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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 2015

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

For the transition period from to .

Commission File Number 001-31812

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

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

210 Main Street West
Baudette, Minnesota
(Address of principal executive offices)

(218) 634-3500
(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ 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 x
Non-accelerated filer ☐ (Do not check if smaller reporting company)	Smaller reporting company ☐

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

As of October 28, 2015, there were 11,489,204 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, 2015
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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

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

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

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

NOTE REGARDING TRADEMARKS

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

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

	September 30, 2015	*December 31, 2014*
Assets		
Current Assets		
Cash and cash equivalents	$ 150,913	$ 169,037
Accounts receivable, net of $9,980 and $8,708 of adjustments for chargebacks and other allowances at September 30, 2015 and December 31, 2014, respectively	21,645	17,297
Inventories, net	13,741	7,518
Prepaid income taxes	972	-
Deferred tax assets, net of valuation allowance	8,266	7,643
Prepaid expenses and other current assets	1,985	1,983
Total Current Assets	197,522	203,478
Property and equipment, net	5,833	5,223
Deferred financing costs, net	2,674	3,307
Deferred tax assets, net of valuation allowance	7,118	7,796
Intangible assets, net	68,291	42,067
Goodwill	1,838	1,838
Total Assets	$ 283,276	$ 263,709
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 2,633	$ 2,654
Current income taxes payable	-	4,253
Accrued expenses and other	2,221	1,269
Accrued compensation and related expenses	1,019	1,348
Accrued Medicaid rebates	4,428	2,264
Returned goods reserve	1,889	1,445
Total Current Liabilities	12,190	13,233
Long-term Liabilities		
Convertible notes, net of discount	115,193	110,691
Total Liabilities	$ 127,383	$ 123,924
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 11,489,204 shares issued and outstanding at September 30, 2015; 11,387,860 shares issued and outstanding at December 31, 2014	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	-	-
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	-	-
Treasury stock, 0 shares of common stock, at cost, at September 30, 2015 and December 31, 2014, respectively	-	-
Additional paid-in capital	163,118	159,509
Accumulated deficit	(7,226)	(19,725)
Total Stockholders' Equity	155,893	139,785
Total Liabilities and Stockholders' Equity	$ 283,276	$ 263,709

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

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

	Three months ended September 30,		*Nine months ended September 30,*	
	2015	*2014*	*2015*	*2014*
Net Revenues	$ 19,972	$ 17,387	$ 58,287	$ 34,933
Operating Expenses:				
Cost of sales (excluding depreciation and amortization)	3,260	3,061	9,152	7,800
Research and development	815	883	2,213	2,110
Selling, general and administrative	5,399	4,057	15,701	13,193
Depreciation and amortization	2,047	1,187	4,789	2,596
Total Operating Expenses	11,521	9,188	31,855	25,699
Operating Income	8,451	8,199	26,432	9,234
Other (Expense)/Income, net				
Interest (expense)/income, net	(2,766)	10	(8,240)	13
Other (expense)/income, net	(28)	82	40	72
Income Before Provision for Income Taxes	5,657	8,291	18,232	9,319
Provision for income taxes	(1,098)	(1,545)	(5,733)	(1,577)
Net Income	$ 4,559	$ 6,746	$ 12,499	$ 7,742
Basic and Diluted Earnings Per Share:				
Basic Earnings Per Share	$ 0.40	$ 0.59	$ 1.09	$ 0.71
Diluted Earnings Per Share	$ 0.39	$ 0.59	$ 1.07	$ 0.70
Basic Weighted-Average Shares Outstanding	11,384	11,235	11,352	10,824
Diluted Weighted-Average Shares Outstanding	11,563	11,302	11,559	10,865

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

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

	Nine months ended September 30,	
	2015	*2014*
Cash Flows From Operating Activities		
Net income	$ 12,499	$ 7,742
Adjustments to reconcile net income to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	2,717	2,719
Deferred taxes	55	-
Depreciation and amortization	4,789	2,596
Loss on disposal of property and equipment	40	-
Non-cash interest relating to convertible notes and loan cost amortization	5,135	-
Changes in operating assets and liabilities:		
Accounts receivable, net	(4,348)	(2,057)
Inventories, net	(6,223)	(3,296)
Prepaid expenses and other current assets	(2)	(19)
Accounts payable	(130)	630
Accrued compensation and related expenses	(329)	(40)
Current income taxes, net	(5,225)	1,124
Accrued Medicaid rebates	2,164	1,023
Accrued expenses, returned goods reserve, and other	1,420	870
Net Cash and Cash Equivalents Provided by Operating Activities	12,562	11,292
Cash Flows From Investing Activities		
Acquisition of product rights and other related assets	(30,500)	(34,634)
Acquisition of property and equipment	(1,078)	(782)
Net Cash and Cash Equivalents Used in Investing Activities	(31,578)	(35,416)
Cash Flows From Financing Activities		
Net proceeds from equity offering	-	46,680
Proceeds from stock option exercises	658	777
Proceeds from warrant exercise	-	180
Excess tax benefit from share-based compensation awards	234	432
Net Cash and Cash Equivalents Provided by Financing Activities	892	48,069
Change in Cash and Cash Equivalents	(18,124)	23,945
Cash and cash equivalents, beginning of period	169,037	11,105
Cash and cash equivalents, end of period	$ 150,913	$ 35,050
Supplemental disclosure for cash flow information:		
Cash paid for interest	$ 2,048	$ -
Cash paid for income taxes	$ 10,668	$ 137
Supplemental non-cash investing and financing activities:		
Contingent payable for asset purchase	$ -	$ 1,000
Property and equipment purchased on credit	$ 109	$ -

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

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

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

Basis of Presentation

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

Principles of Consolidation

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

Use of Estimates

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

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

Recent Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board ("FASB") issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one –year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

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

In April 2015, the FASB issued guidance to simplify the balance sheet disclosure for debt issuance costs. Under the guidance, debt issuance costs related to a recognized debt liability will be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, in the same manner as debt discounts, rather than as an asset. The standard is effective for reporting periods beginning after December 15, 2015 and early adoption is permitted. The adoption of this new accounting pronouncement will result in a reclassification of deferred financing costs from assets to contra-liabilities.

In July 2015, the FASB issued guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

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

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

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

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

Accruals for Chargebacks, Rebates, Returns and Other Allowances

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

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the nine-month periods ended September 30, 2015 and 2014, respectively:

(in thousands)	Accruals for Chargebacks, Rebates, Returns and Other Allowances				
	Chargebacks	Medicaid Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2013	$ 4,076	$ 253	$ 736	$ 735	$ 332
Accruals/Adjustments	27,431	1,434	996	3,690	1,243
Credits Taken Against Reserve	(24,722)	(411)	(554)	(3,394)	(1,152)
Balance at September 30, 2014	$ 6,785	$ 1,276	$ 1,178	$ 1,031	$ 423
Balance at December 31, 2014	$ 6,865	$ 2,264	$ 1,445	$ 1,487	$ 471
Accruals/Adjustments	34,516	4,785	1,402	4,187	1,942
Credits Taken Against Reserve	(32,973)	(2,621)	(958)	(4,570)	(1,813)
Balance at September 30, 2015	$ 8,408	$ 4,428	$ 1,889	$ 1,104	$ 600

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, 2015, four customers represented 25%, 19%, 17%, and 11% of net revenues, respectively. During the nine-month period ended September 30, 2015, these same four customers represented 21%, 21%, 19%, and 14% of net revenues, respectively. As of September 30, 2015, net accounts receivable from these customers totaled $16.9 million. During the three-month period ended September 30, 2014, four customers represented 26%, 23%, 16%, and 15% of net revenues. During the nine-month period ended September 30, 2014, these same four customers represented 26%, 20%, 16%, and 10% of net revenues, respectively.

3. INDEBTEDNESS

Convertible Senior Notes

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

The Notes are convertible at the option of the holder (i) during any calendar quarter beginning after March 31, 2015, if the last reported sale price of the common stock for at least 20 trading days (whether or not consecutive) during a period of 30 consecutive trading days ending on the last trading day of the immediately preceding calendar quarter is greater than or equal to 130% of the conversion price on each applicable trading day, (ii) during the five business days after any five consecutive trading day period in which the trading price per $1,000 principal amount of the Notes for each trading day of such period was less than 98% of the product of the last reported sale price of our common stock and the conversion rate on each such trading day; and (iii) on or after June 1, 2019 until the second scheduled trading day immediately preceding the maturity date.

Upon conversion by the holders, we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof. As a result of our cash conversion option, we separately accounted for the value of the embedded conversion option as a debt discount (with an offset to Additional Paid in Capital (“APIC”)) of $33.6 million. The value of the embedded conversion option was determined based on the estimated fair value of the debt without the conversion feature, which was determined using market comparables to estimate the fair value of similar non-convertible debt (see Note 12). The debt discount is being amortized as additional non-cash interest expense using the effective interest method over the term of the Notes.

Offering costs of $5.5 million have been allocated to the debt and equity components in proportion to the allocation of proceeds to the components, as deferred financing costs and equity issuance costs, respectively. The deferred financing costs of $4.2 million are being amortized as additional non-cash interest expense using the straight-line method over the term of the debt, since this method was not significantly different from the effective interest method. The $1.3 million portion allocated to equity issuance costs was charged to APIC.

3. INDEBTEDNESS – continued

A portion of the offering proceeds was used to simultaneously enter into "bond hedge" (or purchased call) and "warrant" (or written call) transactions with an affiliate of one of the offering underwriters (collectively, the "Call Option Overlay"). We entered into the Call Option Overlay to synthetically raise the initial conversion price of the Notes to $96.21 per share and reduce the potential common stock dilution that may arise from the conversion of the Notes. The exercise price of the bond hedge is $69.48 per share, with an underlying 2,068,792 common shares; the exercise price of the warrant is $96.21 per share of our common stock, also with an underlying 2,068,792 common shares. Because the bond hedge and warrant are both indexed to our common stock and otherwise would be classified as equity, we recorded both elements as equity, resulting in a net reduction to APIC of $15.6 million.

The carrying value of the Notes is as follows as of September 30:

(in thousands)	2015
Principal amount	$ 143,750
Unamortized debt discount	(28,557)
Net carrying value	$ 115,193

The following table sets forth the components of total interest expense related to the Notes recognized in the accompanying consolidated statements of operations for the three and nine-months ended September 30, 2015:

(in thousands)	Three months ended September 30, 2015	Nine months ended September 30, 2015
Contractual coupon	$ 1,078	$ 3,234
Amortization of debt discount	1,521	4,502
Amortization of finance fees	211	633
Capitalized interest	(11)	(26)
	$ 2,799	$ 8,343

The effective interest rate on the Notes is 7.7%, on an annualized basis.

4. EARNINGS PER SHARE

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

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

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

4. EARNINGS PER SHARE – continued

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

Earnings per share for the three and nine-months ended September 30, 2015 and 2014 are calculated for basic and diluted earnings per share as follows:

(in thousands, except per share amounts)	Basic Three months ended September 30,		Diluted Three months ended September 30,		Basic Nine months ended September 30,		Diluted Nine months ended September 30,	
	2015	2014	2015	2014	2015	2014	2015	2014
Net income	$ 4,559	$ 6,746	$ 4,559	$ 6,746	$ 12,499	$ 7,742	$ 12,499	$ 7,742
Net income allocated to warrants	-	(38)	-	(37)	-	(43)	-	(42)
Net income allocated to restricted stock	(30)	(47)	(30)	(47)	(82)	(54)	(82)	(54)
Net income from continuing operations allocated to common shares	$ 4,529	$ 6,661	$ 4,529	$ 6,662	$ 12,417	$ 7,645	$ 12,417	$ 7,646
Basic Weighted-Average Shares Outstanding	11,384	11,235	11,384	11,235	11,352	10,824	11,352	10,824
Dilutive effect of stock options			179	67			207	41
Diluted Weighted-Average Shares Outstanding			11,563	11,302			11,559	10,865
Earnings Per Share	$ 0.40	$ 0.59	$ 0.39	$ 0.59	$ 1.09	$ 0.71	$ 1.07	$ 0.70

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, including the shares underlying the Notes, was 4.5 million and 0.7 million for the three months ended September 30, 2015 and 2014, respectively, and was 4.6 million and 0.7 million for the nine months ended September 30, 2015 and 2014, respectively. Anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the treasury stock method, and out-of-the-money warrants exercisable for common stock.

As of September 30, 2015, we have options outstanding to purchase 0.5 million shares of common stock, warrants outstanding to purchase 2.2 million shares of common stock, and 76 thousand unvested restricted stock awards outstanding.

5. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2015	December 31, 2014
Raw materials	$ 10,563	$ 5,056
Packaging materials	1,023	794
Work-in-progress	573	411
Finished goods	1,775	1,368
	13,934	7,629
Reserve for excess/obsolete inventories	(193)	(111)
Inventories, net	$ 13,741	$ 7,518

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 reliably supply the API required for ongoing product manufacturing. During the three months ended September 30, 2015, we purchased approximately 35% of our inventory from two suppliers. During the nine months ended September 30, 2015, we purchased approximately 44% of our inventory from three suppliers. As of September 30, 2015, amounts payable to these three suppliers totaled $0.7 million. 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.

6. PROPERTY, PLANT, AND EQUIPMENT

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

(in thousands)	September 30, 2015	December 31, 2014
Land	$ 87	$ 87
Buildings	3,682	3,682
Machinery, furniture and equipment	5,440	4,822
Construction in progress	881	426
	10,090	9,017
Less: accumulated depreciation	(4,257)	(3,794)
Property, Plant and Equipment, net	$ 5,833	$ 5,223

6. PROPERTY, PLANT, AND EQUIPMENT – continued

Depreciation expense was $0.2 million for each of the three-month periods ended September 30, 2015 and 2014. Depreciation expense for the nine-month periods ended September 30, 2015 and 2014 totaled $0.5 million and $0.4 million, respectively. During the three and nine-month periods ended September 30, 2015, there was $11 thousand and $26 thousand of interest capitalized into construction in progress, respectively. In the three and nine-month periods ended September 30, 2014, there was no interest capitalized into construction in progress.

7. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. (“BioSante”), we recorded goodwill of $1.8 million in our one reporting unit. We assess the recoverability of the carrying value of goodwill as of October 31 of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value from the most recent assessment on October 31, 2014, through September 30, 2015. No impairment losses were recognized during the three or nine months ended September 30, 2015 or 2014.

Acquisition of Abbreviated New Drug Applications

In March 2015 we purchased from Teva Pharmaceuticals (“Teva”) the Abbreviated New Drug Application (“ANDA”) for a generic product, Flecainide Acetate tablets, for $4.5 million in cash and a percentage of future gross profits from product sales. We accounted for this transaction as an asset purchase. The ANDA is being amortized in full over its useful life of 10 years.

In July 2015, we purchased from Teva the ANDAs for 22 previously marketed generic drug products for $25.0 million in cash and a percentage of future gross profits from product sales. We accounted for this transaction as an asset purchase. The ANDAs are being amortized in full over their useful life of 10 years.

Testosterone Gel NDA

As part of our 2013 merger with BioSante, we acquired a testosterone gel product that was licensed to Teva (the “Teva license”). In May 2015, we acquired from Teva the approved New Drug Application (“NDA”) for the previously-licensed product. Pursuant to the terms of the purchase agreement, upon commercialization, we will pay Teva a royalty of up to $5 million, at a rate of 5% of the consideration we receive as a result of commercial sale of the product. We have assessed the value of the Teva license under the new structure and determined that the asset was not impaired as of the May 2015 acquisition date. We will continue to assess the asset for potential impairment on an on-going basis.

Marketing and Distribution Rights

In August 2015, we entered into a distribution agreement with IDT Australia Limited (“IDT”) to market several products in the U.S. (the “IDT Agreement”). The products have associated ANDAs that require various FDA approvals prior to commercialization. In general, IDT will be responsible for regulatory submissions of the products and the manufacturing of certain products. We made an upfront payment to IDT of $1.0 million and will make additional milestone payments upon FDA approval for commercialization of certain products. Upon approval, IDT will manufacture some of the products and we will manufacture the other products. We will be responsible for marketing and distributing all the products under our label, in the United States, providing a percentage of profits from sales of the drugs to IDT. The $1.0 million upfront payment was recorded as a marketing and distribution rights intangible asset and will be amortized in full over its seven-year useful life.

7. GOODWILL AND INTANGIBLE ASSETS – continued

Definite-Lived Intangible Assets

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

(in thousands)	September 30, 2015		December 31, 2014		Weighted Average
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	Amortization Period
Acquired ANDA intangible assets	$ 42,077	$ (3,138)	$ 12,577	$ (1,312)	10 years
Product rights	22,522	(2,816)	22,522	(1,133)	10 years
Testosterone gel NDA	10,900	(2,230)	10,900	(1,487)	10 years
Marketing and distribution rights	1,000	(24)	-	-	7 years
	$ 76,499	$ (8,208)	$ 45,999	$ (3,932)	

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 the group of ANDAs acquired from Teva in the first quarter of 2014 and the additional ANDAs acquired in 2015. 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 the Lithobid and Vancocin products acquired in the third quarter of 2014. The testosterone gel NDA was acquired in May 2015. Definite-lived intangible assets are stated at cost, net of amortization using the straight line method over the expected useful lives of the intangible assets. Amortization expense was $1.9 million and $1.0 million for the three months ended September 30, 2015 and 2014, respectively. Amortization expense was $4.3 million and $2.2 million for the nine months ended September 30, 2015 and 2014, respectively.

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three and nine months ended September 30, 2015 and 2014 and therefore no impairment loss was recognized in the three and nine months ended September 30, 2015 or 2014.

Expected future amortization expense is as follows:

(in thousands)	
2015 (remainder of the year)	$ 1,894
2016	7,578
2017	7,578
2018	7,578
2019	7,578
2020 and thereafter	36,085
Total	$ 68,291

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, 2015, 0.5 million shares of our common stock remained available for issuance under the 2008 Plan.

Total expense related to stock options for the three months ended September 30, 2015 was $0.9 million, $23 thousand of which was recognized as cost of sales, $31 thousand as research and development expense, and $0.8 million as sales, general, and administrative ("SG&A") expense. Total expense related to stock options for the nine months ended September 30, 2015 was $2.1 million, $60 thousand of which was recognized as cost of sales, $80 thousand as research and development expense, and $2.0 million as SG&A expense. Total expense related to stock options for the three months ended September 30, 2014 was $0.6 million, $18 thousand of which was recognized as cost of sales, $10 thousand as research and development expense, and $0.6 million as SG&A expense. 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 non-recurring catch-up adjustment related to the 325 thousand stock options previously approved by the Board of Directors on July 12, 2013 and August 1, 2013, which were approved at the May 22, 2014 annual meeting. Of the $2.5 million of stock option expense recognized in the nine months ended September 30, 2014, $0.1 million was recognized as cost of sales, $0.1 million as research and development expense, and $2.3 million as SG&A expense. Total expense related to restricted stock grants for the three and nine months ended September 30, 2015 was $0.3 million and $0.6 million, respectively, all of which was recognized as SG&A expense. Total expense related to restricted stock grants for the three and nine months ended September 30, 2014 was $0.1 million and $0.2 million, respectively, all of which was recognized as SG&A expense.

A summary of stock option and restricted stock activity under the Plan during the nine months ended September 30, 2015 and 2014 is presented below:

(in thousands)	Options	RSAs
Outstanding December 31, 2013	120	50
Granted	115	30
Options previously granted, approved by shareholders	325	-
Options Exercised/RSAs Vested	(36)	-
Expired	(64)	-
Outstanding September 30, 2014	460	80
Outstanding December 31, 2014	458	63
Granted	130	28
Options Exercised/RSAs Vested	(81)	(10)
Forfeited	(33)	(5)
Outstanding September 30, 2015	474	76

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.

9. STOCKHOLDER'S EQUITY – continued

Warrants to purchase 0.1 million and 0.3 million shares of common stock expired unexercised during the three and nine months ended September 30, 2015, respectively. No warrants to purchase shares of common stock expired unexercised during the three and nine months ended September 30, 2014. No warrants to purchase shares of common stock were exercised in the three and nine months ended September 30, 2015. In January 2014, warrants to purchase an aggregate of 20 thousand shares of common stock were exercised at $9.00 per share.

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. As of both September 30, 2015 and December 31, 2014, we had provided a valuation allowance against certain state net operating loss carryforwards of approximately $0.1 million. 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 all of our income tax returns remain subject to examination by tax authorities 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 such amounts accrued as of September 30, 2015 and December 31, 2014.

We have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our estimated annual effective rate. The utilization of our NOL carryforwards will be limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code.

