hereby represents and warrants to Buyer that:

(a) Seller and its Subsidiaries have timely paid all Taxes required to be paid on or prior to the date hereof, the non-payment of which would result in a Lien on any Purchased Asset; and

(b) Seller and its Subsidiaries have established, in accordance with GAAP applied on a basis consistent with that of preceding periods, adequate reserves for the payment of, and will timely pay, all Taxes that arise from or with respect to the Purchased Assets and are incurred in or attributable to the Pre-Closing Tax Period, the non-payment of which would result in a Lien on any Purchased Asset.

Section 6.02. *Tax Cooperation; Allocation of Taxes* . (a) Buyer and Seller agree to furnish or cause to be furnished to each other, upon request, as promptly as practicable, such information and assistance relating to the Purchased Assets (including access to books and records) as is reasonably necessary for the filing of all Tax returns, the making of any election relating to Taxes, the preparation for any audit by any Taxing Authority, and the prosecution or defense of any claim, suit or proceeding relating to any Tax. Buyer and Seller (and their respective Subsidiaries) shall retain all books and records with respect to Taxes pertaining to the Purchased Assets for a period of at least six years following the Closing Date. On or after the end of such period, each party shall provide the other with at least 10 days prior written notice before destroying any such books and records, during which period the party receiving such notice can elect to take possession, at its own expense, of such books and records. Seller and Buyer shall cooperate with each other in the conduct of any audit or other proceeding relating to Taxes involving the Purchased Assets.

(b) All personal property taxes and similar *ad valorem* obligations levied with respect to the Purchased Assets for a taxable period that includes (but does not end on) the Closing Date (collectively, the “**Apportioned Obligations**”) shall be apportioned between Seller, on the one hand, and Buyer, on the other hand, based on the number of days of such taxable period included in the Pre-Closing Tax Period and the number of days in the portion of such taxable period beginning on the day after the Closing Date (any such portion of such taxable period, the “**Post-Closing Tax Period**”). Seller shall be liable for the proportionate amount of such Taxes that is attributable to the Pre-Closing Tax Period, and Buyer shall be liable for the proportionate amount of such Taxes that is attributable to the Post-Closing Tax Period.

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(c) All excise, sales, use, value added, registration stamp, recording, documentary, conveyancing, franchise, property, transfer and similar Taxes, levies, charges and fees (collectively, “**Transfer Taxes**”) incurred in connection with the transactions contemplated by this Agreement shall be shared equally by Buyer and Seller. Buyer and Seller shall cooperate in providing each other with any appropriate resale exemption certifications and other similar documentation.

(d) Apportioned Obligations and Transfer Taxes shall be timely paid as provided by Applicable Law. The paying party shall be entitled to reimbursement from the non-paying party in accordance with Section 6.02(b) or Section 6.02(c), as applicable. Upon payment of any such Apportioned Obligation or Transfer Tax, the paying party shall present a statement to the non-paying party setting forth the amount of reimbursement to which the paying party is entitled under Section 6.02(b) or Section 6.02(c), as applicable, together with such supporting evidence as is reasonably necessary to calculate the amount to be reimbursed. The non-paying party shall make such reimbursement promptly but in no event later than 10 days after the presentation of such statement.

Section 6.03. *FIRPTA Certificate* . At or prior to the Closing Date, Seller shall deliver to Buyer a certificate conforming to the requirements of Section 1.1445-2(b)(2) of the United States Treasury regulations in a form reasonably acceptable to Buyer.

ARTICLE 7
SURVIVAL; INDEMNIFICATION

Section 7.01. *Survival* . The representations and warranties of the parties hereto contained in this Agreement shall survive until the first anniversary of the Closing Date; *provided* that the representations and warranties contained in Sections 3.01, 3.02, 3.08, 3.09(a) and (c), 3.12 and 6.01 (collectively, the “**Seller Fundamental Representations**”) and the representations and warranties set forth in Sections 4.01, 4.02 and 4.07 (collectively, the “**Buyer Fundamental Representations**”) shall survive the Closing until the date that is 60 days after the expiration of the applicable statute of limitations or any extension thereof. The other covenants and agreements of the parties hereto contained in this Agreement shall survive the Closing indefinitely or for the shorter period explicitly specified therein, except that for such covenants and agreements that survive for such shorter period, breaches thereof shall survive indefinitely or until the latest date permitted by Applicable Law. Notwithstanding the preceding sentences, any breach of covenant, agreement, representation or warranty in respect of which indemnity may be sought under this Agreement shall survive the time at which it would otherwise terminate pursuant to the preceding sentences if notice of the breach giving rise to such right of indemnity shall have been given to the party against whom such indemnity may be sought prior to such time in accordance with Section 7.03 or 7.04 and Section 8.01.