The effective tax rate for the nine-month period ended September 30, 2015 was 31.4% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2015. The 19.4% effective tax rate for the three-month period ended September 30, 2015 was primarily driven by current quarter changes in forecasted pre-tax income, estimated permanent differences, and state income tax rates, as well as from the impact of current quarter exercises of incentives and non-qualified stock options and disqualifying dispositions of incentive stock options. For the comparable three and nine-month periods ended September 30, 2014, the effective tax rates 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 ended December 31, 2014.

11. COMMITMENTS AND CONTINGENCIES

Asset Acquisition of New Drug Applications

In September 2015, we entered into an asset purchase agreement with Merck Sharp & Dohme B.V. (“Merck”) to purchase, subject to typical closing conditions including regulatory approvals, certain NDAs and associated product rights and manufacturing licenses for $75.0 million in cash and a percentage of future net sales of the products under the NDAs. The asset acquisition is expected to close in January 2016. We anticipate that we will make the $75.0 million cash payment using cash in hand.

Specifically, we will acquire Merck’s right, title and interest in the NDA for purified corticotropin gel, 40 units/mL and 80 units/mL and the NDA for corticotropin-zinc hydroxide, 40 units/mL, along with certain documentation and trademark applications relating to the products under the NDAs. We will also receive a non-exclusive, irrevocable, perpetual right and license to certain manufacturing technology relating to the manufacture of the products under the NDAs.

Operating Leases

We lease equipment under operating leases that expire in May 2017 and September 2018. 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 $0.2 million as of September 30, 2015.

Rent expense for the three months ended September 30, 2015 and 2014 totaled $19 thousand and $17 thousand, respectively. Rent expense for the nine months ended September 30, 2015 and 2014 totaled $57 thousand and $53 thousand, respectively.

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 NDAs or ANDAs. During the three months ended September 30, 2015 and 2014, net revenues for these products totaled $12.5 million and $8.9 million, respectively. During the nine months ended September 30, 2015 and 2014, net revenues for these products totaled $33.8 million and $19.4 million, respectively.

The FDA's policy with respect to the continued marketing of unapproved products is stated in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled “Marketed New Drugs without Approved NDAs or ANDAs.” Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against such unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those marketed as unapproved drugs with potential safety risks or that lack evidence of effectiveness. We believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy. There can be no assurance, however, that the FDA will continue this policy or not take a contrary position with any individual product or group of products. If the FDA were to take a contrary position, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval.

11. COMMITMENTS AND CONTINGENCIES – continued

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, 2015 and 2014 were $0.3 million and $0.2 million, respectively. Our contract manufacturing revenues for these unapproved products for the nine months ended September 30, 2015 and 2014 were $1.1 million and $0.7 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, 2015 and 2014 were $0.1 million. Our royalties on the net sales of these unapproved products for the nine months ended September 30, 2015 and 2014 were $0.3 million and $0.2 million, respectively.

Louisiana Medicaid Lawsuit

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

Other Commitments and Contingencies

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

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

12. FAIR VALUE DISCLOSURES

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, borrowings under line of credit, and other current liabilities) approximate their carrying values because of their short-term nature. While our Notes are recorded on our consolidated balance sheets at their net carrying value of $115.2 million as of September 30, 2015, the Notes are being traded on the bond market and their full fair value is $131.4 million, based on their closing price on September 30, 2015, a Level 1 input.

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

Our contingent value rights (“CVRs”), which were granted coincident with our merger with BioSante, 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 September 30, 2015 and December 31, 2014, and for the three and nine months ended September 30, 2015 and 2014.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of September 30, 2015 and December 31, 2014, by level within the fair value hierarchy:

(in thousands)

Description	Fair Value at September 30, 2015	Level 1	Level 2	Level 3
Liabilities				
CVRs	$ -	$ -	$ -	$ -

Description	Fair Value at December 31, 2014	Level 1	Level 2	Level 3
Liabilities				
CVRs	$ -	$ -	$ -	$ -

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

In December 2014, we issued $143.8M of Notes (see Note 3). Because we have the option to cash settle the potential conversion of the Notes in cash, we separated the embedded conversion option feature from the debt feature and account for each component separately, based on the fair value of the debt component assuming no conversion option. The calculation of the fair value of the debt component required the use of Level 3 inputs, and was determined by calculating the fair value of similar non-convertible debt, using a theoretical interest rate of 9%. The theoretical interest rate was determined from market comparables to estimate what the interest rate would have been if there was no conversion option embedded in the Notes. The fair value of the embedded conversion option was calculated using the residual value method and is classified as equity.

12. FAIR VALUE DISCLOSURES - continued

A portion of the offering proceeds was used to simultaneously enter into "bond hedge" (or purchased call) and "warrant" (or written call) transactions with an affiliate of one of the offering underwriters (see Note 3). The exercise price of the bond hedge is $69.48 per share, with an underlying 2,068,792 common shares; the exercise price of the warrant is $96.21 per share of our common stock, also with an underlying 2,068,792 common shares.

We calculated the fair value of the bond hedge based on the price we paid to purchase the call. We calculated the fair value of the warrant based on the price at which the affiliate purchased the warrants from us. Because the bond hedge and warrant are both indexed to our common stock and otherwise would be classified as equity, we recorded both elements as equity, resulting in a net reduction to APIC of $15.6 million.

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, 2015 and 2014.

In March 2015, we purchased from Teva the ANDA for Flecainide Acetate tablets for $4.5 million in cash and a percentage of future gross profits from product sales. The value of the ANDA was based on the purchase price of $4.5 million.

In July 2015, we purchased from Teva the ANDAs for 22 previously marketed generic drug products for $25.0 million in cash and a percentage of future gross profits from product sales. The value of the ANDAs was based on the total purchase price of $25.0 million.

13. SUBSEQUENT EVENT

In October 2015, our Board of Directors authorized a program to repurchase up to $25.0 million of our common stock. The authorization allows for repurchases to be conducted through open market or privately negotiated transactions through December 31, 2016. The stock repurchase program may be suspended, modified or discontinued at any time at our discretion.

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

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this Form 10-Q quarterly report. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" in our annual report on Form 10-K for the year ended December 31, 2014.

EXECUTIVE OVERVIEW

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

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

Our products include both branded and generic pharmaceuticals, specifically:

Generic Products	Branded Products
Esterified Estrogen with Methyltestosterone	Cortenema
Etodolac	Reglan
Fluvoxamine Maleate	Lithobid
Hydrocortisone Enema	Vancocin
Methazolamide	
Metoclopramide Syrup	
Opium Tincture	
Oxycodone Hydrochloride Oral Solution	
Propafenone	
Vancomycin	

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

- ***Formulation Complexity.*** Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that we intend to leverage in selecting products to develop or manufacture.
- ***Patent Status.*** We seek to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.
- ***Market Size.*** When determining whether to develop or acquire an individual product, we review the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. We 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 product both competitively and at a profit.
- ***Profit Potential.*** We research the availability and cost of active pharmaceutical ingredients in determining which products to develop or acquire. In determining the potential profit of a product, we forecast our anticipated market share, pricing, 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 many generic competitors. Our highly specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies would be able to compete.

GENERAL

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2015	2014	2015	2014
Net revenues	$ 19,972	$ 17,387	$ 58,287	$ 34,933
Operating expenses				
Cost of sales (excluding depreciation and amortization)	3,260	3,061	9,152	7,800
Research and development	815	883	2,213	2,110
Selling, general and administrative	5,399	4,057	15,701	13,193
Depreciation and amortization	2,047	1,187	4,789	2,596
Operating income	8,451	8,199	26,432	9,234
Interest (expense)/income, net	(2,766)	10	(8,240)	13
Other (expense)/income, net	(28)	82	40	72
Income before provision for income taxes	5,657	8,291	18,232	9,319
Provision for income taxes	(1,098)	(1,545)	(5,733)	(1,577)
Net income	$ 4,559	$ 6,746	$ 12,499	$ 7,742

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,	
	2015	2014	2015	2014
Net revenues	100.0%	100.0%	100.0%	100.0%
Operating expenses				
Cost of sales (excluding depreciation and amortization)	16.3%	17.6%	15.7%	22.3%
Research and development	4.1%	5.1%	3.8%	6.0%
Selling, general and administrative	27.0%	23.3%	26.9%	37.8%
Depreciation and amortization	10.3%	6.8%	8.2%	7.4%
Operating income	42.3%	47.2%	45.4%	26.5%
Interest (expense)/income, net	(13.9)%	0.1%	(14.2)%	-%
Other (expense)/income, net	(0.1)%	0.4%	0.1%	0.2%
Income before provision for income taxes	28.3%	47.7%	31.3%	26.7%
Provision for income taxes	(5.5)%	(8.9)%	(9.8)%	(4.6)%
Net income	22.8%	38.8%	21.5%	22.1%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

Net Revenues

(in thousands)	Three Months Ended September 30,			
	2015	2014	Change	% Change
Generic pharmaceutical products	$ 15,102	$ 10,188	$ 4,914	48.2%
Branded pharmaceutical products	2,253	4,806	(2,553)	(53.1)%
Contract manufacturing	1,280	1,350	(70)	(5.2)%
Contract services and other income	1,337	1,043	294	28.2%
Total net revenues	$ 19,972	$ 17,387	$ 2,585	14.9%

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, 2015 were $20.0 million compared to $17.4 for the same period in 2014, an increase of $2.6 million, or 14.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $15.1 million during the three months ended September 30, 2015, an increase of 48.2% compared to $10.2 million for the same period in 2014. The primary reason for the increase was increased Esterified Estrogen with Methyltestosterone tablets (“EEMT”) revenues, due to new customer contracts that began in the third quarter, as well as sales of Methazolamide, launched in the fourth quarter of 2014, and Etodolac and Propafenone both of which were launched in the first quarter of 2015. We also experienced increased sales for our HC Enema product, due to price increases.

  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 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, 2015 and 2014 were $12.5 million and $8.9 million, respectively.

- Net revenues for branded pharmaceutical products were $2.3 million during the three months ended September 30, 2015, a decrease of 53.1% compared to $4.8 million for the same period in 2014. The primary reasons for the decrease were lower unit sales of Reglan, due to decreased purchases by a customer, and decreases in unit sales and increased Medicaid utilization and Medicaid rebates for both Lithobid and Vancocin, each of which are trends we expect to continue.

- Contract manufacturing revenues were $1.3 million during the three months ended September 30, 2015, a decrease of 5.2% compared to $1.4 million for the same period in 2014, 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, 2015 and 2014 were $0.3 million and $0.2 million, respectively.

- Contract services and other income were $1.3 million during the three months ended September 30, 2015, an increase of 28.2% from $1.0 million for the same period in 2014, due primarily to royalties on sales of the authorized generic of Vancocin, the product rights to which were acquired in the third quarter of 2014. In November 2015, we launched an authorized generic for Vancocin under our own label, which will replace the authorized generic product currently on the market.

  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, 2015 and 2014.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended September 30,			
	2015	2014	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 3,260	$ 3,061	$ 199	6.5%

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 unaudited interim condensed consolidated statements of operations.

For the three months ended September 30, 2015, cost of sales increased to $3.3 million from $3.1 million for the same period in 2014, an increase of $0.2 million or 6.5%, primarily as a result of increased sales in the period. Cost of sales as a percentage of net revenues decreased to 16.3% during the three months ended September 30, 2015, from 17.6% during same period in 2014, primarily as a result of a favorable shift in product mix toward higher margin products, principally EEMT.

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 API for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections. During the three months ended September 30, 2015, we purchased 35% of our inventory from two suppliers. As of September 30, 2015, amounts payable to these two suppliers totaled $0.7 million. In the three months ended September 30, 2014, we purchased 49% 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,			
	2015	2014	Change	% Change
Research and development	$ 815	$ 883	$ (68)	(7.7)%
Selling, general and administrative	5,399	4,057	1,342	33.1%
Depreciation and amortization	2,047	1,187	860	72.5%
Total other operating expenses	$ 8,261	$ 6,127	$ 2,134	34.8%

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, 2015, other operating expenses increased to $8.3 million from $6.1 million for the same period in 2014, an increase of $2.1 million, or 34.8%, primarily as a result of the following factors:

- Depreciation and amortization increased from $1.2 million to $2.0 million, an increase of 72.5%, due primarily to amortization of the Flecainide ANDA and the basket of ANDAs acquired from Teva in the first and third quarters of 2015, respectively.

- Research and development expenses decreased slightly from $0.9 million to $0.8 million, a decrease of 7.7%, due to timing of work on development projects. Current projects include work on the ANDAs purchased from Teva in 2014 and 2015 and collaborations with partners.

- Selling, general and administrative expenses increased from $4.1 million to $5.4 million, an increase of 33.1%, primarily due to increased expenses associated with business development activities, increased stock-based compensation expense, and increases in personnel and related costs.

Other (Expense)/Income

(in thousands)	Three Months Ended September 30,			
	2015	2014	Change	% Change
Interest (expense)/income, net	$ (2,766)	$ 10	$ (2,776)	NM(1)
Other (expense)/income, net	(28)	82	(110)	(134.1)%
Total other (expense)/income, net	$ (2,794)	$ 92	$ (2,886)	NM(1)

(1) Not Meaningful

For the three months ended September 30, 2015, we recognized other expense of $2.8 million versus other income of $0.1 million for the same period in 2014, a change of $2.9 million. This change resulted primarily from $2.8 million of interest expense recognized on our convertible debt balance during the period.

Income Taxes

(in thousands)	Three Months Ended September 30,			
	2015	2014	Change	% Change
Provision for income taxes	$ (1,098)	$ (1,545)	$ 447	(28.9)%

Our provision for income taxes consists of current and deferred components, which include changes in our deferred tax assets (“DTAs”), our deferred tax liabilities (“DTLs”), and our valuation allowance. In the fourth quarter of 2014, we reversed the majority of the valuation allowance we had recorded against our net DTAs. The reversal was the result of our determination that it is more likely than not that we will realize the benefits of our net DTAs as a result of our expectation of future profitability, among other factors. Prior to the reversal, we had fully reserved for all our net DTAs.

For the three months ended September 30, 2015, we recognized income tax expense of $1.1 million, versus $1.5 million for the same period in 2014, a decrease of $0.4 million. Of the $1.1 million of total tax expense, $1.3 million is current expense and $0.2 million is a net deferred benefit. The effective tax rate for the three months ended September 30, 2015 was 19.4% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2015. The effective tax rate for the period was primarily driven by current quarter changes in forecasted pre-tax income, estimated permanent differences, and state income tax rates, as well as from the impact of current quarter exercises of incentive and non-qualified stock options and disqualifying dispositions of incentive stock options. The effective tax rate for the three months ended September 30, 2014 was 18.6% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2014.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2015 AND 2014

Net Revenues

(in thousands)	Nine Months Ended September 30,			
	2015	2014	Change	% Change
Generic pharmaceutical products	$ 41,122	$ 23,077	$ 18,045	78.2%
Branded pharmaceutical products	8,662	6,149	2,513	40.9%
Contract manufacturing	3,576	4,121	(545)	(13.2)%
Contract services and other income	4,927	1,586	3,341	210.7%
Total net revenues	$ 58,287	$ 34,933	$ 23,354	66.9%

Net revenues for the nine months ended September 30, 2015 were $58.3 million compared to $34.9 million for the same period in 2014, an increase of $23.4 million, or 66.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $41.1 million during the nine months ended September 30, 2015, an increase of 78.2% compared to $23.1 million for the same period in 2014. The primary reason for the increase was increased EEMT revenues, due to both increases in prices per bottle and to new customer contracts that started in the third quarter of 2015, as well as sales of Methazolamide, launched in the fourth quarter of 2014, and Etodolac and Propafenone, both of which were launched in the first quarter of 2015. We also experienced increased sales for our HC Enema product, due to price increases.

  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 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, 2015 and 2014 were $33.8 million and $19.4 million, respectively.

- Net revenues for branded pharmaceutical products were $8.7 million during the nine months ended September 30, 2015, an increase of 40.9% compared to $6.1 million for the same period in 2014. The primary reasons for the increase were 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 Reglan, due to decreased purchases by a customer, and increased Medicaid utilization and Medicaid rebates for Lithobid and Vancocin, both of which are trends we expect to continue.

- Contract manufacturing revenues were $3.6 million during the nine months ended September 30, 2015, a decrease of 13.2% compared to $4.1 million for the same period in 2014, 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 nine months ended September 30, 2015 and 2014 were $1.1 million and $0.7 million, respectively.

- Contract services and other income were $4.9 million during the nine months ended September 30, 2015, an increase of 210.7% from $1.6 million for the same period in 2014, 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. In the second quarter of 2015, our authorized generic partner for Vancocin adjusted its estimates for chargebacks, rebates, and other deductions from gross sales for the last five months of 2014, which resulted in a non-recurring $1.4 million increase in royalty revenue. In November 2015, we launched an authorized generic for Vancocin under our own label, which will replace the authorized generic product currently on the market.

  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 $0.3 million and $0.2 million for the nine month periods ended September 30, 2015 and 2014, respectively.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Nine Months Ended September 30,			
	2015	2014	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 9,152	$ 7,800	$ 1,352	17.3%

For the nine months ended September 30, 2015, cost of sales increased to $9.2 million from $7.8 million for the same period in 2014, an increase of $1.4 million or 17.3%, primarily as a result of increased sales in the period. Cost of sales as a percentage of net revenues decreased to 15.7% during the nine months ended September 30, 2015, from 22.3% during same period in 2014, primarily as a result of price increases for EEMT and a favorable shift in product mix toward higher margin products, including EEMT and our two branded products, Lithobid and Vancocin, which we acquired in the third quarter of 2014.

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 API for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections. During the nine months ended September 30, 2015, we purchased 44% of our inventory from three suppliers. As of September 30, 2015, amounts payable to these three suppliers totaled $0.7 million. In the nine months ended September 30, 2014, we purchased 43% 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,			
	2015	2014	Change	% Change
Research and development	$ 2,213	$ 2,110	$ 103	4.9%
Selling, general and administrative	15,701	13,193	2,508	19.0%
Depreciation and amortization	4,789	2,596	2,193	84.5%
Total other operating expenses	$ 22,703	$ 17,899	$ 4,804	26.8%

For the nine months ended September 30, 2015, other operating expenses increased to $22.7 million from $17.9 million for the same period in 2014, an increase of $4.8 million, or 26.8%, primarily as a result of the following factors:

- Depreciation and amortization increased from $2.6 million to $4.8 million, an increase of 84.5%, due to amortization of the product rights for Lithobid and Vancocin, which rights were purchased during the third quarter of 2014, as well as amortization of the Flecainide ANDA and the basket of ANDAs, acquired from Teva in the first and third quarters of 2015, respectively.

- Selling, general and administrative expenses increased from $13.2 million to $15.7 million, an increase of 19.0%, primarily due to increased expenses associated with business development activities, increased stock-based compensation expense, and increases in personnel and related costs, partially offset by a non-recurring $1.3 million catch-up adjustment in the second quarter of 2014 for non-cash stock-based compensation expense recognized upon shareholder approval of an increase in shares available for issuance under our stock compensation plan.

- Research and development expenses increased from $2.1 million to $2.2 million, an increase of 4.9%, due to work on development projects, including the ANDAs purchased from Teva in 2014 and 2015 and collaborations with partners.

Other (Expense)/Income, net

(in thousands)	Nine Months Ended September 30,			
	2015	2014	Change	% Change
Interest (expense)/income, net	$ (8,240)	$ 13	$ (8,253)	NM(1)
Other income, net	40	72	(32)	(44.4)%
Total other (expense)/income, net	$ (8,200)	$ 85	$ (8,285)	NM(1)

(1) Not Meaningful

For the nine months ended September 30, 2015, we recognized other expense of $8.2 million versus other income of $0.1 million for the same period in 2014, a change of $8.3 million. This change resulted primarily from $8.3 million of interest expense recognized on our convertible debt balance during the period.

Income Taxes

(in thousands)	Nine Months Ended September 30,			
	2015	2014	Change	% Change
Provision for income taxes	$ (5,733)	$ (1,577)	$ (4,156)	263.5%

Our provision for income taxes consists of current and deferred components, which include changes in our DTAs, our DTLs, and our valuation allowance. In the fourth quarter of 2014, we reversed the majority of the valuation allowance we had recorded against our net DTAs. The reversal was the result of our determination that it is more likely than not that we will realize the benefits of our net DTAs as a result of our expectation of future profitability, among other factors. Prior to the reversal, we had fully reserved for all our net DTAs.

For the nine months ended September 30, 2015, we recognized income tax expense of $5.7 million, versus $1.6 million for the same period in 2014, an increase of $4.2 million. Of the $5.7 million of total tax expense, $5.4 million is current expense and $0.3 million is net deferred expense. The effective tax rate for the nine months ended September 30, 2015 was 31.4% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2015. The effective tax rate for the period was primarily driven by changes in forecasted pre-tax income, estimated permanent differences, and state income tax rates, as well as from the impact of exercises of non-qualified stock options and disqualifying dispositions of incentive stock options. Changes in the estimated annual effective rate during the year are primarily driven by periodic changes to our forecasted pre-tax income. The effective tax rate for the nine months ended September 30, 2014 was 16.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2014.

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	September 30, 2015	December 31, 2014
Cash and cash equivalents	$ 150,913	$ 169,037
Accounts receivable, net	21,645	17,297
Inventories, net	13,741	7,518
Prepaid income taxes	972	-
Deferred tax assets, net of valuation allowance	8,266	7,643
Prepaid expenses and other current assets	1,985	1,983
Total current assets	$ 197,522	$ 203,478
Accounts payable	$ 2,633	$ 2,654
Accrued expenses and other	2,221	1,269
Accrued compensation and related expenses	1,019	1,348
Current income taxes payable	-	4,253
Accrued Medicaid rebates	4,428	2,264
Returned goods reserve	1,889	1,445
Total current liabilities	$ 12,190	$ 13,233

At September 30, 2015, we had $150.9 million in unrestricted cash and cash equivalents. At December 31, 2014, we had $169.0 million in unrestricted cash and cash equivalents. We generated $12.6 million of cash from operations in the nine months ended September 30, 2015. In the first quarter of 2015, we acquired an ANDA from Teva for $4.5 million. In the third quarter of 2015, we acquired a basket of ANDAs from Teva for $25.0 million.

In September 2015, we entered into an asset purchase agreement with Merck Sharp & Dohme B.V. to purchase, subject to typical closing conditions including regulatory approvals, certain NDAs and associated product rights and manufacturing licenses for $75.0 million in cash and a percentage of future net sales of the products under the NDAs. The asset acquisition is expected to close in January 2016. We anticipate that we will make the $75.0 million cash payment using cash on hand.

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

We believe that our financial resources, consisting of current working capital 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,	
	2015	2014
Operating Activities	$ 12,562	$ 11,292
Investing Activities	$ (31,578)	$ (35,416)
Financing Activities	$ 892	$ 48,069

Net Cash Provided By Operations

Net cash provided by operating activities was $12.6 million for the nine months ended September 30, 2015, compared to $11.3 million during the same period in 2014, an increase of $1.3 million between the periods. This increase was due to changes in net income, partially offset by changes in current assets and current liabilities. Net income from operations for the nine months ended September 30, 2015 increased by $12.2 million from the same period in 2014, after adjusting for non-cash expenses.

Changes in current assets and current liabilities for the nine months ended September 30, 2015 used $12.7 million of cash compared to $1.8 million in the same period in 2014, a difference of approximately $10.9 million between the periods. Inventory increased $6.2 million in the nine months ended September 30, 2015 as compared with an increase of $3.3 million in the prior year period. Changes in current income taxes, net were a $5.2 million use of cash in the nine months ended September 30, 2015, as compared with providing $1.1 million in the prior year period. Accounts receivable increased by $4.3 million in the nine months ended September 30, 2015 as compared with an increase of $2.1 million in the prior year period. Accounts payable decreased by $0.1 million in the nine months ended September 30, 2015 as compared with an increase of $0.6 million in the prior year period. Accrued compensation and related expenses decreased by $0.3 million in the nine months ended September 30, 2015, as compared with a decrease of $40 thousand in the prior year period. These increases to cash used were partially offset by a $2.2 million increase in accrued Medicaid rebates in the nine months ended September 30, 2015, as compared with a $1.0 million increase in the prior year period, as well as a $1.4 million increase in accrued expense, returned goods, and other, as compared with a $0.9 million increase in the prior year period.

Net Cash Used In Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2015 was $31.6 million, principally due to the March 2015 $4.5 million asset acquisition of the ANDA for Flecainide Acetate tablets, the July 2015 asset acquisition of a basket of ANDAs for $25.0 million, the August 2015 payment of $1.0 million for marketing and distribution rights, and $1.1 million of capital expenditures during the period. Net cash used in investing activities was $35.4 million during the same period in 2014, relating primarily to the $12.5 million asset acquisition from Teva of ANDAs related to 31 generic products, $22 million in asset purchases related to Lithobid and Vancocin, and $0.8 million of capital expenditures during the period.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $0.9 million for the nine months ended September 30, 2015, resulting primarily from $0.7 million of proceeds from stock option exercises and $0.2 million of excess tax benefit from stock-based compensation awards. Net cash provided by financing activities was $48.1 million during the same period in 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, $0.4 million of excess tax benefit from stock-based compensation awards, and $0.2 million from warrant exercises during the nine months ended September 30, 2014.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited interim condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our unaudited 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, income tax provision, 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, 2014. 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, 2014.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

In May 2014, the Financial Accounting Standards Board (“FASB”) issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

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

In April 2015, the FASB issued guidance to simplify the balance sheet disclosure for debt issuance costs. Under the guidance, debt issuance costs related to a recognized debt liability will be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, in the same manner as debt discounts, rather than as an asset. The standard is effective for reporting periods beginning after December 15, 2015 and early adoption is permitted. The adoption of this new accounting pronouncement will result in a reclassification of deferred financing costs from assets to contra-liabilities.

In July 2015, the FASB issued guidance for inventory. Under the guidance, an entity should measure inventory within the scope of this guidance at the lower of cost and net realizable value, except when inventory is measured using LIFO or the retail inventory method. Net realizable value is the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. In addition, the FASB has amended some of the other inventory guidance to more clearly articulate the requirements for the measurement and disclosure of inventory. The standard is effective for reporting periods beginning after December 15, 2016. The amendments in this pronouncement should be applied prospectively, with earlier application permitted. We are currently evaluating the impact, if any, that this new accounting pronouncement will have on our financial statements.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2015 and December 31, 2014, 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

As of September 30, 2015, our only debt obligation was related to our Notes. In order to reduce the potential equity dilution that would result upon conversion of the Senior Convertible Notes we issued in December 2014, we entered into note hedge transactions with a financial institution affiliated with one of the underwriters of the Senior Convertible Note offering. The note hedge transactions are expected generally, but not guaranteed, to reduce the potential dilution to our common stock and/or offset the cash payments we are required to make in excess of the principal amount upon any conversion of Senior Convertible Notes, in the event that the market price per share of our common stock, as measured under the terms of the Convertible Note Hedge Transactions, is greater than the conversion price of the Senior Convertible Notes, which is initially approximately $69.48. In addition, in order to partially offset the cost of the note hedge transactions, we issued warrants to the hedge counterparty to purchase approximately 2.1 million shares of our common stock at a strike price of $96.21. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock exceeds the strike price of the warrants. In addition, non-performance by the counterparties under the hedge transactions would potentially expose us to dilution of our common stock to the extent our stock price exceeds the conversion price.

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

We are exposed to risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the three and nine months ended September 30, 2015 by approximately $3 thousand and $10 thousand, respectively.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of September 30, 2015. 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, 2015 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, 2014 under the heading "Part I — Item 1A. Risk Factors." The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition and/or operating results. There have been no material changes to those risk factors since their disclosure in our most recent annual report on Form 10-K.

Item 2. Unregistered Sales of Equity and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits

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

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 3, 2015

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

Date: November 3, 2015

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

INDEX TO EXHIBITS

Exhibit No.	Description
10.1*	Asset Purchase Agreement between Teva Pharmaceuticals, Inc. and ANI Pharmaceuticals, Inc. Dated as of July 10, 2015.
10.2*	Asset Purchase Agreement between Merck Sharp & Dohme B.V. and ANI Pharmaceuticals, Inc. Dated as of September 18, 2015.
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: [***]

AMENDMENT NO. 2 TO ASSET PURCHASE AGREEMENT

This Amendment No. 2 to Asset Purchase Agreement is dated as of July 10, 2015 (the "**Amendment**") and is by and between Teva Pharmaceuticals USA, Inc., a Delaware corporation and those of its affiliates that own the Amendment No. 2 ANDAs (as defined below) (collectively, "**Teva**"), on the one hand, and ANI Pharmaceuticals, Inc., a Delaware corporation ("**Buyer**") on the other hand.

WHEREAS, Buyer and Teva are parties to that certain Asset Purchase Agreement effective as of December 26, 2013, as amended by Amendment No. 1 (defined below) (the "**Original Agreement**"), pursuant to which Buyer acquired the Purchased Assets from Teva;

WHEREAS, Buyer and Teva entered into Amendment No. 1 to Asset Purchase Agreement as of March 4, 2015 ("**Amendment No. 1**"), pursuant to which Buyer acquired the New ANDAs from Teva on the same terms and conditions as the Original Agreement, except for changes required to reflect (i) the date of the purchase of the New Purchased Assets thereunder, (ii) the payment of the Third Payment upon execution of the New Bill of Sale and (iii) a different Royalty percentage to be paid with respect to the New Products under the New ANDAs, in each case as reflected in Amendment No. 1 (with all such capitalized terms having the same meaning as defined in Amendment No. 1);

WHEREAS, Teva owns those additional ANDAs that are set forth on Exhibit A hereto (the "**Amendment No. 2 ANDAs**"), with respect to the generic pharmaceutical products set forth on such Exhibit A (the "**Amendment No. 2 Products**") that Buyer also wishes to acquire on and pursuant to the terms of the Original Agreement, as amended hereby; and

WHEREAS, Teva has agreed to sell Buyer the Amendment No. 2 ANDAs pursuant to the terms of the Original Agreement as amended hereby.

NOW, THEREFORE, in consideration of the mutual covenants and conditions hereinafter expressed, Buyer and Teva agree as follows:

1. Upon the terms and subject to the conditions of the Original Agreement and this Amendment, as promptly as practicable, but in no event later than ten (10) Business Days after the date hereof, (A) Teva will transfer, sell, convey, assign and deliver to Buyer the Amendment No. 2 ANDAs and the related documents whether in paper or electronic form the related documents, only to the extent made available to Buyer for inspection at its Horsham, PA site on June 23, 2015 (the "**Amendment No. 2 Purchased Assets**") and Buyer will purchase, accept and assume, all of Teva's right, title and interest in and to the Amendment No. 2 Purchased Assets and (B) the Parties shall execute and deliver a Bill of Sale with respect to such Amendment No. 2 Purchased Assets, in the form attached hereto as Exhibit B (the "**Amendment No. 2 Bill of Sale**").

2. Upon execution of the Amendment No. 2 Bill of Sale and delivery by Teva of the Amendment No. 2 Purchased Assets to Buyer in accordance with Section 1, Buyer shall pay to Teva, by wire transfer of immediately available funds into an account designated in writing to Buyer by Teva, the sum of Twenty Five Million U.S. Dollars ($25,000,000) (the "**Amendment No. 2 Payment**").

3. From and after the delivery of the Amendment No. 2 Payment, with respect to the Amendment No. 2 Purchased Assets, Buyer will be in control of and responsible for the Liabilities involving the Amendment No. 2 Products, as set forth in Section 5 of the Original Agreement, *mutatis mutandis*.

4. Undefined capitalized terms used herein shall have the meanings ascribed to them in the Original Agreement; provided, however, that it is understood and agreed that the following definitions are hereby further amended as follows:

a. The term "**ANDAs**" shall include the Amendment No. 2 ANDAs from and after the date hereof.

b. The term "**Assumed Liabilities**" shall include the Liabilities set forth in Section 4 of the Original Agreement with respect to the Amendment No. 2 Purchased Assets from and after the date hereof.

c. The term "**Bill of Sale**" shall include the Amendment No. 2 Bill of Sale from and after the date hereof.

d. The term "**Products**" shall include the Amendment No. 2 Products from and after the date hereof.

e. The term "**Purchased Assets**" shall include the Amendment No. 2 Purchased Assets from and after the date hereof.

f. The term "**Up-Front Payments**" shall include the Amendment No. 2 Payment from and after the date hereof.

g. For purposes of Sections 6(c) and 6(e) of the Original Agreement only, the date hereof shall be deemed the "**Effective Date**" with respect to the Amendment No. 2 ANDAs and the Amendment No. 2 Purchased Assets.

5. It is understood and agreed that with respect to the Amendment No. 2 Products, the Royalty, as set forth in the Original Agreement, including Exhibit C thereof, shall be equal to [***] percent ([***]%) and that the Royalty Term shall be from Product Year One through Product Year [***].

6. Each of Teva and Buyer restate the representations and warranties set forth in Section 7 of the Original Agreement as of the date hereof (which, for purposes of clause (b) thereof, shall be limited to the Amendment No. 2 Purchased Assets) and agree that they shall survive and remain operative and in full force and effect for a period of twelve (12) months following the date hereof.

7. Teva shall dispatch a letter to FDA in the form set forth in Exhibit D of the Original Agreement with respect to the Amendment No. 2 ANDAs, with such changes as may be applicable to reflect the transactions contemplated by this Amendment, within five (5) Business Days after Buyer's payment to Teva of the Amendment No. 2 Payment.

8. Within five (5) days after Teva has sent the letter referenced in Section 7 hereof, Buyer shall send a letter to the FDA indicating that the transfer from Teva of the Amendment No. 2 ANDAs has been accepted by the Buyer and that the Buyer is the new owner of the Amendment No. 2 ANDAs as of the date hereof, and Buyer shall promptly provide Teva with a copy of said letter.

9. The recitals set forth above are deemed incorporated herein and a part hereof. All necessary conforming changes to the Original Agreement occasioned by reason of this Amendment are hereby deemed to be made. Except as amended hereby, the Original Agreement shall remain in full force and effect and is in all respects hereby ratified and affirmed.

10. This Amendment may be executed in two or more counterparts, each of which shall be deemed an original bit all of which, taken together, shall constitute one and same instrument. PDF and facsimile signatures shall constitute original signatures.

[The remainder of this page is intentionally left blank]

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first written above.

TEVA PHARMACEUTICALS USA, INC.

By: /s/ Vikram Seoni
Name: Vikram Seoni
Title: SVP, BD & Alliance MGMT

By: /s/ Brian McCrudden
Name: Brian McCrudden
Title: Sr. Director, Alliance MGMT

ANI PHARMACEUTICALS, INC.

By: /s/ Charlotte Arnold
Name: Charlotte Arnold
Title: Vice President & CFO

Exhibit A

ANDA#	Molecule	Form	Strength
065190	Cefuroxime Axetil	Tablets	250, 500 mg
084910, 085032, 085031 085030	Amitriptyline Hydrochloride	Tablets	10, 25, 50, 75 mg
074085	Alprazolam*	Tablets	0.25, 0.5, 1, 2 mg
070028	Sulfamethoxazole / Trimethoprim*	Oral Suspension	200/5, 40/5 mg/mL
084975, 084657	Meclizine Hydrochloride	Tablets	12.5, 25 mg
077396	Lorazepam*	Tablets	0.5, 1, 2 mg
086727	Diphenoxylate HCI / Atropine Sulfate	Tablets	2.5/0.025 mg
074387, 074497	Glipizide	Tablets	5, 10 mg
075898, 075897	Fluvoxamine Maleate*	Tablets	25, 50, 100 mg
040512	Pyridostigmine Bromide*	Tablets	30, 60 mg
074498, 074299	Indapamide	Tablets	1.25, 2.5 mg
072972, 072973	Sulindac	Tablets	150, 200 mg
074970, 073467	Triamterene / HCTZ	Tablets	37.5/25 mg
062055	Erythromycin Ethylsuccinate		
070869, 070870	Acetohexamide	Tablets	250, 500 mg
074554	Cholestyramine	Oral Susp.	4 g/packet 4 g/scoop
073282	Clemastine Fumarate	Tablets	1.34 mg
071144	Ibuprofen	Tablets	200 mg
072901	Ibuprofen	Tablets (0.406" round diameter)	200 mg
072903	Ibuprofen	Tablets (Caplets)	200 mg
062222	Oxacillin Sodium	Capsules	250, 500 mg
083734	Probenecid / Colchicine	Tablets	500/0.5 mg
070704, 070705	Propranolol HCl / HCTZ	Tablets	40/25, 80/25 mg
072042, 072043	Propranolol HCl / HCTZ	Tablets	40/25, 80/25 mg
080142	Sulfisoxazole	Tablets	500 mg

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: [***]

Exhibit B

Form of Amendment No. 2 Bill of Sale

THIS BILL OF SALE (the "Amendment No. 2 Bill of Sale"), dated as of July 10, 2015, is made and delivered by Teva Pharmaceuticals USA, Inc., a corporation organized under the laws of the State of Delaware and those of its affiliates that own the Amendment No. 2 ANDAs (as defined in the Amendment) ("Teva"), to ANI Pharmaceuticals, Inc., a company organized under the laws of the State of Delaware ("Purchaser"), (each a "Party", collectively the "Parties").

WHEREAS, pursuant to that certain asset purchase agreement, dated as of December 26, 2013, by and between Teva and Purchaser, as amended by Amendment No. 1 to the Asset Purchase Agreement, dated as of March 4, 2015 (the "Purchase Agreement") and as further amended by Amendment No. 2 to the Asset Purchase Agreement, dated as of July 10, 2015 (such Amendment No. 2, the "Amendment"), Teva has agreed to transfer, sell, convey, assign and deliver to Purchaser, and Purchaser has agreed to purchase, accept and assume as of the date hereof, all right, title and interest, within the Territory, of the Amendment No. 2 Purchased Assets (as defined in the Amendment); and

WHEREAS, the Parties desire to deliver to each other such instruments as are required in order to effectuate and evidence the sale by Teva and purchase by Purchaser of the Amendment No. 2 Purchased Assets.

NOW, THEREFORE, in consideration of the premises and in accordance with the provisions of the Purchase Agreement, as amended by the Amendment and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, Teva and Purchaser hereby each agree as follows:

1. The terms of the Purchase Agreement, as amended by the Amendment are incorporated herein by reference and capitalized terms used but not defined in this Amendment No. 2 Bill of Sale shall have the meanings ascribed thereto in the Purchase Agreement, as amended by the Amendment.

2. Teva hereby irrevocably and unconditionally transfers, sells, conveys, assigns, and delivers to Purchaser, and Purchaser hereby irrevocably and unconditionally purchases, accepts and assumes, all of Teva's right, title and interest, within the Territory, in and to all of the Amendment No. 2 Purchased Assets, free and clear of any liens, charges or other encumbrances.

3. The Parties, their respective divisions, subsidiaries, officers, directors, employees, stockholders, agents, representatives, advisors, consultants, attorneys, independent contractors and successors and assigns hereby release and discharge the other and their respective Affiliates, divisions, subsidiaries, officers, directors, employees, stockholders, agents, representatives, advisors, consultants, attorneys, independent contractors and successors and assigns, from any and all claims, causes of actions, obligations, investigations, demands, suits and/or liabilities, of any nature whatsoever, whether asserted or unasserted, known or unknown, or suspected or unsuspected to exist from the beginning of time, in any way arising under or in any way relating to the Amendment No. 2 Purchased Assets, except with respect to fraud or any representation, warranty or covenant expressly made by it in the Purchase Agreement, as amended by the Amendment.

4. All of the terms and provisions of this Amendment No. 2 Bill of Sale shall be binding upon Teva and its successors and assigns, and shall be binding upon Purchaser and its successors and assigns.

5. This Amendment No. 2 Bill of Sale and any all matters arising directly or indirectly herefrom shall be governed by and construed and enforced in accordance with the laws of the State of New York, U.S.A. applicable to agreements made and to be performed entirely in such State.

6. It is acknowledged and agreed that this Amendment No. 2 Bill of Sale is intended to document the sale and assignment of the Amendment No. 2 Purchased Assets to Purchaser.

7. This Amendment No. 2 Bill of Sale may be executed by PDF and in one or more counterparts, each of which shall be deemed an original and all of which together shall constitute a single instrument.

IN WITNESS WHEREOF, the undersigned have executed this Amendment No. 2 Bill of Sale as of the date first set forth above.

TEVA PHARMACEUTICALS USA, INC.

By: /s/ Vikram Seoni
Name: Vikram Seoni
Title: SVP, BD & Alliance MGMT

By: /s/ Brian McCrudden
Name: Brian McCrudden
Title: Sr. Director, Alliance MGMT

ANI PHARMACEUTICALS, INC.

By: /s/ Charlotte Arnold
Name: Charlotte Arnold
Title: Vice President & CFO

Exhibit 10.2

EXECUTION

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

By and between

MERCK SHARP & DOHME B.V.

and

ANI PHARMACEUTICALS, INC.