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Section 7.02. *Indemnification* . (a) Effective at and after the Closing, subject to the limitations set forth in this Article 7, Seller hereby indemnifies Buyer, its Affiliates, officers, directors, employees and agents (each, a “**Buyer Indemnitee**”) from and against and agrees to hold each of them harmless from any and all Liabilities, demands, assessments, judgments, levies, losses, fines, penalties, damages (including compensatory damages), costs and expenses, including reasonable attorneys’ accountants’, investigators’ and experts’ fees and expenses (“**Damages**”) incurred by Buyer (or any Buyer Indemnitee) to the extent such Damages arise from or are related to any of the following:

- (i) any misrepresentation or breach of any representation or warranty (each such misrepresentation or breach, a “**Warranty Breach**”), made by Seller in this Agreement or any Transaction Document;
- (ii) any breach, nonperformance or violation of any covenant, agreement or other obligation made or to be performed by Seller or any of its Affiliates pursuant to this Agreement or any other Transaction Document; or
- (iii) any Excluded Liability;

provided that with respect to indemnification by Seller for Warranty Breaches pursuant to Section 7.02(a)(i) (other than, in each case below, Warranty Breaches in respect of a Seller Fundamental Representation), (A) Seller shall not be liable unless the aggregate amount of Damages with respect to such Warranty Breaches exceeds \$[***] (the “**Deductible**”) and [***], and (B) Seller shall not be liable for any Damages arising out of any individual claim unless such Damages exceed \$[***], and Damages that are disregarded pursuant to this clause (B) [***] (A), and (C) Seller’s maximum liability for all such Warranty Breaches shall not exceed \$[***] (the “**Cap**”); and *provided, further*, that Seller’s maximum liability for indemnification under Section 7.02(a)(i) shall not exceed the [***] by Seller.

(b) Effective at and after the Closing, subject to the limitations set forth in this Article 7, Buyer hereby indemnifies Seller and its Affiliates against and agrees to hold each of them harmless from any and all Damages actually suffered by Seller or any of its Affiliates arising out of:

- (i) any Warranty Breach of any representation or warranty made by Buyer in this Agreement or any Transaction Document;

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- (ii) any breach of a covenant or agreement made or to be performed by Buyer or any of its Affiliates pursuant to this Agreement or any other Transaction Document; or
- (iii) any Assumed Liability; or
- (iv) except to the extent they constitute Excluded Liabilities pursuant to Section 2.04(a), the provision of services by Seller under Section 5.10, except to the extent caused by Seller's fraud or intentional misconduct;

provided that with respect to indemnification by Buyer for Warranty Breaches pursuant to Section 7.02(b)(i) (other than Warranty Breaches in respect of a Buyer Fundamental Representation), (A) Buyer shall not be liable unless the aggregate amount of Damages with respect to such Warranty Breaches exceeds the Deductible and then only to the extent of such excess, and (B) Buyer shall not be liable for any Damages arising out of any individual claim unless such Damages exceed \$[***], and any Damages that are disregarded pursuant to this clause (B) [***] (A).

(c) For purposes of this Article 7, Warranty Breaches and any resulting Damages shall be determined without regard to any materiality or other similar qualification contained in, or otherwise applicable to, such representation or warranty (except for any such qualifications to the extent it qualifies an affirmative requirement to list specified items on a section of the Seller Disclosure Schedule (if any)).