Dated as of September 18, 2015

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

SCHEDULES

INDEX OF DEFINED TERMS

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 made and executed as of September 18, 2015 (the "**Effective Date**"), by and between Merck Sharp & Dohme B.V., a limited liability company (*a Besloten Vennootschap*) organized and existing under the Laws of the Netherlands ("**Seller**"), and ANI Pharmaceuticals, Inc., a Delaware corporation ("**Buyer**"). Seller and Buyer are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Seller wishes to sell and transfer to Buyer, and Buyer desires to purchase and assume from Seller, the Purchased Assets and the Assumed Liabilities, upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Agreement and of the representations, warranties, conditions, agreements and promises contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

DEFINITIONS

1.1 Certain Defined Terms. As used herein, the following terms shall have the following meanings:

1.1.1 "**Accountants**" means an accounting firm of national reputation in the United States (excluding each of Seller's and its Affiliates' and Buyer's and its Affiliates' respective regular outside accounting firms) mutually acceptable to Seller and Buyer; *provided*, *however*, if Seller and Buyer are unable to agree on such accounting firm within 10 calendar days or any such mutually selected accounting firm is unwilling or unable to serve, then Seller shall deliver to Buyer a list of three other accounting firms of national reputation in the United States that have not performed services for Seller or its Affiliates or Buyer or its Affiliates in the preceding three years, and Buyer shall select one of such three accounting firms.

1.1.2 "**Act**" means the United States Federal Food, Drug, and Cosmetic Act.

1.1.3 "**Affiliate**" means, with respect to a Person, any other Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with such first Person. For purposes of this definition, "control" and, with correlative meanings, the terms "controlled by" and "under common control with" mean (a) the possession, directly or indirectly, of the power to direct the management or policies of a business entity, whether through the ownership of voting securities, by contract relating to voting rights or corporate governance, or otherwise or (b) the ownership, directly or indirectly, of at least 50% of the voting securities or other ownership interest of a business entity (or, with respect to a limited partnership or other similar entity, its general partner or controlling entity).

1.1.4 "**Ancillary Agreements**" means the Bill of Sale and the Trademark Assignment.

1.1.5 "**Assumed Liabilities**" means all Liabilities of Seller or any of its Affiliates under or relating to the Purchased Assets and all Liabilities arising out of or related to the Exploitation of the Products or the exercise by Buyer, its Affiliates or any Sublicensee of the license to the Licensed Manufacturing Technology granted pursuant to Section 5.11, in each case, excluding the Excluded Liabilities.

1.1.6 "**Bill of Sale**" means that certain Bill of Sale and Assignment and Assumption Agreement, in substantially the form of Exhibit A.

1.1.7 "**Business Day**" means any day other than Saturday, Sunday or a day on which banking institutions in New York, New York are permitted or obligated by Law to remain closed.

1.1.8 "**Buyer FDA Transfer Letters**" means the letters to the FDA in the form of Exhibit B, indicating Buyer's acceptance of the rights to the Purchased Regulatory Approvals from Seller.

1.1.9 "**Buyer Material Adverse Effect**" means any event, fact, condition, occurrence, change or effect that prevents the consummation by Buyer of the transactions contemplated by this Agreement or the Ancillary Agreements.

1.1.10 "**Buyer Related Party**" means any licensee or sublicensee of Buyer or any of Buyer's Affiliates.

1.1.11 "**Calendar Quarter**" means the respective periods of three consecutive calendar months ending on March 31, June 30, September 30 and December 31, except that the first Calendar Quarter under this Agreement with respect to a Product shall commence on the date of the First Commercial Sale thereof and end on the first March 31, June 30, September 30 or December 31 to occur after such date.

1.1.12 "**Calendar Year**" means each successive period of 12 calendar months commencing on January 1 and ending on December 31, except that the first Calendar Year under this Agreement with respect to a Product shall commence on the on the date of the First Commercial Sale thereof and end on December 31 of the year in which such date occurs.

1.1.13 "**Closing Date**" means the date on which the Closing occurs in accordance with Section 2.4.1.

1.1.14 "**Code**" means the Internal Revenue Code of 1986.

1.1.15 "**Combination Product**" means any pharmaceutical product containing as active ingredients (a) an active ingredient in Corticotropin or Corticotropin Zinc Hydroxide and (b) one or more other pharmaceutically active ingredients.

1.1.16 "**Competition Laws**" means the HSR Act and other similar Laws of any jurisdiction that are designed or intended to prohibit, restrict or regulate actions having an anticompetitive effect or purpose.

1.1.17 "**Confidentiality Agreement**" means that certain Three-Way Confidential Disclosure Agreement, dated March 2, 2015, by and among Merck Sharp & Dohme Corp., [***] and ANI Pharmaceuticals, Inc.

1.1.18 "**Contract**" means any contract, agreement, lease, sublease, license, sublicense or other legally binding commitment or arrangement.

1.1.19 "**Corticotropin**" means the strengths and package sizes and types of the pharmaceutical product specified in NDA #8975, including all supplements thereto.

1.1.20 "**Corticotropin Zinc Hydroxide**" means the strengths and package sizes and types of the pharmaceutical product specified in NDA #9854, including all supplements thereto.

1.1.21 "**Diligent Efforts**" means [***].

1.1.22 "**Disclosure Schedules**" means the disclosure schedules of Seller related to the representations and warranties of Seller set forth in Section 3.1.

1.1.23 "**Excluded Assets**" means the Licensed Manufacturing Technology and all other assets, property, rights and interests of Seller and its Affiliates other than the Purchased Assets.

1.1.24 "**Excluded Liabilities**" means all Liabilities of Seller or any of its Affiliates to the extent arising out of units of Products manufactured or sold prior to the Closing Date.

1.1.25 "**Exploit**" or "**Exploitation**" means to make, have made, manufacture, import, export, use, sell, offer for sale, have sold, research, develop, commercialize, hold or keep (whether for disposal or otherwise), transport, distribute, promote, market, or otherwise dispose of.

1.1.26 "**FDA**" means the United States Food and Drug Administration and any successor agency thereto.

1.1.27 "**First Commercial Sale**" means, with respect to a Subject Product, the first purchase and sale for monetary value to any Third Party (other than a Buyer Related Party) after the Closing Date.

1.1.28 "**GAAP**" means generally accepted accounting principles in the United States, consistently applied.

1.1.29 "**Governmental Authority**" means any supranational, international, federal, state or local court, administrative agency or commission or other governmental authority or instrumentality, domestic or foreign, including the FDA and any corresponding foreign agency.

1.1.30 "**HSR Act**" means the U.S. Hart-Scott-Rodino Antitrust Improvements Act of 1976.

1.1.31 "**Intellectual Property**" means any or all rights in and to intellectual property, whether owned or held for use, including (a) patents, inventions, invention disclosures, discoveries and improvements, whether or not patentable, Trade Secrets, copyrights, Trademarks and domain names or uniform resource locators, in each case including any registrations of, applications or register and renewals, modifications and extensions of, any of the foregoing, with or by any Governmental Authority in the United States or, the case of domain names or uniform resource locators, with or by any registry of the same and (b) any rights equivalent to any of the foregoing anywhere in the United States.

1.1.32 "**Law**" means any domestic or foreign, federal, state or local statute, law, treaty, judgment, ordinance, rule, administrative interpretation, regulation, order or other requirement having the force of law of any Governmental Authority.

1.1.33 "**Liabilities**" means any debts, liabilities, obligations, commitments, claims or complaints, whether accrued or fixed, known or unknown, fixed or contingent, determined or determinable (including all adverse reactions, recalls, product and packaging complaints and other liabilities) and whether or not the same would be required to be reflected in financial statements or disclosed in the notes thereto.

1.1.34 "**Licensed Manufacturing Technology**" means all technical, scientific and other know-how and information described on Schedule 1.1.34.

1.1.35 "**Liens**" means, with respect to any Purchased Asset, any lien, security interest, mortgage, pledge, assessment, hypothecation, easement, title retention clause, or other encumbrance, or any Contract to give any of the foregoing.

1.1.36 "**Litigation**" means any claim, action, arbitration, mediation, hearing, proceeding, suit, warning letter, or notice of violation.

1.1.37 "**Loss**" or "**Losses**" means any Liabilities, losses, damages, judgments, fines, penalties, amounts paid in settlement and reasonable costs and expenses incurred in connection therewith, including reasonable costs and expenses of suits and proceedings, and reasonable fees and disbursements of counsel.

1.1.38 "**Material Adverse Effect**" means an event, fact, condition, occurrence, change or effect ("**Effect**") that, considered together with all other Effects, (a) is, or would reasonably be expected to be, materially adverse to the Purchased Assets and the Assumed Liabilities, taken as a whole, or (b) prevents the consummation by Seller of the transactions contemplated by this Agreement or the Ancillary Agreements; *provided*, *however*, that none of the following, and no Effects resulting from the following, shall be deemed (individually or in combination) to constitute, or shall be taken into account in determining whether there has been, a "Material Adverse Effect": (i) political or economic conditions or conditions affecting the capital or financial markets generally; (ii) conditions generally affecting any industry or industry sector in which the Products, individually or in the aggregate, are Exploited, including increases in operating costs; (iii) any change in accounting requirements or applicable Law; (iv) any hostility, act of war, sabotage, terrorism or military actions, or any escalation of any of the foregoing; (v) any hurricane, flood, tornado, earthquake or other natural disaster or force majeure event; (vi) the failure of the Products, individually or in the aggregate, to achieve any financial projections, predictions or forecasts (*provided*, that the underlying causes of such failure shall not be excluded); (vii) the public announcement, execution or delivery of this Agreement or the pendency of the transactions contemplated hereby; (viii) Seller's or any of its Affiliates' actions to the extent (A) required by the terms and conditions of this Agreement, (B) that Buyer has requested in writing Seller or its Affiliates take such actions or (C) to which Buyer has consented in writing; and (ix) any matter attributable to the regulatory status of Buyer or any of its Affiliates; except, in each of clauses (i) through (iii), for those Effects that have a disproportionate effect on the Purchased Assets and Assumed Liabilities, taken as a whole, relative to other Persons operating businesses in the industry or industry sector in which the Products, individually or in the aggregate, are Exploited.

1.1.39 "**NDA**" means a New Drug Application as defined in the Act.

1.1.40 "**Net Sales**" means the gross invoice price (not including value added Taxes, sales Taxes, or similar Taxes) of Subject Product sold by a Payment Obligor to a Third Party (other than a Buyer Related Party) after deducting, if not previously deducted, from the amount invoiced or received:

(a) trade and quantity discounts other than early payment cash discounts;

(b) returns, recalls, rebates, chargebacks and other allowances;

(c) retroactive price reductions that are actually allowed or granted; and

(d) early payment cash discounts, transportation and insurance and custom duties.

Notwithstanding the foregoing, transfers or dispositions of Subject Products by or on behalf of Buyer or any of its Affiliates for patient assistance programs, research or development or complimentary samples shall not in each case be deemed "sales" for the purposes of calculating Net Sales.

1.1.41 "**Payment Obligor**" means Buyer, its Affiliates, and each of Buyer's and its Affiliates' licensees, sublicensees and distributors with respect to any Subject Product.

1.1.42 "**Permitted Lien**" means any (a) Lien approved in writing by Buyer as a Permitted Lien, (b) title defect or irregularity affecting the Purchased Assets, that, individually or in the aggregate, would not reasonably be expected to detract from the value or impair the use of the asset subject thereto, (c) Lien for Taxes not yet due or delinquent, and (d) Lien caused by Law for amounts not material or overdue that does not or would not be reasonably expected to materially detract from the current value of, or materially interfere with, the present use and enjoyment of any Purchased Asset subject thereto.

1.1.43 "**Person**" means any individual, partnership, limited partnership, limited liability company, joint venture, syndicate, sole proprietorship, corporation, unincorporated association, trust, trustee, executor, administrator or other legal personal representative, or any other legal entity, including a Governmental Authority.

1.1.44 "**Products**" means, collectively, Corticotropin and Corticotropin Zinc Hydroxide, and "**Product**" means either of the foregoing.

1.1.45 "**Purchase Price**" means the sum of the Closing Payment, and to the extent actually paid by Buyer in accordance with Section 2.3.2, the Contingent Payments.

1.1.46 "**Purchased Documents**" means the documents set forth on Schedule 1.1.46.

1.1.47 "**Purchased Regulatory Approvals**" means NDA #8975 and NDA #9854 and all supplements to either such NDA.

1.1.48 "**Purchased Trademark Applications**" means, collectively, U.S. Trademark application for the Trademark CORTROPHIN, U.S. Serial No. 86534100 and the U.S. Trademark application for the Trademark CORTROPHIN-ZINC, U.S. Serial No. 86534102, both for "medicinal hormone preparation."

1.1.49 "**Seller FDA Transfer Letters**" means the letters to the FDA in the form of Exhibit C, transferring the rights to the Purchased Regulatory Approvals to Buyer.

1.1.50 "**Seller's Knowledge**" means the actual knowledge the individuals listed on Schedule 1.1.50 have or would have following reasonable inquiry into the subject matter in the course of performing their respective duties.

1.1.51 "**Subject Products**" means, collectively, (a) the Products, (b) Combination Products and (c) any line extensions, synthetic versions, other administration forms, presentations, dosages, formulations, back-ups, improvements or next generation products for or of any Product or Combination Product, whether prescription or over-the-counter; *provided*, that any product described in any of the preceding clauses (a) through (c) that is sold by a Payment Obligor to a Third Party (other than a Buyer Related Party) in any country outside of the U.S. Territory shall be a Subject Product only if the regulatory approval pursuant to which such product is distributed, marketed or sold references, incorporates or relies upon, in whole or in material part, any of the Purchased Assets, including any data contained therein.

1.1.52 "**Tax Return**" means any return, declaration, report, claim for refund, information return or statement relating to Taxes, including any schedule or attachment thereto, filed or maintained, or required to be filed or maintained, in connection with the calculation, determination, assessment or collection of any Tax and includes any amended returns required as a result of examination adjustments made by the Internal Revenue Service or other Tax authority.

1.1.53 "**Taxes**" means all taxes of any kind including all U.S. federal, state, local or non-U.S. net income, capital gains, gross income, gross receipt, property, franchise, sales, use, excise, withholding, payroll, employment, social security, worker's compensation, unemployment, occupation, capital stock, transfer, gains, windfall profits, net worth, asset, transaction and other taxes, and any interest, penalties or additions to tax with respect thereto, imposed upon any Person by any taxing authority or other Governmental Authority under applicable Law.

1.1.54 "**Territory**" means worldwide.

1.1.55 "**Third Party**" means any Person other than Seller, Buyer and their respective Affiliates and permitted successors and assigns.

1.1.56 "**Trademark**" means any word, name, symbol, color, product shape, designation or device or any combination thereof that functions as a source identifier, including any trademark, trade dress, brand mark, service mark, trade name, brand name, product configuration, logo or business symbol, whether or not registered, and all goodwill associated therewith and symbolized thereby.

1.1.57 "**Trademark Assignment**" means that certain Trademark Assignment Agreement, in substantially the form of Exhibit D.

1.1.58 "**Trade Secret**" means information that derives independent economic value from not being generally known to, and not being readily ascertainable by proper means by, other Persons that can obtain economic value from its disclosure or use.

1.1.59 "**U.S. Territory**" means the United States and its territories and possessions.

1.2 Construction. Except where the context otherwise requires, wherever used, the singular includes the plural, the plural the singular, the use of any gender shall be applicable to all genders and the word "or" is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein does not limit the generality of any description preceding such term. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party. Unless otherwise specified or where the context otherwise requires, (a) references in this Agreement to any Article, Section, Schedule or Exhibit are references to such Article, Section, Schedule or Exhibit of this Agreement; (b) references in any Section to any clause are references to such clause of such Section; (c) "hereof," "hereto," "hereby," "herein" and "hereunder" and words of similar import when used in this Agreement refer to this Agreement as a whole and not to any particular provision of this Agreement; (d) references to a Person are also to its permitted successors and assigns; (e) references to a Law include any amendment or modification to such Law and any rules or regulations issued thereunder, in each case, as in effect at the relevant time of reference thereto; (f) references to any agreement, instrument or other document in this Agreement refer to such agreement, instrument or other document as originally executed or, if subsequently amended, replaced or supplemented from time to time, as so amended, replaced or supplemented and in effect at the relevant time of reference thereto; (g) "extent" in the phrase "to the extent" means the degree to which a subject or other thing extends, and such phrase does not mean simply "if"; and (h) references to monetary amounts are denominated in United States Dollars.

SALE AND PURCHASE OF ASSETS AND LIABILITIES

2.1 Sale of Purchased Assets.

2.1.1 Purchase and Sale of Purchased Assets. Upon the terms and subject to the conditions of this Agreement and the Ancillary Agreements, at and effective as of the Closing, Seller shall (or shall cause its applicable Affiliates to) sell, transfer, convey, assign and deliver to Buyer, and Buyer shall purchase and accept from Seller (or such Affiliates), all rights and interests of Seller or its Affiliates to or in the following (collectively, the "**Purchased Assets**"), free and clear of any Liens other than Permitted Liens:

(a) the Purchased Regulatory Approvals;

(b) the Purchased Documents; and

(c) the Purchased Trademark Applications.

2.1.2 Excluded Assets. Buyer shall not acquire pursuant to this Agreement or any Ancillary Agreement, and Seller shall retain following the Closing, the Excluded Assets.

2.2 Liabilities.

2.2.1 Assumed Liabilities. Upon the terms and subject to the conditions of this Agreement, at the Closing, Seller shall assign and Buyer shall unconditionally assume and agree to pay and discharge when due the Assumed Liabilities.

2.2.2 Excluded Liabilities. Buyer shall not assume any Liabilities of Seller or any of its Affiliates other than the Assumed Liabilities, including the Excluded Liabilities, and the Excluded Liabilities shall remain the sole obligation and responsibility of Seller and its Affiliates.

2.3 Consideration.

2.3.1 Consideration. In consideration for the Purchased Assets, Buyer shall pay to Seller (a) Seventy Five Million Dollars ($75,000,000) (the "**Closing Payment**") to be paid on the Closing Date by wire transfer of immediately available funds to the account or accounts designated by Seller by written notice to Buyer, and (b) the Contingent Payments, as and to the extent provided in Section 2.3.2.

2.3.2 Contingent Consideration.

(a) Buyer shall pay to Seller as additional consideration hereunder a percentage of Net Sales of all Subject Products in the Territory in each Calendar Year as set forth on Schedule 2.3.2(a) (each, a "**Contingent Payment**").

(b) Buyer shall pay Seller the applicable Contingent Payments within 30 calendar days after the end of each Calendar Quarter. All calculations of Contingent Payments shall be subject to quarterly adjustments by Buyer following the preparation of its unaudited quarterly financial statements as follows:

(i) In the event Buyer determines that it made Contingent Payments to Seller in respect of any prior Calendar Quarter in excess of the correct Contingent Payment applicable thereto, Buyer shall promptly advise Seller of its determination and, subject to Section 2.3.4(g) below, shall be entitled to deduct the amount of such overpayments from the Contingent Payments due to Seller for the following Calendar Quarter (and, if applicable, successive Calendar Quarters until the amount of the overpayment has been reduced to $0).

(ii) In the event Buyer determines that additional Contingent Payments are due to Seller in respect of the Contingent Payments applicable to any prior Calendar Quarter, then it shall promptly advise Seller of its determination and, subject to Section 2.3.4(g) below, pay over such amounts to Seller no later than (A) 30 calendar days following Buyer's filing of its unaudited quarterly financial statements with the U.S. Securities and Exchange Commission or (B) if Buyer is not required to file financial statements with the U.S. Securities and Exchange Commission, no later than 75 calendar days following the end of the Calendar Quarter for which such Contingent Payments are payable.

(c) In addition to quarterly adjustments pursuant to Section 2.3.2(b), all calculations of Contingent Payments shall be subject to an annual adjustment by Buyer following the preparation of its audited annual financial statements as follows:

(i) In the event that, after giving effect to any adjustments made pursuant to Section 2.3.2(b), Buyer determines that it made Contingent Payments to Seller in respect of any prior Calendar Year in excess of the correct Contingent Payment applicable thereto, Buyer shall promptly advise Seller of its determination and, subject to Section 2.3.4(g) below, shall be entitled to deduct the amount of such overpayments from the Contingent Payments due to Seller for the first Calendar Quarter following such Calendar Year (and, if applicable, successive Calendar Quarters until the amount of the overpayment has been reduced to $0).

(ii) In the event that, after giving effect to any adjustments made pursuant to Section 2.3.2(b), Buyer determines that additional Contingent Payments are due to Seller in respect of the Contingent Payments applicable to any prior Calendar Year, then it shall promptly advise Seller of its determination and, subject to Section 2.3.4(g) below, pay over such amounts to Seller no later than (A) 30 calendar days following Buyer's filing of its audited annual financial statements with the U.S. Securities and Exchange Commission or (B) if Buyer is not required to file financial statements with the U.S. Securities and Exchange Commission, no later than 90 calendar days following the end of the Calendar Year for which such Contingent Payments are payable.

(d) Buyer shall use good faith Diligent Efforts to Exploit the Subject Products in the Territory.

2.3.3 Mode of Payment; Interest; Tax Treatment. Buyer shall pay to Seller the Contingent Payments by wire transfer of immediately available funds to such bank account or accounts as Seller may from time to time designate by advance written notice to Buyer. All payments to be made by Buyer to Seller under this Agreement shall be made in United States dollars. For purposes of calculating Net Sales for any Subject Products sold in a currency other than United States dollars, the rate of exchange to be used in computing the currency equivalent in United States dollars due to Seller shall be a well-established and widely recognized rate of exchange used by Buyer for reporting such sales for United States financial statement purposes, consistently applied. If Buyer fails to make any payment pursuant to this Agreement when due, any such late payment shall bear simple interest, to the extent not prohibited by Law, at a per annum rate equal to the U.S. Prime Rate, as reported in The Wall Street Journal, Eastern Edition, for the first date on which such payment was delinquent, plus two percent, beginning on the first date on which such payment was delinquent and ending on the date on which such payment is made, calculated based on the actual number of days such payment is overdue. The Contingent Payments shall be treated as an adjustment to the Purchase Price for all Tax purposes, unless otherwise required by applicable Law and unless any portion of such Contingent Payment is required to be treated as interest in respect of deferred consideration for Tax purposes.

2.3.4 Financial Records; Audits.

(a) Within five Business Days after the end of each calendar month, commencing with the calendar month in which the First Commercial Sale of a Subject Product occurs, Buyer shall deliver to Seller a report, solely for informational purposes, setting out estimated Net Sales in such prior calendar month for each Subject Product, on a country-by-country basis (each, an "**Estimated Monthly Net Sales Report**"), including:

(i) estimated gross amount invoiced for sales of each Subject Product sold in each country in such calendar month;

(ii) estimated Net Sales of each Subject Product in each country in such calendar month; and

(iii) all relevant deductions from the estimated gross amount invoiced in accordance with this Agreement to calculate such Net Sales.

(b) Within 15 Business Days after the end of each calendar month, commencing with the calendar month in which the First Commercial Sale of a Subject Product occurs, Buyer shall deliver to Seller a report setting out Net Sales in such prior calendar month for each Subject Product, on a country-by-country basis (each, a "**Monthly Net Sales Report**"), including:

(i) gross amount invoiced for sales of each Subject Product sold in each country in such calendar month;

(ii) Net Sales of each Subject Product in each country in such calendar month; and

(iii) all relevant deductions from the gross amount invoiced in accordance with this Agreement to calculate such Net Sales.

(c) Within 30 calendar days after the end of each Calendar Quarter, commencing with the Calendar Quarter in which the First Commercial Sale of a Subject Product occurs, Buyer shall deliver to Seller a report setting out Net Sales in such prior Calendar Quarter for each Subject Product, on a country-by-country basis (each, a "**Quarterly Net Sales Report**"), including:

(i) gross amount invoiced for sales of each Subject Product sold in each country in such Calendar Quarter;

(ii) Net Sales of each Subject Product in each country in such Calendar Quarter;

(iii) all relevant deductions from the gross amount invoiced in accordance with this Agreement to calculate such Net Sales; and

(iv) a reconciliation of the amounts set forth in the Monthly Net Sales Report delivered for the calendar month in the applicable Calendar Quarter to the amounts set forth in the Quarterly Net Sales Report.

The report for the fourth Calendar Quarter of each Calendar Year (the "**Annual Net Sales Report**") shall include the items in the preceding clauses (i) through (iii) for both such Calendar Quarter and the full Calendar Year in which such Calendar Quarter occurs and include a reconciliation of the amounts set forth in the Quarterly Net Sales Reports delivered for the applicable Calendar Year to the amounts set forth in the Annual Net Sales Report.

(d) Commencing with the Calendar Year in which the First Commercial Sale of a Subject Product occurs, Buyer shall deliver to Seller a report setting out Buyer's forecasted Net Sales for each Subject Product on a calendar month-by-calendar month and country-by-country basis (the "**Net Sales Forecast**") according to the following schedule:

(i) by April 15 of each Calendar Year, the Net Sales Forecast for the current Calendar Year and the following four Calendar Years;

(ii) by July 15 of each Calendar Year, the Net Sales Forecast for the current Calendar Year and the following Calendar Year; and

(iii) by October 15 of each Calendar Year, the Net Sales Forecast for the current Calendar Year and the following two Calendar Years;

provided, however, that Buyer shall not be required to deliver to Seller any Net Sales Forecast for a Subject Product that was due in accordance with this Section 2.3.4(d) on a date prior to the date of the First Commercial Sale of the applicable Subject Product.

(e) Each Estimated Monthly Net Sales Report, Monthly Net Sales Report, Quarterly Net Sales Report and Annual Net Sales Report delivered pursuant to Section 2.3.4 shall specifically set forth the amount deducted for each of the categories ((a) through (d)) in the definition of Net Sales in this Agreement.

(f) Buyer shall, and shall cause the other Payment Obligors to, keep complete and accurate books and records pertaining to the sale, delivery and use of the Subject Products, including books and records of Net Sales (including any deductions from the gross amount invoiced to calculate Net Sales), to the extent required to calculate and verify all Contingent Payments payable hereunder ("**Net Sales Information**"). Buyer shall, and shall cause the other Payment Obligors to, retain the Net Sales Information until the later of [***] after the end of the period to which such Net Sales Information pertains and the expiration of the applicable Tax statute of limitations (or any extensions thereof), or for such longer period as may be required by Law.

(g) At the request of Seller, Buyer shall, and shall cause the other Payment Obligors to, permit an independent certified public accountant retained by Seller, during normal business hours and upon reasonable notice, to audit the Net Sales Information in order to confirm the amount of the Contingent Payments made hereunder. Such audits may not (i) be conducted for any Calendar Quarter or Calendar Year more than [***] after the end of such Calendar Quarter or Calendar Year, (ii) be conducted more than once in any 12-month period (unless a previous audit with respect to the Contingent Payments for a Calendar Quarter or Calendar Year ending less than 12 months prior to the date of the request for such audit revealed an underpayment of at least [***] with respect to such period or Buyer restates or revises such books and records for such 12-month period) or (iii) be repeated for any Calendar Quarter or Calendar Year (unless a previous audit for such Calendar Quarter or Calendar Year revealed an underpayment of at least [***] with respect to such period or Buyer restates or revises such books and records for such Calendar Quarter or Calendar Year). The cost of any audit shall be borne by Seller, unless the audit reveals a variance of more than [***] from the reported amounts of the Contingent Payments, in which case Buyer shall bear the cost of the audit. Unless disputed pursuant to Section 2.3.4(h), if such audit concludes that additional payments with respect to the Contingent Payments were owed or that excess payments were made during such period, Buyer shall pay the additional amounts, with interest from the date originally due as provided in Section 2.3.3, or Seller shall reimburse such excess payments, within 30 calendar days after the date on which such audit is completed and the conclusions thereof are notified to the Parties.

(h) In the event of a dispute over the results of any audit conducted pursuant to Section 2.3.4(g), the disputing Party shall deliver a dispute notice to the other Party setting forth in reasonable detail its calculation of the amounts due or owed within ten calendar days following the completion of such audit (the "**Dispute Notice**"). The other Party shall deliver a response to the Dispute Notice no later than ten calendar days following its receipt of the Dispute Notice setting forth in reasonable detail its calculation of the amounts due or owed (the "**Dispute Response**"). Seller and Buyer shall work in good faith to resolve such dispute. If the Parties are unable to reach a mutually acceptable resolution of any such dispute within 30 calendar days of the date of notice of such dispute, then either Party shall be entitled to submit the dispute for arbitration to the Accountants, together with copies of the Dispute Notice and the Dispute Response. The Accountants shall not be entitled to reach a decision that is more or less than the greatest or least amounts set forth by the Parties in the Dispute Notice and Dispute Response, as applicable. The decision of the Accountants shall be final and the costs of such arbitration as well as the initial audit shall be borne between the Parties in such manner as the Accountants shall determine. Not later than 30 calendar days after such decision and in accordance with such decision, Buyer shall pay the additional Contingent Payments, as applicable, with interest from the date originally due as provided in Section 2.3.3 or Seller shall reimburse such excess payments, as applicable.

(i) Seller shall treat all information subject to review under Section 2.3.4(g) in accordance with the confidentiality provisions of Section 5.3 and (i) Seller shall cause the independent public accountant retained by Seller pursuant to Section 2.3.4(g) and (ii) Seller and Buyer shall cause the Accountants to, as applicable, enter into a reasonably acceptable confidentiality agreement with Buyer or its Affiliates or (sub)licensees, as the case may be, that includes an obligation to retain all such Confidential Information (as defined in Section 5.3) in confidence.

2.3.5 Transfer of Products. Any transfer, sale, license, conveyance or other disposition of any Subject Product, Purchased Regulatory Approval or any material right (including Intellectual Property) related to a Subject Product by any Payment Obligor (other than commercial sales of inventory of a Subject Product in the ordinary course of business) shall require that the transferee, licensee or assignee thereof agree to be bound by the obligations with respect to the Contingent Payments set forth in this Section 2.3 and in such case shall thereafter be deemed to be a Payment Obligor. Buyer shall remain primarily responsible for the payment of the Contingent Payments to Seller notwithstanding any such transfer, sale, license, conveyance or other disposition; *provided*, that, in connection with any such transfer, sale, license, conveyance or other disposition, Buyer may request that Seller waive Buyer's obligation to remain primarily responsible for the payment of the Contingent Payments, which waiver shall not be unreasonably withheld, conditioned or delayed.

2.3.6 Allocation of Consideration. Buyer shall allocate the Purchase Price (including the Assumed Liabilities, to the extent properly taken into account under Section 1060 of the Code) among the Purchased Assets in accordance with Section 1060 of the Code (the "**Allocation**") prior to or within 90 calendar days following the Closing and shall deliver to Seller a copy of such Allocation (IRS Form 8594) promptly after such determination. Seller shall have the right to review and raise any objections in writing to the Allocation during the 10-Business Day period after its receipt thereof. If Seller disagrees with respect to any item in the Allocation, the Parties shall negotiate in good faith to resolve the dispute. If the Parties are unable to agree on the Allocation within 30 calendar days after the commencement of such good faith negotiations (or such longer period as Seller and Buyer may mutually agree in writing), then the Accountants shall be engaged at that time to review the Allocation, and shall make a determination as to the resolution of such Allocation. The determination of the Accountants regarding the Allocation shall be delivered as soon as practicable following engagement of the Accountants, but in no event more than 60 calendar days thereafter, and shall be final, conclusive and binding upon Seller and Buyer, and Buyer shall revise the Allocation accordingly. Seller, on the one hand, and Buyer on the other hand, shall each pay one-half of the cost of the Accountants. The Parties agree to file all Tax Returns (including IRS Form 8594 and, if required, supplemental Forms 8594, in accordance with the instructions to Form 8594) and any other forms, reports or information statements required to be filed pursuant to Section 1060 of the Code and the applicable regulations thereunder, and any similar or corresponding provision of U.S. state, local or non-U.S. Tax Law, in a manner that is consistent with the finalized Allocation and to refrain from taking any position inconsistent therewith unless required by applicable Law.

2.4 Closing.

2.4.1 Closing. Pursuant to the terms and subject to the conditions of this Agreement, the closing of the transactions contemplated hereby (the "**Closing**") shall take place at the New York, NY offices of Covington & Burling LLP on the first Business Day following the later of (a) five Business Days following the satisfaction of all conditions (other than those that may be or by their terms are to be satisfied or taken at the Closing) set forth in Article 6 (or, to the extent permitted by applicable Law, waived by the Party entitled to the benefits thereof) and (b) [***], or such other time and place, including remotely, as Buyer and Seller may agree in writing. The Closing shall be deemed to have occurred at 12:00 a.m., eastern time, on the Closing Date, such that Buyer shall be deemed the owner of the Purchased Assets on and after the Closing Date.

2.4.2 Closing Deliveries.

(a) Except as otherwise indicated below, at the Closing, Seller shall deliver or make available, as applicable, the following to Buyer:

(i) each of the Ancillary Agreements, validly executed by a duly authorized representative of Seller;

(ii) the Purchased Assets; *provided*, that (A) all files, documents, instruments, papers, books and records included in the Purchased Assets will be made available to Buyer only in electronic format and none of such Purchased Assets shall be delivered to Buyer in hard copy and (B) prior to delivering or making available any files, documents, instruments, papers, books and records to Buyer, Seller shall be entitled to redact from such files, documents, instruments, papers, books and records any information to the extent that it does not relate to the Products; and

(iii) a certificate, dated as of the Closing Date, validly executed by a duly authorized representative of Seller, certifying that all of the conditions set forth in Section 6.2.1 and Section 6.2.2 have been satisfied.

(b) At the Closing, Buyer shall deliver the following to Seller:

(i) each of the Ancillary Agreements, validly executed by a duly authorized representative of Buyer;

(ii) the Closing Payment in accordance with Section 2.3.1; and

(iii) a certificate, dated as of the Closing Date, validly executed by a duly authorized representative of Buyer, certifying that all of the conditions set forth in Section 6.3.1 and Section 6.3.2 have been satisfied.

REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of Seller. Seller represents and warrants to Buyer as follows, with each such representation and warranty subject to such exceptions, if any, as are set forth in the Disclosure Schedules. Disclosures in any section or paragraph of the Disclosure Schedules are made generally and shall not only address the corresponding section or paragraph of this Agreement, but also other sections or paragraphs of this Agreement to the extent that it is reasonably apparent from the face of such disclosure that such disclosure is applicable to such other sections or paragraphs.

3.1.1 Entity Status. Seller is a limited liability company (*a Besloten Vennootschap*) duly organized, validly existing under the Laws of the Netherlands. Each Affiliate of Seller that owns any Purchased Assets (each, a "**Specified Affiliate**") is duly organized and validly existing under the Laws of the jurisdiction of its organization. Seller and each Specified Affiliate are duly qualified to do business and in good standing (to the extent such concept is recognized by the applicable jurisdiction) in each jurisdiction in which the ownership of the Purchased Assets so requires, except to the extent the failure to be so qualified and in good standing would not constitute a Material Adverse Effect.

3.1.2 Authority.

(a) Seller has the requisite organizational power and authority to (i) own the Purchased Assets owned by it and (ii) enter into this Agreement and the Ancillary Agreements to which it will be a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the Ancillary Agreements to which Seller will be a party and the consummation of the transactions contemplated hereby and thereby have been duly authorized by all necessary organizational actions of Seller. This Agreement constitutes, and, when executed and delivered by Seller, each Ancillary Agreement to which it will be a party will constitute, the valid and legally binding obligation of Seller, enforceable against Seller in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors' rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

(b) Each Specified Affiliate has the requisite entity power and authority to (i) own the Purchased Assets owned by it and (ii) enter into, deliver and perform its obligations under each Ancillary Agreement to which it will be a party, to perform its obligations thereunder and to consummate the transactions contemplated thereby. The execution and delivery of the Ancillary Agreements to which any Specified Affiliate will be a party and the consummation of the transactions contemplated thereby have been duly authorized by all necessary organizational actions of such Specified Affiliate. Each Ancillary Agreement to which a Specified Affiliate is a party, when executed and delivered by such Specified Affiliate, will constitute the valid and legally binding obligation of such Specified Affiliate, enforceable against such Specified Affiliate in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors' rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

3.1.3 Non-Contravention. The execution, delivery and performance by Seller of this Agreement and each Ancillary Agreement to which it is a party, and the execution, delivery and performance by each Specified Affiliate of each Ancillary Agreement to which it is a party, do not (a) violate the organizational documents of Seller or such Specified Affiliate, (b) violate any Law applicable to (x) Seller or such Specified Affiliate or (y) the Purchased Assets or (c) subject to obtaining the Consents referred to in Section 3.1.4(b), (i) violate, breach or constitute a default under or result in the termination of any Contract to which (x) Seller or such Specified Affiliate is a party or (y) the Purchased Assets are subject, or (ii) violate any order or judgment of a Governmental Authority to which Seller or such Specified Affiliate is subject relating exclusively to the Purchased Assets, except, in the case of (b)(x) or (c)(i)(x), for such violations, breaches, defaults or terminations that would not constitute a Material Adverse Effect.

3.1.4 No Litigation; Consents.

(a) As of the Effective Date, (i) there is no Litigation pending or, to Seller's Knowledge, threatened in writing against Seller or any of its Affiliates before any Governmental Authority relating to the Purchased Assets, and (ii) there is no order or judgment of a Governmental Authority to which Seller or any of its Affiliates is subject relating primarily to the Purchased Assets, except, in the case of (i) immediately above, for such Litigation, orders and judgments that would not reasonably be expected to materially and adversely affect the Purchased Assets, taken as a whole.

(b) Except for (i) Consents that if not received, or declarations, filings or registrations that if not made, would not reasonably be expected to materially and adversely affect the Purchased Assets, (ii) Consents, declarations or registrations that have become applicable solely as a result of the specific regulatory status of Buyer or its Affiliates and (iii) Consents required under applicable Competition Laws and the filing with the FDA of the Seller FDA Transfer Letters and Buyer FDA Transfer Letters, no notice to, filing with, permit of, authorization of, exemption by, or consent of, any Governmental Authority or other Person (collectively, "**Consents**") is required for Seller to consummate the transactions contemplated hereby or by the Ancillary Agreements.

3.1.5 Purchased Assets. Seller has, or one of its Specified Affiliates has, good title to, or valid contract rights in, as applicable, the Purchased Assets, free and clear of all Liens other than Permitted Liens. This Section 3.1.5 does not relate to Intellectual Property, which is the subject of Section 3.1.7.

3.1.6 Regulatory Matters. The Purchased Regulatory Approvals are approved but in a "discontinued" state, per the definition of that term in the Drugs@FDA Glossary of Terms. No proceeding is pending or, to Seller's Knowledge, threatened regarding the revocation of any Purchased Regulatory Approval. Neither Seller nor any of its Affiliates is in material violation of the terms of any Purchased Regulatory Approval.

3.1.7 Intellectual Property. Seller or a Specified Affiliate is the owner of intent-to-use applications currently pending before the United States Patent and Trademark Office that constitute the Purchased Trademark Applications, and which are more fully identified in Section 3.1.7(a) of the Disclosure Schedules. Except as disclosed in Section 3.1.7(b) of the Disclosure Schedules, as of the Effective Date, (i) Seller does not own, license or otherwise hold for use any material Intellectual Property in respect of or in connection with the Purchased Assets and (ii) to Seller's Knowledge, neither of the Purchased Trademark Applications in the U.S. Territory is the subject of any material concurrent use or opposition proceeding or any other material Litigation.

3.1.8 No Broker. There is no broker, finder or financial advisor acting or who has acted on behalf of Seller or any of its Affiliates, who is entitled to receive any brokerage or finder's or financial advisory fee from Buyer or any of its Affiliates in connection with the transactions contemplated by this Agreement.

3.2 Exclusivity of Representations. BUYER ACKNOWLEDGES AND AGREES THAT, EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES CONTAINED IN SECTION 3.1, (A) NEITHER SELLER NOR ANY OF ITS AFFILIATES OR REPRESENTATIVES HAS MADE ANY REPRESENTATION OR WARRANTY WHATSOEVER HEREIN OR OTHERWISE RELATED TO THE TRANSACTIONS CONTEMPLATED HEREBY AND (B) BUYER HAS NOT RELIED ON ANY REPRESENTATION OR WARRANTY IN CONNECTION WITH THE TRANSACTIONS CONTEMPLATED HEREBY. WITHOUT LIMITING THE GENERALITY OF THE FOREGOING, BUYER ACKNOWLEDGES AND AGREES THAT, EXCEPT AS EXPRESSLY PROVIDED IN SECTION 3.1, BUYER IS ACQUIRING THE PURCHASED ASSETS ON AN "AS IS, WHERE IS" BASIS WITHOUT ANY EXPRESS OR IMPLIED WARRANTIES, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, INCLUDING ANY WARRANTY AS TO QUALITY, THE FITNESS FOR A PARTICULAR PURPOSE, MERCHANTABILITY, CONDITION OF THE ASSETS OR AS TO ANY OTHER MATTER.

3.3 Representations and Warranties of Buyer. Buyer represents and warrants to Seller as follows:

3.3.1 Entity Status. Buyer is a corporation duly organized, validly existing and in good standing under the Laws of the State of Delaware. Each Affiliate of Buyer that will be a party to any Ancillary Agreement is (or as of the Closing will be) a legal entity duly organized, validly existing and in good standing under the Laws of the jurisdiction of its organization or incorporation.