Section 7.03 . *Third Party Claim Procedures.* (a) Any Person seeking indemnification under Section 7.02 (the “ **Indemnified Party** ”) shall give prompt notice in writing to the Person from whom indemnification is to be sought (the “ **Indemnifying Party** ”) of the assertion of any claim or the commencement of any suit, action or proceeding by any third party (“ **Third Party Claim** ”) in respect of which indemnity may be sought under such Section. Such notice shall set forth in reasonable detail such Third Party Claim and the basis for indemnification (taking into account the information then available to the Indemnified Party). The failure to so notify the Indemnifying Party shall not relieve the Indemnifying Party of its obligations hereunder, except to the extent such failure shall have adversely prejudiced the Indemnifying Party. Thereafter, the Indemnified Party shall deliver to the Indemnifying Party, as promptly as reasonably practicable following the Indemnified Party's receipt thereof, copies of all written notices and documents (including any court papers) received by the Indemnified Party relating to the Third Party Claim and the Indemnified Party shall provide the Indemnifying Party with such other information with respect to any such Third Party Claim reasonably requested by the Indemnifying Party.

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(b) The Indemnifying Party shall be entitled to participate in the defense of any Third Party Claim and, subject to the limitations set forth in this Section 7.03, shall be entitled to control and appoint lead counsel for such defense, in each case at its own expense. If the Indemnifying Party fails to assume or declines to assume the defense of any such proceeding within thirty (30) days after notice thereof, or fails to prosecute the defense of such claim in good faith and with reasonable diligence, the Indemnified Party may assume the defense thereof for the account and at the risk of the Indemnifying Party (including with respect to reasonable attorney's fees in connection therewith, but subject to the limitations set forth in this Article 7). To the extent the Indemnifying Party is controlling the defense of a Third Party Claim, the Indemnified Party may participate at his or its own expense in the defense of such Third Party Claim; *provided* that the reasonable costs and expenses of separate counsel to the Indemnified Party shall be borne by the Indemnifying Party (to the extent such costs and expenses constitute indemnifiable Damages hereunder) if, in the opinion of external counsel to the Indemnified Party, there is a material conflict of interest between the Indemnifying Party and the Indemnified Party with respect to such proceeding. The Indemnifying Party shall pay promptly to the Indemnified Party any Losses to which the Indemnified Party is finally determined to be entitled under this Article 7.

(c) Notwithstanding anything in this Section 7.03 to the contrary, neither the Indemnifying Party nor the Indemnified Party shall, without the written consent of the other party, settle or compromise any Third Party Claim or permit a default or consent to entry of any judgment. Notwithstanding the foregoing, consent of the Indemnified Party shall not be required for any such settlement if (i) the sole relief provided is monetary damages that are paid in full by the Indemnifying Party (other than, for the avoidance of doubt, the payment of the Deductible, to the extent applicable), (ii) such settlement does not permit any order, injunction or other equitable relief to be entered, directly or indirectly, against the Indemnified Party and (iii) such settlement includes a release of such Indemnified Party from all Liability on claims that are the subject matter of such Third Party Claim. If the Indemnifying Party makes any payment on any Third Party Claim, then the Indemnifying Party shall be subrogated, to the extent of such payment, to all rights and remedies of the Indemnified Party to any insurance benefits or other claims of the Indemnified Party with respect to such Third Party Claim (net of the costs and expenses of the Indemnified Party associated with the collection thereof).

(d) Each party shall cooperate, and cause its respective Affiliates to cooperate, in the defense or prosecution of any Third Party Claim and shall furnish or cause to be furnished such records, information and testimony, and attend such conferences, discovery proceedings, hearings, trials or appeals, as may be reasonably requested in connection therewith, the reasonable costs of which shall be deemed Damages for purposes hereof.

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Section 7.04 . *Direct Claim Procedures*. In the event an Indemnified Party has a claim for indemnity under Section 7.02 against an Indemnifying Party that does not involve a Third Party Claim, the Indemnified Party agrees to give prompt notice in writing of such claim to the Indemnifying Party. Such notice shall set forth in reasonable detail such claim and the basis for indemnification and the amount of such Damages incurred or that such Indemnified Party reasonably estimates in good faith is likely to be incurred in connection with such claim (taking into account the information then available to the Indemnified Party). The failure to so notify the Indemnifying Party shall not relieve the Indemnifying Party of its obligations hereunder, except to the extent such failure shall have actually prejudiced the Indemnifying Party. The Indemnified Party shall reasonably cooperate with and assist the Indemnifying Party in determining the validity of any such claim for indemnity by the Indemnified Party. If the Indemnifying Party disputes its indemnity obligation for any Damages with respect to such claim, the parties shall proceed in good faith to negotiate a resolution of such dispute and, if not resolved through negotiations, such dispute shall be resolved by litigation in an appropriate court of jurisdiction determined pursuant to Section 8.06.

Section 7.05. *Certain Limitations* . (a) The amount of any Damages payable under Section 7.02 by the Indemnifying Party shall be net of any (i) amounts recovered or recoverable by the Indemnified Party under applicable insurance policies, or from any other Person alleged to be responsible therefor and (ii) Tax benefit actually realized by the Indemnified Party arising from the incurrence or payment of any such Damages. If the Indemnified Party receives any amounts under applicable insurance policies, or from any other Person alleged to be responsible for any Damages, then such Indemnified Party shall promptly reimburse the Indemnifying Party for any payment made or expense incurred by such Indemnifying Party in connection with providing such indemnification payment up to the amount received by the Indemnified Party, but net of any expenses incurred by such Indemnified Party in collecting such amount.

(b) The Indemnifying Party shall not be liable under Section 7.02 for any (i) indirect, consequential, punitive or other speculative forms of Damages, (ii) Damages for lost profits or (iii) Damages that would not exist if not for, or to the extent aggravated by, any act or wrongful omission by the Indemnified Party, except, in the cases of clauses (i) or (ii), to the extent any Indemnified Party is liable for such Damages to any third party based on any final judgment of a court of competent jurisdiction.

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(c) The Indemnifying Party shall have no obligation to indemnify the Indemnified Party for any Damages arising out of a Warranty Breach to the extent that the recovery of Damages would constitute a duplicative payment of amounts otherwise recovered for Damages arising out of any claim made in respect of an Assumed Liability or Excluded Liability, as the case may be; and the Indemnifying Party shall have no obligation to indemnify the Indemnified Party for any Damages arising out of any such claim arising out of an Assumed Liability or Excluded Liability, as the case may be, to the extent that the recovery of Damages would constitute a duplicative payment of amounts otherwise recovered for Damages arising out of a Warranty Breach.

(d) Each Indemnified Party shall use commercially reasonable efforts to mitigate any Damage for which such Indemnified Party may seek indemnification under this Agreement. If such Indemnified Party mitigates its Damages after the Indemnifying Party has paid the Indemnified Party under any indemnification provision of this Agreement in respect of that loss, the Indemnified Party shall notify the Indemnifying Party and pay to the Indemnifying Party the extent of the value of the benefit to the Indemnified Party of that mitigation (less the Indemnified Party's reasonable costs of mitigation (which, for the avoidance of doubt, shall not exceed the value of the benefit to the Indemnified Party)) within ten (10) Business Days after the benefit is received.

(e) Each Indemnified Party shall use commercially reasonable efforts to collect any amounts available under insurance coverage, or from any other Person alleged to be responsible, for any Damages payable under Section 7.02.

Section 7.06. *Assignment of Claims* . If the Indemnified Party receives any payment from an Indemnifying Party in respect of any Damages pursuant to Section 7.02 and the Indemnified Party could have recovered all or a part of such Damages from a third party (a “**Potential Contributor**”) based on the underlying claim asserted against the Indemnifying Party, the Indemnified Party shall assign such of its rights to proceed against the Potential Contributor as are necessary to permit the Indemnifying Party to recover from the Potential Contributor the amount of such payment.

Section 7.07. *Specific Performance*. The parties hereto agree that irreparable damage would occur if any provision of this Agreement and the other Transaction Documents were not performed in accordance with the terms hereof and that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement or to enforce specifically the performance of the terms and provisions hereof in the courts specified in Section 8.06, in addition to any other remedy to which they are entitled at law or in equity.