3.3.2 Authority.

(a) Buyer has the requisite corporate power and authority to enter into this Agreement and the Ancillary Agreements to which it will be a party, to perform its obligations hereunder and thereunder and to consummate the transactions contemplated hereby and thereby. The execution and delivery of this Agreement and the Ancillary Agreements to which Buyer will be a party and the consummation of the transactions contemplated hereby and thereby have been (or prior to the Closing will have been) duly authorized by the necessary corporate actions of Buyer. This Agreement constitutes, and, when executed and delivered by Buyer, each Ancillary Agreement to which Buyer will be a party will constitute, the valid and legally binding obligation of Buyer, enforceable against Buyer in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors' rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

(b) Each Affiliate of Buyer that will enter into an Ancillary Agreement has (or as of the Closing will have) the requisite entity power and authority to enter into the Ancillary Agreements to which it is a party, to perform its obligations thereunder and to consummate the transactions contemplated thereby. The execution and delivery of the Ancillary Agreements to which any Affiliate of Buyer will be a party and the consummation of the transactions contemplated thereby have been (or prior to the Closing will have been) duly authorized by the necessary organizational actions of such Affiliate. Each Ancillary Agreement to which any Affiliate of Buyer will be party, when executed and delivered by such Affiliate, will constitute the valid and legally binding obligation of such Affiliate, enforceable against such Affiliate in accordance with its terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium or similar Laws of general application affecting or relating to the enforcement of creditors' rights generally, and subject to equitable principles of general applicability, whether considered in a proceeding at law or in equity.

3.3.3 Non-Contravention. The execution, delivery and performance by Buyer of this Agreement and of each Ancillary Agreement to which it will be a party and the execution, delivery and performance by each Affiliate of Buyer of each Ancillary Agreement to which such Affiliate will be a party do not (a) violate the certificate of incorporation or bylaws, or comparable organization documents, of Buyer or such Affiliate, as applicable, (b) violate any Law or other restriction of any Governmental Authority applicable to Buyer or such Affiliate or (c) violate, breach or constitute a default under or result in the termination of any material Contract to which Buyer or such Affiliate is a party.

3.3.4 Litigation; Consents.

(a) (i) There is no Litigation pending or, to the knowledge of Buyer, threatened against Buyer or any of its Affiliates before any Governmental Authority, and (ii) there is no order or judgment of a Governmental Authority to which Buyer or any of its Affiliates is subject, except for such Litigation, orders and judgments that would not reasonably be expected to have a Buyer Material Adverse Effect.

(b) Except for (i) Consents that if not received, or declarations, filings or registrations that if not made, would not reasonably be expected to have a Buyer Material Adverse Effect and (ii) Consents required under applicable Competition Laws and the filing with the FDA of the Seller FDA Transfer Letters and Buyer FDA Transfer Letters, no Consent of any Governmental Authority or other Person is required for Buyer to consummate the transactions contemplated hereby or by the Ancillary Agreements.

3.3.5 Financial Capacity. Buyer has immediately available cash that is sufficient to enable it to complete the transactions contemplated hereby and to perform all of its obligations under this Agreement and the Ancillary Agreements.

3.3.6 No Broker. There is no broker, finder, financial advisor or other Person acting or who has acted on behalf of Buyer or its Affiliates, who is entitled to receive any brokerage or finder's or financial advisory fee from Seller or any of its Affiliates in connection with the transactions contemplated by this Agreement.

PRE-CLOSING COVENANTS

4.1 Access and Information. During the period commencing on the Effective Date and ending on the earlier to occur of (a) the Closing and (b) the termination of this Agreement in accordance with Article 8 (the "**Pre-Closing Period**"), Seller shall afford Buyer and its officers, employees, agents, attorneys, consultants, advisors and other representatives (collectively, "**Representatives**"), continued electronic access to the books and records of Seller and its Affiliates made available to Buyer and its Representatives in an electronic data room on and prior to the Effective Date.

4.2 Ordinary Course of Business.

4.2.1 During the Pre-Closing Period, except (a) as set forth in Schedule 4.2 or as otherwise expressly required by this Agreement or (b) as Buyer shall otherwise consent in writing, which consent shall not be unreasonably withheld, conditioned or delayed, Seller shall and shall cause each of its Affiliates, including the Specified Affiliates (i) to maintain the Purchased Assets in the ordinary course of business, except as otherwise required by applicable Law, and (ii) not to (A) sell, transfer or otherwise dispose of any Purchased Assets, (B) permit any Purchased Assets to be subject to a Lien (other than a Permitted Lien) or (C) permit any Purchased Regulatory Approval or Purchased Trademark Application to lapse or be abandoned. Nothing contained in this Agreement is intended to give Buyer or its Affiliates, directly or indirectly, the right to control or direct the business of Seller and its Affiliates with respect to the Purchased Assets prior to the Closing, and nothing contained in this Agreement is intended to give Seller or its Affiliates, directly or indirectly, the right to control or direct Buyer's operations. Prior to the Closing, each of Buyer and its Affiliates, on the one hand, and Seller and its Affiliates, on the other hand, shall exercise, consistent with the terms and conditions of this Agreement, complete control and supervision over its and its Affiliates' respective operations.

4.2.2 [***]

4.3 Obligation to Consummate the Transaction. Each Party agrees that, subject to Section 4.4, it shall use its reasonable best efforts to take, or cause to be taken, all actions, and to do, or cause to be done, all things necessary, proper or advisable to the extent permissible under applicable Law, to consummate and make effective the transactions contemplated by this Agreement and to ensure that the conditions set forth in Article 6 are satisfied, insofar as such matters are within such Party's control.

4.4 Competition Filings.

4.4.1 Each of Buyer and Seller (or, if applicable, their respective ultimate parent entities) shall file or cause to be filed as soon as practicable but in any event no later than 30 calendar days following the Effective Date, all filings required under the HSR Act in respect of the transactions contemplated hereby and, if required pursuant to applicable Law, any notifications required under any other applicable Competition Laws. In connection with such filings, each of Buyer and Seller hereby agree to expressly request early termination of all applicable waiting periods required under the HSR Act and any other applicable Competition Law. Thereafter, each of Buyer and Seller shall use commercially reasonable efforts to respond in good faith as promptly as practicable to any inquiries or requests received from any Governmental Authority for additional information or documentation and to request and cause the approval waiting periods under applicable Competition Laws to terminate or expire at the earliest possible date after the date of filing. Buyer and Seller shall notify the other promptly upon the receipt of (a) any comments or communication it or any of its Affiliates receives from any officials of any Governmental Authority in connection with any filings made pursuant to this Section 4.4.1 and (b) any request by any officials of any such Governmental Authority for amendments or supplements to any filings made pursuant to, or information provided to comply in all material respects with, any applicable Law. Buyer and Seller shall permit the other to review in advance any proposed communication by such Party to any Governmental Authority with respect to any filings made pursuant to this Section 4.4.1. Whenever any event occurs that is required to be set forth in an amendment or supplement to any filing made pursuant to this Section 4.4.1, Buyer or Seller, as the case may be, will promptly inform the other of such occurrence and cooperate in filing with the applicable Governmental Authority such amendment or supplement. Neither Buyer, on the one hand, nor Seller, on the other hand, shall (or permit any of their respective Affiliates to) agree to participate in any meeting or other discussion with any Governmental Authority in respect of any filings, investigation (including any settlement of the investigation, Litigation or other inquiry) relating to this Section 4.4 unless it consults with the other in advance and, to the extent permitted by such Governmental Authority, gives the other the opportunity to attend and participate at such meeting or other discussion.

4.4.2 In connection with the filings under Section 4.4.1, Buyer and Seller shall cooperate with each other in good faith and shall (a) promptly prepare and file all necessary documentation and (b) effect all necessary applications, notices, petitions and filings and execute all agreements and documents. In connection with the foregoing, Buyer shall have the right to review and reasonably approve in advance all characterizations of the information relating to Buyer and its Affiliates; Seller shall have the right to review and reasonably approve in advance all characterizations of the information relating to Seller and its Affiliates; and each of Buyer and Seller shall have the right to review and reasonably approve in advance all characterizations of the information relating to the transactions contemplated hereby, in each case, that appear in any material filing made in connection with this Section 4.4. Each Party may, as it deems advisable or necessary, designate any competitively sensitive materials provided to the other Party under this Section 4.4 as "outside counsel only." Any materials so designated may be provided to the other Party's outside legal counsel but shall not be provided to the other Party without the prior written consent of the Party providing such materials.

4.4.3 All filing fees under applicable Competition Laws, and all reasonable out-of-pocket expenses (other than legal fees and expenses, which shall be borne by the Party incurring such expenses) incurred in complying with any request for additional information or documentary material from any applicable Governmental Authority, including any necessary merger notifications and investigations, shall be borne by Buyer.

4.4.4 Neither Seller nor Buyer shall, and each shall cause its respective Affiliates not to, enter into any transaction or any Contract, whether oral or written, to effect any transaction (including any merger or acquisition) that would reasonably be expected to make it more difficult, or to increase the time required, to: (a) obtain the expiration or early termination of the waiting period under the HSR Act (or obtain clearance or approval under applicable foreign Competition Law) applicable to the transactions contemplated by this Agreement, (b) avoid the entry of, the commencement of Litigation seeking the entry of, or to effect the dissolution of, any injunction, temporary restraining order or other order that would materially delay or prevent the consummation of the transactions contemplated hereby or (c) obtain all authorizations, consents, orders and approvals of Governmental Authorities necessary for the consummation of the transactions contemplated by this Agreement.

ADDITIONAL COVENANTS AND AGREEMENTS

5.1 Further Assurances. Each of Seller and Buyer shall, at any time or from time to time after the Closing, at the request and expense of the other, execute and deliver to the other all such instruments and documents or further assurances as the other may reasonably request in order to (a) vest in Buyer all of Seller's right, title and interest in and to the Purchased Assets as contemplated hereby, (b) effectuate Buyer's assumption of the Assumed Liabilities and (c) grant to each Party all rights contemplated herein to be granted to such Party under the Ancillary Agreements; *provided*, *however*, that after the Closing, apart from such customary further assurances, neither Seller nor Buyer shall have any other obligations except as specifically set forth and described herein or in the Ancillary Agreements. Without limitation of the foregoing, neither Seller nor Buyer shall have any obligation to assist or otherwise participate in the amendment or supplementation of the Purchased Regulatory Approvals or otherwise to participate in any filings or other activities relating to the Purchased Regulatory Approvals other than as necessary to effect the assignment thereof to Buyer in connection with the Closing pursuant to this Agreement.

5.2 Publicity. No public announcement related to this Agreement or the transactions contemplated herein will be issued without the joint written approval of Seller and Buyer, which approval shall not be unreasonably withheld, conditioned or delayed, except in any public disclosure which either Seller or Buyer, in its good faith judgment, believes is required by applicable Law or by any stock exchange on which its securities or those of its Affiliates are listed. If either Party, in its good faith judgment, believes such disclosure is required, such Party shall use its commercially reasonable efforts to (or in the case of any press release issued, or report filed with the U.S. Securities and Exchange Commission, in connection with the execution of this Agreement or any version of this Agreement or any Ancillary Agreement filed with the U.S. Securities and Exchange Commission, shall) consult with the other Party and its Representatives, and consider in good faith any revisions timely proposed by the other Party or its Representatives, as applicable, prior to making (or prior to any of its Affiliates making) such disclosure, and shall limit such disclosure to only that information which is legally required to be disclosed. Notwithstanding the foregoing, Buyer, on the one hand, and Seller, on the other hand, may make public announcements that are consistent with prior public communications made in compliance with this Section 5.2.

5.3 Confidentiality.

5.3.1 All Confidential Information provided by one Party (or its Representatives or Affiliates) (collectively, the "**Disclosing Party**") to the other Party (or its Representatives or Affiliates) (collectively, the "**Receiving Party**") shall be subject to and treated in accordance with the terms of this Section 5.3. As used in this Section 5.3, "**Confidential Information**" means (a) all information disclosed to the Receiving Party by the Disclosing Party in connection with this Agreement or any Ancillary Agreement, including all information with respect to the Disclosing Party's licensors, licensees, sublicensees or Affiliates, (b) all information disclosed to the Receiving Party by the Disclosing Party under the Confidentiality Agreement and (c) all memoranda, notes, analyses, compilations, studies and other materials prepared by or for the Receiving Party to the extent containing or reflecting the information in the preceding clause (a) or (b). Confidential Information shall include the Estimated Monthly Net Sales Reports, Monthly Net Sales Reports, Quarterly Net Sales Reports, Annual Net Sales Reports and Net Sales Forecasts delivered pursuant to Section 2.3.4 (the "**Confidential Net Sales Information**"). Notwithstanding the foregoing, Confidential Information shall not include information that, in each case as demonstrated by competent written documentation:

(i) was already known to the Receiving Party other than under an obligation of confidentiality, at the time of disclosure by the Disclosing Party;

(ii) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;

(iii) became generally available to the public or otherwise part of the public domain after its disclosure to the Receiving Party other than through any act or omission of the Receiving Party in breach of this Agreement or the Confidentiality Agreement;

(iv) is subsequently disclosed to the Receiving Party by a Third Party without obligations of confidentiality with respect thereto; or

(v) is subsequently independently discovered or developed by the Receiving Party without the aid, application or use of Confidential Information.

5.3.2 All Confidential Information (a) obtained by Seller (or its Affiliates or Representatives) from Buyer (or its Affiliates or Representatives) and (b) effective as of the Closing Date, relating solely to the Products, the Purchased Assets and the Assumed Liabilities (the "**Buyer Confidential Information**") shall be deemed to be Confidential Information disclosed by Buyer to Seller for purposes of this Section 5.3 and shall be used by Seller and its Affiliates solely as required to (i) perform its or their obligations or exercise or enforce its or their rights under this Agreement or any Ancillary Agreement, (ii) with respect to the Confidential Net Sales Information, prepare internal reports, forecasts and related financial statements and prepare the consolidated financial statements of Seller and its Affiliates, in each case, in the ordinary course of business or (iii) comply with applicable Law (each of (i) through (iii), a "**Seller Permitted Purpose**"), and for no other purpose. For a period of 10 years after the Effective Date, Seller shall not disclose, or permit the disclosure of, any of the Buyer Confidential Information to any Person except those Persons to whom such disclosure is necessary in connection with any Seller Permitted Purpose. Seller shall treat, and shall cause its Affiliates and the Representatives of Seller or any of its Affiliates to treat, the Buyer Confidential Information as confidential, using the same degree of care as Seller normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care.

5.3.3 All Confidential Information obtained by Buyer (or its Affiliates or Representatives) from Seller (or its Affiliates or Representatives) other than the Buyer Confidential Information (the "**Seller Confidential Information**") shall be used by Buyer and its Affiliates solely as required to (a) perform its or their obligations or exercise or enforce its or their rights under this Agreement or any Ancillary Agreement or (b) comply with applicable Law (each of (a) and (b), a "**Buyer Permitted Purpose**"), and for no other purpose. For a period of 10 years after the Effective Date, Buyer shall not disclose, or permit the disclosure of, any of the Seller Confidential Information to any Person except those Persons to whom such disclosure is necessary in connection with a Buyer Permitted Purpose. Buyer shall treat, and will cause its Affiliates and the Representatives of Buyer or any of its Affiliates to treat, Seller Confidential Information as confidential, using the same degree of care as Buyer normally employs to safeguard its own confidential information from unauthorized use or disclosure, but in no event less than a reasonable degree of care. Notwithstanding the foregoing, Buyer shall, and shall cause its Affiliates, Representatives, transferees and permitted Sublicensees to, maintain the confidentiality of and protect the Trade Secrets included in the Licensed Manufacturing Technology for such period of time in excess of 10 years after the Effective Date that such Trade Secrets constitute trade secrets under applicable Law.

5.3.4 In the event either Party is requested pursuant to, or required by, applicable Law to disclose any of the other Party's Confidential Information (*i.e.*, Seller Confidential Information or Buyer Confidential Information, as applicable), it will notify the other Party in a timely manner so that such Party may seek a protective order or other appropriate remedy or, in such Party's sole discretion, waive compliance with the confidentiality provisions of this Agreement. Each Party will cooperate in all reasonable respects in connection with any reasonable actions to be taken for the foregoing purpose. In any event, the Party requested or required to disclose such Confidential Information may furnish it as requested or required pursuant to applicable Law (subject to any such protective order or other appropriate remedy) without liability hereunder, *provided* that such Party furnishes only that portion of the Confidential Information which such Party is advised by an opinion of its counsel is legally required, and such Party exercises reasonable efforts to obtain reliable assurances that confidential treatment will be accorded such Confidential Information.

5.3.5 Nothing in this Section 5.3 shall be construed as preventing or in any way inhibiting either Party from complying with applicable Law governing activities and obligations undertaken pursuant to this Agreement or any Ancillary Agreement in any manner which it reasonably deems appropriate.

5.4 FDA Letters. Buyer and Seller shall file the Buyer FDA Transfer Letters and the Seller FDA Transfer Letters, respectively, with the FDA within five Business Days after the Closing Date. Transfer of title to the Purchased Regulatory Approvals shall be effective as of the Closing.

5.5 Regulatory Responsibilities. Except as required by a Party to comply with applicable Law or to exercise its rights and obligations hereunder or under any Ancillary Agreement, Buyer, from and after the date on which the Buyer FDA Transfer Letters and Seller FDA Transfer Letters are filed with the FDA (the "**FDA Transfer Date**"), shall have the sole right and responsibility for preparing, obtaining and maintaining the Purchased Regulatory Approvals, and for conducting communications with Governmental Authorities of competent jurisdiction, for the Products. Seller shall retain such rights and responsibilities during the period prior to the FDA Transfer Date.

5.6 Pharmacovigilance.

5.6.1 Legacy Safety Data. As soon as reasonably practicable following the Closing Date, and solely to the extent in Seller's possession or under its control, Seller shall provide to Buyer, in the form of an electronic copy of the CIOMS I form, a copy of all legacy data of adverse events with respect to the Products, both serious and non-serious, as are necessary for Buyer to hold the global safety database for the Products (the "**Global Safety Database**").

5.6.2 Transfer of Global Safety Database. Seller shall transfer the Global Safety Database to Buyer as soon as reasonably practicable following Seller's receipt of written notice from Buyer that Buyer is ready to accept such transfer; *provided*, that Buyer shall accept such transfer no later than the date that is 30 calendar days after the FDA Transfer Date. Following such transfer, Buyer shall maintain the Global Safety Database pursuant to its own policy and standard operating procedures.

5.6.3 Obligations Prior to the FDA Transfer Date. Until the FDA Transfer Date, Seller shall be responsible for reporting adverse event information received with respect to Products as required by Law.

5.6.4 Obligations Commencing on FDA Transfer Date. Effective on the FDA Transfer Date, Buyer shall be responsible for reporting of adverse event information received with respect to the Products as required by Law. If Seller receives any adverse event information with respect to the Products following the Closing, Seller shall provide to Buyer any source documents concerning such adverse event information within one Business Day following receipt, but in any event, not longer than three calendar days after receipt.

5.7 Certain Tax Matters.

5.7.1 Withholding Taxes. If applicable Laws require withholding of Taxes imposed upon any payments made by Buyer to Seller pursuant to this Agreement, Buyer shall make such withholding payments as may be required and shall subtract such withholding payments from such payments. To the extent such amounts are so deducted or withheld, such amounts will be treated for all purposes under this Agreement as having been paid to Seller. Buyer shall submit appropriate proof of payment of the withholding Taxes to Seller within a reasonable period of time.

5.7.2 Transfer Taxes. All amounts payable hereunder or under any Ancillary Agreement are exclusive of all recordation, transfer, documentary, excise, sales, value added, use, stamp, conveyance or other similar Taxes, duties or governmental charges, and all recording or filing fees or similar costs, imposed or levied by reason of, in connection with or attributable to this Agreement and the Ancillary Agreements or the transactions contemplated hereby and thereby (collectively, "**Transfer Taxes**"). Buyer shall be solely responsible for the payment of all Transfer Taxes. Buyer shall pay all amounts due and owing in respect of any Transfer Taxes, or upon receipt of invoice from Seller shall reimburse Seller for the Transfer Taxes in addition to the sums otherwise payable, at the rate in force at the due time for payment or such other time as is stipulated under applicable Law. All applicable filings, reports and returns shall be filed, as provided by applicable Law.

5.7.3 Cooperation and Exchange of Information. Each of Seller and Buyer shall (a) provide the other with such assistance as may reasonably be requested by the other in connection with the preparation of any Tax Return, audit or other examination by any taxing authority or judicial or administrative proceeding relating to Liability for Taxes in connection with the Purchased Assets, (b) retain and provide the other with any records or other information that may be relevant to such Tax Return, audit or examination, proceeding or determination and (c) inform the other of any final determination of any such audit or examination, proceeding or determination that affects any amount required to be shown on any Tax Return of the other for any period.