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Section 7.08. *Exclusivity* . After the Closing, except in the case of fraud and subject to Section 7.07, Section 7.02 will provide the exclusive remedy of Buyer, Seller or any of their respective Affiliates for (i) any misrepresentation, breach of representation or warranty, covenant or other agreement or other claim arising out of this Agreement or any other Transaction Document (and the transactions contemplated hereby and thereby) or (ii) any other matter relating to the Purchased Assets, the Assumed Liabilities, the Product or the Business, whether at law or in equity and regardless of the legal theory under which such claim may be made.

Section 7.09. *Purchase Price Adjustment* . Any indemnification payment made under Article 7 will be treated as an adjustment to the Purchase Price.

ARTICLE 8
MISCELLANEOUS

Section 8.01 . *Notices* . All notices, requests and other communications to any party hereunder shall be in writing (including facsimile or e-mail transmission, so long as a receipt of such e-mail is requested and received) and shall be given,

if to Buyer, to:

ANI Pharmaceuticals, Inc.
210 Main Street West
Baudette, MN 56623
Attention: Chief Executive Officer
Facsimile No.: 218-634-3540

with a copy (which shall not constitute notice) to:

Dentons US LLP
1221 Avenue of the Americas
New York, NY 10022
Attention: Paul A. Gajer
Facsimile No.: 212-768-6700
Email: paul.gajer@dentons.com

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if to Seller, to:

Shire ViroPharma Incorporated
300 Shire Way
Lexington MA 02421
Attention: Legal Department
Facsimile No.: 781-482-2918

with a copy (which shall not constitute notice) to:

Davis Polk & Wardwell LLP
450 Lexington Avenue
New York, New York 10017
Attention: William J. Chudd
Facsimile No.: 212-701-5800
Email: william.chudd@davispolk.com

or such other address or facsimile number as such party may hereafter specify for the purpose by notice to the other parties hereto. All such notices, requests and other communications shall be deemed received on the date of receipt by the recipient thereof if received prior to 5:00 p.m. in the place of receipt and such day is a Business Day in the place of receipt. Otherwise, any such notice, request or communication shall be deemed not to have been received until the next succeeding Business Day in the place of receipt.

Section 8.02 . *Amendments and Waivers* . (a) Any provision of this Agreement may be amended or waived if, but only if, such amendment or waiver is in writing and is signed, in the case of an amendment, by each party to this Agreement, or in the case of a waiver, by the party against whom the waiver is to be effective.

(b) No failure or delay by any party in exercising any right, power or privilege hereunder shall operate as a waiver thereof nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege. The rights and remedies herein provided shall be cumulative and not exclusive of any rights or remedies provided by law.

Section 8.03 . *Expenses* . Except as otherwise provided herein, all costs and expenses incurred in connection with this Agreement shall be paid by the party incurring such cost or expense.

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Section 8.04 . *Successors and Assigns* . The provisions of this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns; *provided* that no party may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the consent of each other party hereto (and any attempted assignment without such consent shall be void), *provided* that either party may assign its rights and obligations under this Agreement without the other party's prior written consent upon written notice to the other party in connection with the transfer or sale of all or substantially all of the assets or business of such party and its Subsidiaries (whether by asset sale, stock sale or merger or consolidation); *provided* that no assignment or delegation hereunder shall limit or effect the assignor's obligations hereunder; and *provided further* that the Buyer may provide its lenders with a security interest in its rights under this Agreement in accordance with the terms of their security and collateral agreements in connection with any credit facility provided by such lenders to the Buyer and that such lenders may foreclose upon such security interest in accordance with the terms of such security and collateral agreements.

Section 8.05 . *Governing Law* . This Agreement shall be governed by and construed in accordance with the law of the State of New York, without regard to the conflicts of law rules of such state.

Section 8.06 . *Jurisdiction* . The parties hereto agree that any suit, action or proceeding seeking to enforce any provision of, or based on any matter arising out of or in connection with, this Agreement or the transactions contemplated hereby shall be brought in the United States District Court for the Southern District of New York or any New York State court sitting in New York City, so long as one of such courts shall have subject matter jurisdiction over such suit, action or proceeding, and that any cause of action arising out of this Agreement shall be deemed to have arisen from a transaction of business in the State of New York, and each of the parties hereby irrevocably consents to the jurisdiction of such courts (and of the appropriate appellate courts therefrom) in any such suit, action or proceeding and irrevocably waives, to the fullest extent permitted by law, any objection that it may now or hereafter have to the laying of the venue of any such suit, action or proceeding in any such court or that any such suit, action or proceeding brought in any such court has been brought in an inconvenient forum. Process in any such suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any such court. Without limiting the foregoing, each party agrees that service of process on such party as provided in Section 8.01 shall be deemed effective service of process on such party.

Section 8.07 . *WAIVER OF JURY TRIAL* . EACH OF THE PARTIES HERETO HEREBY IRREVOCABLY WAIVES ANY AND ALL RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF OR RELATED TO THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY.

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Section 8.08 . *Counterparts; Effectiveness; Third Party Beneficiaries* . This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument. This Agreement shall become effective when each party hereto shall have received a counterpart hereof signed by the other party hereto. Until and unless each party has received a counterpart hereof signed by the other party hereto, this Agreement shall have no effect and no party shall have any right or obligation hereunder (whether by virtue of any other oral or written agreement or other communication). Except as explicitly set forth herein, no provision of this Agreement is intended to confer any rights, benefits, remedies, or Liabilities hereunder upon any Person other than the parties hereto and their respective successors and assigns.

Section 8.09 . *Entire Agreement* . This Agreement, the Transaction Documents and the Confidentiality Agreement constitute the entire agreement between the parties with respect to the subject matter of this Agreement, and supersede all prior agreements and understandings, both oral and written, between the parties with respect to the subject matter of this Agreement.

Section 8.10 . *Bulk Sales Laws* . Buyer and Seller each hereby waive compliance by Seller with the provisions of the “bulk sales”, “bulk transfer” or similar laws of any jurisdiction.

Section 8.11 . *Severability* . If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction or other Governmental Authority to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions of this Agreement shall remain in full force and effect and shall in no way be affected, impaired or invalidated so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially adverse to any party. Upon such a determination, the parties shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the fullest extent possible.

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Section 8.12 . *Seller Disclosure Schedule* . The parties hereby agree that any matter set forth in any Section of the Seller Disclosure Schedule shall be deemed to be an exception to (or, as applicable, a disclosure for purposes of) (a) the representations and warranties of Seller that are contained in the corresponding Section of this Agreement and (b) any other representations and warranties of Seller that are contained in this Agreement if such matter's relevance as an exception to (or a disclosure for purposes of) such representations and warranties would be reasonably apparent to the Person to which such disclosure is being made. The parties acknowledge and agree that (i) the Seller Disclosure Schedule may include certain items and information solely for informational purposes for the convenience of Buyer and (ii) the disclosure by Seller of any matter in the Seller Disclosure Schedule shall not be deemed to constitute an acknowledgment by Seller that the matter is required to be disclosed by the terms of this Agreement or that the matter is material.

[*Remainder of this page intentionally left blank*]

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed by their respective authorized officers as of the day and year first above written.

ANI PHARMACEUTICALS, INC.

By: /s/ Charlotte C. Arnold

Name: Charlotte C. Arnold

Title: Vice President & Chief Financial Officer

SHIRE VIROPHARMA INCORPORATED

By: /s/ Ellen Rosenberg

Name: Ellen Rosenberg

Title: Secretary

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Arthur S. Przybyl, certify that:

1. I have reviewed this quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2014

/s/ Arthur S. Przybyl

Arthur S. Przybyl
President and
Chief Executive Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Charlotte C. Arnold, certify that:

2. I have reviewed this quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 10, 2014

/s/ Charlotte C. Arnold

Charlotte C. Arnold
Vice President and
Chief Financial Officer

**CERTIFICATION
PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED
PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended September 30, 2014 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

This certification is provided solely pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

Dated: November 10, 2014

/s/ Arthur S. Przybyl
Arthur S. Przybyl
President and
Chief Executive Officer
(principal executive officer)

Dated: November 10, 2014

/s/ Charlotte C. Arnold
Charlotte C. Arnold
Vice President and
Chief Financial Officer
(principal financial officer)

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.