5.7.4 Survival of Covenants. The covenants contained in this Section 5.7 shall survive until 30 calendar days after the expiration of the applicable statute of limitations (including extensions thereof).

5.8 Insurance. As of the Closing Date, Buyer shall have and maintain adequate insurance coverage, including: (a) products liability coverage and comprehensive general liability insurance of not less than [***] prior to the First Commercial Sale of any Subject Product; and (b) any other insurance, including workers' compensation, cyber liability and professional liability, necessary to cover its obligations under this Agreement and that are consistent with normal business practices of prudent companies similarly situated. Such policies shall be blanket policies and shall insure against Liabilities on the part of Buyer and its Affiliates, as their interests may appear, due to injury, disability or death of any person or persons, or injury to property, arising from the Exploitation of the Subject Product. Such policies maintained by Buyer shall name Seller and its Affiliates as additional insureds. All insurers providing such policies shall have an AM Best (A-) or higher rating. Buyer shall provide Seller with certificates of insurance evidencing that the policies required to be maintained by Buyer hereunder are in full force and effect annually and, upon Seller's request, copies of such policies shall be provided. Should any of the policies be cancelled, terminated or otherwise materially altered before the expiration date thereof, notice will be delivered in accordance with the policy provisions in writing to Seller. Buyer's insurers shall waive all rights of subrogation against Seller, its Affiliates and its and their officers, directors and employees. Buyer's insurance shall be primary with no contribution by Seller's insurance. On or prior to the Closing Date, Buyer shall deliver to Seller an insurer or insurer's agent's signed Certificate of Insurance in customary form, evidencing that Buyer has obtained the foregoing insurance policies, with the insurers, coverages and limits of insurance as are specified in this Section 5.8, and that such policies are in full force and effect.

5.9 FCPA.

5.9.1 In performing its obligations hereunder, Buyer acknowledges that the corporate policy of Seller requires that Seller's business must be conducted within the letter and spirit of all applicable Laws, including the Foreign Corrupt Practices Act (the "**FCPA**"), and is applied worldwide. Buyer agrees to conduct, and to cause each of its Affiliates and its and their respective Representatives, distributors and Sublicensees, to conduct, the activities contemplated herein and in each Ancillary Agreement with respect to the Subject Products and the Licensed Manufacturing Technology, in a manner which is consistent with all applicable Laws, including the FCPA.

5.9.2 Without limitation of Section 5.9.1, Buyer represents and warrants that, to its knowledge, as of the date hereof, none of its or its Affiliates' officers, directors, employees or agents are officials, officers, agents, or representatives of any Governmental Authority having authority to make or participate in any decisions regarding any Purchased Regulatory Approvals and any pricing or reimbursement with respect to the Subject Products. Buyer further covenants that neither it nor any of its Affiliates or its or their respective officers, directors, employees or agents shall make any payment, either directly or indirectly, of money or other assets, including any compensation derived from this Agreement or any Ancillary Agreement (collectively, a "**Payment**"), to government or political party officials, officials of international public organizations, candidates for public office, or representatives of other businesses or Persons acting on behalf of any of the foregoing (collectively, "**Officials**") where such Payment would constitute a violation of any applicable Law, including the FCPA. In addition, regardless of legality, Buyer shall not, and shall cause its Affiliates and its and their respective officers, directors, employees and agents not to, make any Payment, either directly or indirectly, to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any Ancillary Agreement.

5.9.3 Buyer acknowledges that no employee of Seller or its Affiliates has authority to give any direction, either written or oral, relating to the making of any commitment by Buyer or its agents to any Third Party in violation of the terms of this Section 5.9.

5.9.4 Buyer shall not use (and shall cause its Affiliates not to use) any Person (including any employee, officer, director, Sublicensee, or Third Party contractor or distributor) who is (or has been) on the Exclusions List of the Office of Inspector General, U.S. Department of Health & Human Services, or who is (or has been) in violation of the terms of this Section 5.9 in connection with the performance of any activities hereunder. Buyer certifies to Seller that, as of the Effective Date, Buyer has screened itself, and its officers and directors (and its Affiliates, Sublicensees and Third Party contractors and distributors and their respective officers and directors) against the Exclusions List of the Office of Inspector General, U.S. Department of Health & Human Services. Buyer shall notify Seller in writing promptly of any breach of this Section 5.9.

5.10 Wrong Pockets. For a period of up to nine months after the Closing Date, if either Buyer or Seller becomes aware that any of the Purchased Assets has not been transferred to Buyer or that any of the Excluded Assets has been transferred to Buyer, it shall promptly notify the other and the Parties shall, as soon as reasonably practicable, ensure that such property is transferred, with any necessary prior Third Party Consent, to (a) Buyer, in the case of any Purchased Asset which was not transferred to Buyer at the Closing; or (b) Seller, in the case of any Excluded Asset which was transferred to Buyer at the Closing.

5.11 Licensed Manufacturing Technology.

5.11.1 Effective as of the Closing, upon the terms and subject to the conditions of this Agreement, Seller (on behalf of itself and its Affiliates) hereby grants to Buyer and its Affiliates, and Buyer (on behalf of itself and its Affiliates) hereby accepts, a non-exclusive, irrevocable, fully-paid up, royalty-free, perpetual right and license, with the right to grant sublicenses in accordance with Section 5.11.2, to the Licensed Manufacturing Technology solely to the extent necessary to manufacture or have manufactured the Products worldwide for Exploitation. The right and license granted to Buyer and its Affiliates under this Section 5.11.1 shall be transferable solely to a transferee, licensee or assignee pursuant to Section 2.3.5.

5.11.2 Buyer shall have the right to grant sublicenses under the license granted in Section 5.11.1 to Third Parties retained by Buyer to provide manufacturing services to Buyer (each, a "**Sublicensee**"); *provided*, *however*, that all such sublicenses shall be limited to the sole purpose of providing such manufacturing services to or for the benefit of a Payment Obligor in connection with the manufacture of the Products (including engaging any contract manufacturing organization); *provided*, *further* that Buyer shall (a) remain jointly and severally liable for the performance or non-performance of any such Sublicensee and (b) provide to Seller a written notice setting forth in reasonable detail the nature of such sublicense and the identity of the Sublicensee, which written notice shall include a copy of any such proposed sublicense agreement. A copy of any sublicense agreement executed by Buyer pursuant to this Section 5.11.2 (*provided* that the financial terms of any such sublicense agreement may be redacted to the extent not pertinent to an understanding of either Party's obligations or benefits under this Agreement) shall be provided to Seller within 14 calendar days after its execution by the parties thereto. Buyer hereby guarantees the performance of its Affiliates and permitted Sublicensees and acknowledges that the grant of any such sublicense shall not relieve Buyer of its obligations under this Agreement.

5.11.3 Notwithstanding anything to the contrary in this Section 5.11, Seller retains sole ownership of and title to the Licensed Manufacturing Technology and no ownership interest in or title to the Licensed Manufacturing Technology is or was transferred or conveyed to Buyer or any other Person by this Agreement; *provided*, *however*, that any sale of the Licensed Manufacturing Technology by Seller shall be made subject to the rights of the Buyer hereunder. Buyer acknowledges and agrees that Buyer shall not at any time claim adversely to Seller or any of its Affiliates any right, title or interest in or to the Licensed Manufacturing Technology, except as provided in this Section 4.11.

CONDITIONS PRECEDENT

6.1 Conditions to Obligations of Buyer and Seller. The obligations of Buyer and Seller to complete the transactions contemplated by this Agreement are subject to the satisfaction at or prior to the Closing of the following conditions:

6.1.1 No Adverse Law; No Injunction. No Law shall have been enacted, entered, promulgated or enforced by any Governmental Authority that prohibits the consummation of all or any material part of the transactions contemplated by this Agreement, and no order by any Governmental Authority restraining, enjoining or otherwise preventing the consummation of the transactions contemplated hereby shall be in effect; and

6.1.2 Governmental Approvals. Any applicable waiting period under the HSR Act and any other applicable Competition Law shall have expired or been terminated.

6.2 Conditions to Obligations of Buyer. The obligation of Buyer to complete the transactions contemplated by this Agreement is subject to the satisfaction or waiver by Buyer at or prior to the Closing of the following additional conditions:

6.2.1 Representations and Warranties. The representations and warranties of Seller contained in (a) Section 3.1.1, Section 3.1.2, Section 3.1.5 and Section 3.1.8 shall be true and correct in all but any *de minimis* respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct in all but any *de minimis* respects as of such date); (b) Section 3.1.3 and Section 3.1.6 shall be true and correct (i) in all respects (in the case of any representation or warranty in Section 3.1.3 or Section 3.1.6 that is qualified by materiality or Material Adverse Effect) at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date) or (ii) in all material respects (in the case of any representation or warranty in Section 3.1.3 or Section 3.1.6 that is not qualified by materiality or Material Adverse Effect) at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct in all material respects as of such date); and (c) Section 3.1.4 and Section 3.1.7 shall be true and correct in all respects (disregarding any materiality or Material Adverse Effect qualifiers therein) at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date), in the case of this clause (c), except for breaches of such representations and warranties that would not, individually or in the aggregate, have a Material Adverse Effect;

6.2.2 Covenants. Seller shall have performed and complied in all material respects with all covenants, agreements and obligations required to be performed or complied with on or prior to the Closing Date; and

6.2.3 Closing Deliveries. Seller shall have delivered to Buyer each of the items listed in Section 2.4.2(a).

6.3 Conditions to Obligations of Seller. The obligation of Seller to complete the transactions contemplated by this Agreement is subject to the satisfaction or waiver by Seller at or prior to the Closing of the following additional conditions:

6.3.1 Representations and Warranties. The representations and warranties of Buyer contained in (a) Section 3.3.1, Section 3.3.2, Section 3.3.5 and Section 3.3.6 shall be true and correct in all but any *de minimis* respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct in all but any *de minimis* respects as of such date); (b) Section 3.3.3 shall be true and correct in all material respects at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct in all material respects as of such date); and (c) Section 3.3.4 shall be true and correct in all respects (disregarding any materiality or Buyer Material Adverse Effect qualifiers therein) at and as of the Closing Date as if made at and as of such date (except that those representations and warranties that address matters only as of a particular date need only be true and correct as of such date), in the case of this clause (c), except for breaches of such representations and warranties that would not, individually or in the aggregate, have a Buyer Material Adverse Effect;

6.3.2 Covenants. Buyer shall have performed and complied in all material respects with all covenants, agreements and obligations required to be performed or complied with on or prior to the Closing Date; and

6.3.3 Closing Deliveries. Buyer shall have delivered to Seller each of the items listed in Section 2.4.2(b) and Seller shall have received the Closing Payment.

6.4 Frustration of Closing Conditions. With respect to the conditions to Buyer's and Seller's respective obligations to consummate the transactions contemplated by this Agreement as provided hereunder and each Party's right to terminate this Agreement as provided in Article 8, neither Buyer nor Seller may rely on the failure of any condition set forth in this Article 6 to be satisfied if such failure was caused by such Party's failure to act in good faith or to use its reasonable best efforts to cause the condition to be satisfied to the extent required by Section 4.3.

INDEMNIFICATION

7.1 Indemnification.

7.1.1 Indemnification by Seller. Following the Closing, but subject to the provisions of this Article 7, Seller shall indemnify, defend and hold harmless Buyer and its Affiliates, and its and their respective officers, directors, employees and agents (collectively, "**Buyer Indemnitees**") from and against, and compensate or reimburse the Buyer Indemnitees for, any and all Losses incurred by any Buyer Indemnitee arising out of or related to:

(a) any breach by Seller of any of the representations or warranties made by Seller in Section 3.1;

(b) any failure of Seller to perform or any breach by Seller of any of its covenants, agreements or obligations contained in this Agreement; or

(c) any Excluded Liability.

7.1.2 Indemnification by Buyer. Following the Closing, but subject to the provisions of this Article 7, Buyer shall indemnify and hold harmless Seller and its Affiliates, and their respective licensors, licensees, officers, directors, employees and agents (collectively, "**Seller Indemnitees**") from and against, and compensate or reimburse the Seller Indemnitees for, any and all Losses incurred by any Seller Indemnitee arising out of or related to:

(a) any breach by Buyer of any of the representations or warranties made by Buyer in this Agreement;

(b) any failure of Buyer to perform or any breach by Buyer of any of its covenants, agreements or obligations contained in this Agreement; or

(c) any Assumed Liability (except to the extent Seller is required to indemnify any Buyer Indemnitee for such Losses pursuant to Section 7.1.1(a)).

7.2 Claim Procedure.

7.2.1 Indemnification Claim Procedure. Except as provided in Section 7.2.2 with respect to Third Party claims, in the event of a claim made by a Buyer Indemnitee or a Seller Indemnitee (the "**Indemnified Party**"), the Indemnified Party shall give reasonably prompt written notice to the other Party (the "**Indemnifying Party**"), which notice (an "**Indemnification Certificate**") shall: (a) state that the Indemnified Party has paid or properly accrued or reasonably anticipates that it will have to pay or accrue Losses that are subject to indemnification by the Indemnifying Party pursuant to Section 7.1.1 or Section 7.1.2, as applicable, and (b) specify in reasonable detail the individual items and amounts of such Losses, the date each such item was paid or properly accrued, or the basis for such anticipated Liability, and a description of the basis of such Indemnified Party's claim for indemnification; *provided*, *however*, that the failure to give reasonably prompt notice shall not relieve the applicable Indemnifying Party of its indemnification obligations under this Agreement except to the extent that the Indemnifying Party is materially prejudiced by any delay in receiving such notice. In the event that the Indemnifying Party agrees to or is determined to have an obligation to reimburse the Indemnified Party for Losses as provided in this Article 7, the Indemnifying Party shall, subject to the provisions of Section 7.3, promptly (but, in any event, within 30 calendar days) pay such amount to the Indemnified Party by wire transfer of immediately available funds to the account specified in writing by the Indemnified Party. The Indemnifying Party may defer making such payment if it objects in a written statement to the claim made in the Indemnification Certificate and delivers such statement to the Indemnifying Party prior to the expiration of such 30- calendar day period. An Indemnifying Party's failure to object within such 30- calendar day period to any claim set forth in an Indemnification Certificate shall be deemed to be the Indemnifying Party's acceptance of, and waiver of any objections to, such claim. If an Indemnifying Party shall so object in writing to any claim or claims made in any Indemnification Certificate, the Indemnifying Party and the Indemnified Party shall attempt in good faith for a period of 20 calendar days following the Indemnified Party's receipt of such objection notice to agree upon the respective rights of the parties with respect to each of such claims. If no such agreement can be reached after such 20- calendar day period of good faith negotiation, either the Indemnifying Party or the Indemnified Party may initiate Litigation for purposes of having the matter settled in accordance with the terms of this Agreement.

7.2.2 Third Party Claim Procedure. In the event an Indemnified Party becomes aware of a claim made by a Third Party (including any action or proceeding commenced or threatened to be commenced by any Third Party) that such Indemnified Party reasonably believes may result in an indemnification claim pursuant to Section 7.1, such Indemnified Party shall promptly (and in any event within three Business Days after becoming aware of such claim) notify the Indemnifying Party in writing of such claim (such notice, the "**Claim Notice**"). The Claim Notice shall be accompanied by reasonable supporting documentation submitted by the Third Party making such claim and shall describe in reasonable detail (to the extent known by the Indemnified Party) the facts constituting the basis for such claim and the amount of the claimed damages; *provided*, *however*, that no delay or failure on the part of the Indemnified Party in delivering a Claim Notice shall relieve the Indemnifying Party from any Liability hereunder except to the extent of any damage or Liability caused by or arising out of such delay or failure. Within 30 calendar days after receipt of any Claim Notice, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of the claim referred to therein at the Indemnifying Party's sole cost and expense (which shall be subject to Section 7.3) with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not so assume control of the defense of such claim, the Indemnified Party shall control the defense of such claim. The Party not controlling the defense of such claim (the "**Non-Controlling Party**") may participate therein at its own expense; *provided*, *however*, that if the Indemnifying Party assumes control of the defense of such claim and the Indemnifying Party and the Indemnified Party have materially conflicting interests or different defenses available with respect to such claim that cause the Indemnified Party to hire its own separate counsel with respect to such proceeding, the reasonable fees and expenses of a single counsel to the Indemnified Party shall be considered "Losses" for purposes of this Agreement. The Party controlling the defense of such claim (the "**Controlling Party**") shall keep the Non-Controlling Party reasonably advised of the status of such claim and the defense thereof and shall consider in good faith recommendations made by the Non-Controlling Party with respect thereto. The Non-Controlling Party shall furnish the Controlling Party with such information as it may have with respect to such claim (including copies of any summons, complaint or other pleading that may have been served on such party and any written claim, demand, invoice, billing or other document evidencing or asserting the same) and shall otherwise cooperate with and assist the Controlling Party in the defense of such claim. Neither the Indemnified Party nor the Indemnifying Party shall agree to any settlement of, or the entry of any judgment arising from, any such claim without the prior written consent of the other Party, which consent shall not be unreasonably withheld, conditioned or delayed; *provided*, *however*, that the consent of the Indemnified Party shall not be required with respect to any such settlement or judgment if the Indemnifying Party agrees in writing to pay or cause to be paid any amounts payable pursuant to such settlement or judgment (net of the applicable deductible amount specified in Section 7.3.1) and such settlement or judgment includes no admission of liability by or other obligation on the part of the Indemnified Party and includes a complete release of the Indemnified Party from further Liability.

7.3 Limitations on Indemnification.

7.3.1 The provisions for indemnity under Section 7.1.1(a) or Section 7.1.2(a) shall be effective only (a) for any individual claim or series of related claims arising from the same facts and circumstances where the Loss exceeds [***] and (b) when the aggregate amount of all Losses for claims or series of related claims arising from the same facts and circumstances in excess of [***] for which indemnification is sought from the Indemnifying Party exceeds [***], in which case the Indemnified Party shall be entitled to indemnification of the Indemnified Party's Losses in excess thereof. In no event shall any Indemnifying Party have liability for indemnification under Section 7.1.1(a) or Section 7.1.2(a), as applicable, for any amount exceeding, in the aggregate, [***].

7.3.2 The Indemnified Party shall take all commercially reasonable steps to mitigate any Losses incurred by such Party upon and after becoming aware of any event or condition that would reasonably be expected to give rise to any indemnification rights hereunder. The amount of Losses recovered by an Indemnified Party under Section 7.1.1 or Section 7.1.2, as applicable, shall be reduced by (a) any amounts actually recovered by the Indemnified Party from a Third Party in connection with such claim and (b) the amount of any insurance proceeds paid to the Indemnified Party relating to such claim, in each case ((a) and (b)), out of the Indemnified Party's costs of recovery. Buyer shall use its reasonable best efforts to collect insurance proceeds for any Loss that is subject to indemnification by Seller under Section 7.1.1. If any amounts referenced in the preceding clauses (a) and (b) are received after payment by the Indemnifying Party of the full amount otherwise required to be paid to an Indemnified Party pursuant to this Article 7, the Indemnified Party shall repay to the Indemnifying Party, promptly after such receipt, any amount that the Indemnifying Party would not have had to pay pursuant to this Article 7 had such amounts been received prior to such payment.

7.3.3 If the Indemnified Party receives any payment from an Indemnifying Party in respect of any Losses pursuant to Section 7.1.1 or Section 7.1.2 and the Indemnified Party could have recovered all or a part of such Losses from a Third Party based on the underlying claim asserted against the Indemnifying Party, the Indemnified Party shall assign such of its rights to proceed against such Third Party as are necessary to permit the Indemnifying Party to recover from the Third Party the amount of such payment.

7.3.4 The representations and warranties of Seller and Buyer contained in this Agreement shall survive the Closing and continue in full force and effect thereafter through and including the date that is [***] after the Closing Date. None of the covenants or agreements contained in this Agreement shall survive the Closing other than those that by their terms expressly contemplate performance after the Closing Date and such surviving covenants and agreements shall survive the Closing until fully performed.

7.3.5 TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW AND EXCEPT AS A RESULT OF COMMON LAW FRAUD, NEITHER BUYER NOR SELLER SHALL BE LIABLE TO THE OTHER, OR THEIR AFFILIATES, FOR ANY CLAIMS, DEMANDS OR SUITS FOR CONSEQUENTIAL, INCIDENTAL, SPECIAL, EXEMPLARY, PUNITIVE, INDIRECT OR MULTIPLE DAMAGES, INCLUDING LOSS OF PROFITS, REVENUE OR INCOME, DIMINUTION IN VALUE OR LOSS OF BUSINESS OPPORTUNITY (WHETHER OR NOT FORESEEABLE AT THE EFFECTIVE DATE), CONNECTED WITH OR RESULTING FROM ANY BREACH OF THIS AGREEMENT, OR ANY ACTIONS UNDERTAKEN IN CONNECTION HEREWITH, OR RELATED HERETO, INCLUDING ANY SUCH DAMAGES WHICH ARE BASED UPON BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE AND MISREPRESENTATION), BREACH OF WARRANTY, STRICT LIABILITY, STATUTE, OPERATION OF LAW OR ANY OTHER THEORY OF RECOVERY.

7.3.6 For the avoidance of doubt, no Indemnitee shall be entitled to indemnification under this Article 7 in respect of any Loss to the extent such Indemnitee has been previously indemnified or reimbursed in respect of such Loss pursuant to any other provision of this Agreement or any provision of any Ancillary Agreement.

7.4 Tax Treatment of Indemnification Payments. All payments made pursuant to this Article 7 shall be treated as adjustments to the Purchase Price for all Tax purposes, unless otherwise required by applicable Law.

7.5 Exclusive Remedy. Except as expressly provided otherwise in this Agreement and subject to Section 9.9, each Party acknowledges and agrees that, following the Closing, the remedies provided for in this Article 7 shall be the sole and exclusive remedies for claims and damages available to the Parties and their respective Affiliates arising out of or relating to this Agreement and the transactions contemplated hereby, except that nothing herein shall limit the Liability of either Party for common law fraud. Notwithstanding anything to the contrary contained in this Agreement, no breach of any representation, warranty, covenant or agreement contained herein shall, after the consummation of the transactions contemplated by this Agreement, give rise to any right on the part of Buyer, on the one hand, or Seller, on the other hand, to rescind this Agreement or any of the transactions contemplated hereby.

7.6 Setoff Rights. Except as provided in Sections 2.3.2(b) and (c) above, neither Party shall have any right of setoff of any amounts due and payable, or any Liabilities arising, under this Agreement against any other amounts due and payable under this Agreement or any amounts due and payable, or any Liabilities arising, under any Ancillary Agreement. The payment obligations under each of this Agreement and the Ancillary Agreements remain independent obligations of each Party, irrespective of any amounts owed to any other Party under this Agreement or the respective Ancillary Agreements.

7.7 Disclaimer. Except as expressly set forth in any representation or warranty in Section 3.1, Buyer acknowledges and agrees that it and other Buyer Indemnitees shall have no claim or right to indemnification pursuant to this Article 7 (or otherwise) with respect to any information, documents, or materials furnished to or for Buyer or its Representatives by Seller or any of its Affiliates or any of their Representatives, including any information, documents, or material made available to Buyer in any "data room," "teaser," management presentation or other form in connection with the transactions contemplated by this Agreement or any Ancillary Agreement.

TERMINATION

8.1 Termination. Prior to the Closing, this Agreement shall terminate on the earliest to occur of any of the following events:

8.1.1 the mutual written agreement of Buyer and Seller;

8.1.2 by written notice delivered by either Buyer or Seller to the other, if the Closing shall not have occurred on or prior to [***] (the "**End Date**") (other than (a) due to a breach of any representation or warranty hereunder of the Party seeking to terminate this Agreement, (b) as a result of the failure on the part of the Party seeking to terminate this Agreement to comply with or perform any of its covenants, agreements or obligations under this Agreement or (c) as a result of any closing condition in favor of the non-terminating Party not being satisfied, which closing condition has been waived by the non-terminating Party); *provided*, *however*, that (i) Buyer shall not have the right to terminate this Agreement pursuant to this Section 8.1.2 during the pendency of any Litigation brought prior to the End Date by Seller for specific performance of this Agreement and (ii) Seller shall not have the right to terminate this Agreement pursuant to this Section 8.1.2 during the pendency of any Litigation brought before the End Date by Buyer for specific performance of this Agreement;

8.1.3 by written notice delivered by Buyer to Seller, if (a) there has been a breach by Seller of a representation or warranty of Seller contained in this Agreement or (b) there shall be a material breach by Seller of any covenant, agreement or obligation of Seller in this Agreement, and such failure or material breach described in clause (a) or (b) would result in the failure of a condition set forth in Section 6.2.1 or Section 6.2.2 that has not been waived by Buyer, or in the case of a breach of any covenant or agreement, is not cured upon the earlier to occur of (i) the 30th day after written notice thereof is given by Buyer to Seller and (ii) the Business Day prior to the End Date; *provided*, that Buyer may not terminate this Agreement pursuant to this Section 8.1.3 if Buyer is in material breach of its agreements or covenants contained in this Agreement;

8.1.4 by written notice delivered by Seller to Buyer, if (a) there has been a breach by Buyer of a representation or warranty of Buyer contained in this Agreement or (b) there shall be a material breach by Buyer of any covenant, agreement or obligation of Buyer in this Agreement, and such failure or breach described in clause (a) or clause (b) would result in the failure of a condition set forth in Section 6.3.1 or Section 6.3.2 that has not been waived by Seller, or in the case of a breach of any covenant or agreement, is not cured upon the earlier to occur of (i) the 30th day after written notice thereof is given by Seller to Buyer and (ii) the Business Day prior to the End Date; *provided*, that Seller may not terminate this Agreement pursuant to this Section 8.1.4 if Seller is in material breach of its agreements or covenants contained in this Agreement; or

8.1.5 by written notice delivered by Seller to Buyer or by Buyer to Seller if the condition set forth in Section 6.1.1 cannot be satisfied prior to the End Date; *provided*, *however*, that the right to terminate this Agreement pursuant to this Section 8.1.5 shall not be available to a Party if the inability to satisfy the condition set forth in Section 6.1.1 is a result of the failure of such Party to perform any of its covenants, agreements or obligations under this Agreement.

8.2 Procedure and Effect of Termination.

8.2.1 Notice of Termination. Termination of this Agreement by either Buyer or Seller shall be by delivery of a written notice to the other. Such notice shall state the termination provision in this Agreement that such terminating Party is claiming provides a basis for termination of this Agreement. Termination of this Agreement pursuant to the provisions of Section 8.1 shall be effective upon and as of the date of delivery of such written notice as determined pursuant to Section 9.2 or such other date as is provided in Section 8.1 above.

8.2.2 Effect of Termination. In the event of the termination of this Agreement pursuant to Section 8.1 by Buyer or Seller, this Agreement shall be terminated and have no further effect, and there shall be no liability hereunder on the part of Seller, Buyer or any of their respective Affiliates, except that Sections 5.2 (*Publicity*), 5.3 (*Confidentiality*), 8.2.2 (*Effect of Termination*), 8.2.3 (*Withdrawal of Certain Filings*) and Article 9 (*Miscellaneous*) shall survive any termination of this Agreement. For clarity, in the event of termination of this Agreement pursuant to Section 8.1, the Parties shall not enter into any of the Ancillary Agreements or have any obligations thereunder. Nothing in this Section 8.2.2 shall relieve any Party to this Agreement of liability for common law fraud in connection with, or any breach of, this Agreement prior to the termination hereof.

8.2.3 Withdrawal of Certain Filings. As soon as practicable following a termination of this Agreement for any reason, but in no event more than 30 calendar days after such termination, Buyer or Seller shall, to the extent practicable, withdraw all filings, applications and other submissions relating to the transactions contemplated by this Agreement filed or submitted by or on behalf of such Party, any Governmental Authority or other Person.

MISCELLANEOUS

9.1 Governing Law, Jurisdiction, Venue and Service.

9.1.1 Governing Law. This Agreement shall be governed by and construed in accordance with the Laws of the State of New York, excluding any conflicts or choice of Law rule or principle that might otherwise refer construction or interpretation of or any matter in dispute under this Agreement to the substantive Law of another jurisdiction.

9.1.2 Jurisdiction. Subject to Section 9.9, the Parties hereby irrevocably and unconditionally consent to the exclusive jurisdiction of the courts of the State of New York sitting in the Borough of Manhattan and the United States District Court for the Southern District of New York (the "**Applicable Courts**") for any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement or the transactions contemplated hereby, and agree not to commence any action, suit or proceeding (other than appeals therefrom) related thereto except in such courts. Notwithstanding the foregoing, any judgment or order issued by any Applicable Court may be enforced in any other court or applicable Governmental Authority, and neither Party shall challenge any such judgment or order in any court other than the Applicable Courts. The Parties irrevocably and unconditionally waive their right to a jury trial for any action, suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.1.3 Venue. The Parties further hereby irrevocably and unconditionally waive any objection to the laying of venue of any action, suit or proceeding (other than appeals therefrom) arising out of or relating to this Agreement or the transactions contemplated hereby in the Applicable Courts, and hereby further irrevocably and unconditionally waive and agree not to plead or claim in any Applicable Court that any such action, suit or proceeding brought in any such court has been brought in an inconvenient forum.

9.1.4 Service. Each Party further agrees that service of any process, summons, notice or document by registered mail to its address set forth in Section 9.2.2 shall be effective service of process for any action, suit or proceeding brought against it under this Agreement or in connection with the transactions contemplated hereby in any such court.

9.2 Notices.

9.2.1 Notice Requirements. Any notice, request, demand, waiver, consent, approval or other communication permitted or required under this Agreement (each, a "**Notice**") shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if delivered by hand or sent by facsimile transmission (with transmission confirmed) or by internationally recognized overnight delivery service that maintains records of delivery, addressed to the Parties at their respective addresses specified in Section 9.2.2 or to such other address as the Party to whom notice is to be given may have provided to the other Party at least 10 calendar days' prior to such address taking effect in accordance with this Section 9.2. Such Notice shall be deemed to have been given as of the date delivered by hand or internationally recognized overnight delivery service or confirmed that it was received by facsimile (with receipt confirmed by telephone or email). Any Notice delivered by facsimile shall be confirmed by a hard copy delivered as soon as practicable thereafter.

9.2.2 Address for Notice.

If to Seller, to:

Merck Sharp & Dohme B.V.
Waarderweg 39
2031 BN
Haarlem
Netherlands
Facsimile: + 31 41 266 2559
Attention: Legal Department

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

Merck Sharp & Dohme Corp.
One Merck Drive
Whitehouse Station, NJ 08889
Facsimile: (908) 735-1246
Attention: Office of Secretary

and to:

Covington & Burling LLP
One CityCenter, 850 Tenth Street, N.W.
Washington, DC 20001
Facsimile: (202) 778-5168
Attention: Michael J. Riella

If to Buyer, to:

ANI Pharmaceuticals, Inc.
210 Main Street West
Baudette, MN 56623
Attn: Charlotte C. Arnold
Facsimile: 218-634-3540

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

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

9.3 No Benefit to Third Parties. The covenants and agreements set forth in this Agreement are for the sole benefit of the Parties and their successors and permitted assigns, and, except for the rights of Buyer Indemnitees and Seller Indemnitees under Article 7, they shall not be construed as conferring any rights on any other Persons.

9.4 Waiver and Non-Exclusion of Remedies. Any term or condition of this Agreement may be waived at any time by the Party that is entitled to the benefit thereof, but no such waiver shall be effective unless set forth in a written instrument duly executed by or on behalf of the Party waiving such term or condition. The waiver by either Party of any right hereunder or of the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise. The rights and remedies provided herein are cumulative and do not exclude any other right or remedy provided by applicable Law or otherwise available except as expressly set forth herein.

9.5 Expenses. Except as otherwise specified herein, and whether or not the Closing takes place, each Party shall bear any costs and expenses incurred by it with respect to the transactions contemplated herein.

9.6 Assignment. Neither this Agreement nor Buyer's rights or obligations hereunder may be assigned or delegated by Buyer without the prior written consent of Seller, and any attempted assignment or delegation of this Agreement or any of such rights or obligations by Buyer without the prior written consent of Seller shall be void and of no effect, except that no such consent shall be required in connection with (a) the sale of all or substantially all of the assets of the Buyer in one or a series of related transactions or (b) Buyer's assignment of this Agreement and all of its rights and obligations hereunder to an Affiliate of Buyer during the Pre-Closing Period; *provided*, that no assignment by Buyer pursuant to the preceding clause (b) shall relieve Buyer of any of its obligations hereunder. Seller may assign this Agreement or assign or delegate any of Seller's rights or obligations hereunder without the prior written consent of Buyer. Subject to the preceding sentences, this Agreement will be binding upon, inure to the benefit of, and be enforceable by, the Parties and their respective successors and permitted assigns.

9.7 Amendment. This Agreement may not be modified, amended, altered or supplemented except upon the execution and delivery of a written agreement executed by both Parties.

9.8 Severability. If any provision of this Agreement is held to be illegal, invalid or unenforceable under any present or future Law, and if the rights or obligations of either Party under this Agreement will not be materially and adversely affected thereby, (a) such provision shall be fully severable, (b) this Agreement shall be construed and enforced as if such illegal, invalid or unenforceable provision had never comprised a part hereof, (c) the remaining provisions of this Agreement shall remain in full force and effect and shall not be affected by the illegal, invalid or unenforceable provision or by its severance herefrom and (d) in lieu of such illegal, invalid or unenforceable provision, there shall be added automatically as a part of this Agreement a legal, valid and enforceable provision as similar in terms to such illegal, invalid or unenforceable provision as may be possible and reasonably acceptable to the Parties.

9.9 Equitable Relief. The Parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the Parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any court of the United States or any state having jurisdiction, this being in addition to any other remedy to which they are entitled at law or in equity. Each Party hereby waives (a) any requirement that the other Party post a bond or other security as a condition for obtaining any such relief, and (b) any defenses in any action for specific performance, including the defense that a remedy at law would be adequate.

9.10 English Language. This Agreement shall be written and executed in, and all other communications under or in connection with this Agreement shall be in, the English language. Any translation into any other language shall not be an official version thereof, and in the event of any conflict in interpretation between the English version and such translation, the English version shall control.

9.11 Bulk Sales Statutes. Buyer hereby waives compliance by Seller with any applicable bulk sales statutes in any jurisdiction in connection with the transactions under this Agreement.

9.12 Counterparts. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

9.13 Entire Agreement. This Agreement, together with the Schedules and Exhibits expressly contemplated hereby and attached hereto, the Disclosure Schedules, the Ancillary Agreements and the other agreements, certificates and documents delivered in connection herewith or therewith or otherwise in connection with the transactions contemplated hereby and thereby, contain the entire agreement between the Parties with respect to the transactions contemplated hereby or thereby and supersede all prior agreements, understandings, promises and representations, whether written or oral, between the Parties with respect to the subject matter hereof and thereof, including the Confidentiality Agreement. In the event of any inconsistency between any such Schedules and Exhibits and this Agreement, the terms of this Agreement shall govern.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

MERCK SHARP & DOHME B.V.

By: _____

Name:
Title:

ANI PHARMACEUTICALS, INC.

By: _____

Name:
Title:

[Signature Page to Asset Purchase Agreement]

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: [***]

Schedule 1.1.34

Licensed Manufacturing Technology

[***]

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: [***]

Schedule 1.1.46

Purchased Documents

[***]

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: [***]

Schedule 1.1.50

Seller's Knowledge

[***]

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: [***]

Schedule 2.3.2(a)

Contingent Payments

[***]
[***]
[***]

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: [***]

Schedule 4.2

Ordinary Course of Business

[***]

EXHIBIT A

BILL OF SALE AND
ASSIGNMENT AND ASSUMPTION AGREEMENT

This Bill of Sale and Assignment and Assumption Agreement (this "**Agreement**") is made as of this [•] day of _____, 2016, by and between Merck Sharp & Dohme B.V., a limited liability company (*a Besloten Vennootschap*) organized and existing under the Laws of the Netherlands ("**MSD BV**"), Merck Sharp & Dohme Corp., a New Jersey corporation, Organon USA, Inc., a New Jersey corporation (each, a "**Seller**") on the one hand and [ANI Pharmaceuticals, Inc., a Delaware corporation] ("**Buyer**") on the other. Each Seller and Buyer is sometimes referred to herein individually as a "**Party**" and are referred to herein collectively as the "**Parties**."

RECITALS

WHEREAS, MSD BV and Buyer have entered into that certain Asset Purchase Agreement, dated as of September 18, 2015 (the "**Asset Purchase Agreement**"); and

WHEREAS, pursuant to the Asset Purchase Agreement, Buyer has agreed to acquire the Purchased Assets and assume the Assumed Liabilities from MSD BV or its Specified Affiliates, and MSD BV has agreed to sell, transfer, convey, assign and deliver to Buyer all of MSD BV's or its Specified Affiliates' rights, title and interest in and to the Purchased Assets and transfer the Assumed Liabilities to Buyer.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Agreement and of the representations, warranties, conditions, agreements and promises contained in the Asset Purchase Agreement, this Agreement and the other Ancillary Agreements, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. **Defined Terms**. Unless otherwise specifically provided herein, capitalized terms used in this Agreement and not otherwise defined herein shall have the respective meanings ascribed thereto in the Asset Purchase Agreement.

2. **Conveyance and Acceptance**. In accordance with the provisions of the Asset Purchase Agreement, (a) each Seller hereby sells, transfers, conveys, assigns and delivers to Buyer, free and clear of any Liens other than Permitted Liens, all of its right, title, and interest in and to the Purchased Assets, and (b) Buyer hereby accepts such sale, transfer, conveyance, assignment and delivery.

3. **Assumption of Assumed Liabilities**. Each Seller hereby assigns to Buyer the Assumed Liabilities and Buyer hereby unconditionally assumes and agrees to pay and discharge when due the Assumed Liabilities.

4. **Asset Purchase Agreement Controls**. Notwithstanding any other provision of this Agreement to the contrary, nothing contained herein shall in any way supersede, modify, replace, amend, change, rescind, waive, exceed, expand, enlarge or in any way affect the provisions, including warranties, covenants, agreements, conditions, representations or, in general any of the rights and remedies, or any of the obligations of Buyer or MSD BV set forth in the Asset Purchase Agreement. This Agreement is subject to, and governed entirely in accordance with, the terms and conditions of the Asset Purchase Agreement. Nothing contained herein is intended to modify or supersede any of the provisions of the Asset Purchase Agreement.

5. **Counterparts**. This Agreement may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Agreement by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Agreement.

[*Signature page follows*]

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

MERCK SHARP & DOHME B.V.

By: _____
Name:
Title:

MERCK SHARP & DOHME CORP.

By: _____
Name:
Title:

ORGANON USA, INC.

By: _____
Name:
Title:

[ANI PHARMACEUTICALS, INC.]

By: _____
Name:
Title:

EXHIBIT B-1
BUYER FDA TRANSFER LETTERS

_____ __, 2016

Jean-Marc Guettier, M.D., Director
Division of Metabolism and
Endocrinology Products (DMEP)
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

ACCEPTANCE OF OF NDA OWNERSHIP

SUBJECT: **NDA 08975**
Purified Cortrophin gel (Corticotropin) Injection, 40 Units/mL and 80 Units/mL

Dear Dr. Guettier:

In accordance with 21 CFR § 314.72(a)(2),[[name of subsidiary], a wholly owned subsidiary of ANI Pharmaceuticals, Inc.], is accepting the transfer of ownership, including all rights to the New Drug Application (NDA) 08975: Purified Cortrophin gel (Corticotropin) Injection, 40 Units/mL and 80 units/ml from Merck Sharp & Dohme Corp. (Please refer to **Module 1.3.1.5 Change in Ownership of an Application).**

Merck Sharp & Dohme Corp. (Merck), a subsidiary of Merck & Co., Inc., notified the agency of the transfer on behalf of Organon, USA Inc., which is also a subsidiary of Merck & Co., Inc. of this ownership in the Transfer of NDA Ownership letter dated _____ __, 2016. The effective date of the change of ownership is _____ __, 2016.

New Owner of NDA	**Previous Owner of NDA**
[name of subsidiary] 210 Main Street West Baudette, MN 56623	[Merck]

By accepting the ownership of this NDA 08975, [name of subsidiary] commits to all agreements, promises and conditions made by the former owner (Merck) and contained in the application. [name of subsidiary] has received a copy of the approved application, including supplements and records that are required to be kept under 21 CFR § 314.81. If at any time during the review of the transferred records [name of subsidiary]. becomes aware of absent documents that are required, we commit to making a request from the FDA's files under the fee schedule in 21 CFR § 20.45 of FDA's public information regulations.

In accordance with 21 CFR § 314.72(b), [name of subsidiary] will advise the FDA about any change in the conditions in the approved applications under 21 CFR § 314.70. Additionally, [name of subsidiary] will include in the subsequent annual report any changes to the drug product's label or labeling to change the product's brand or the name of the manufacturer, packer, or distributor.

Please note the contact information for the Responsible official at ANI Pharmaceuticals, Inc. for all regulatory inquiries: (Refer to **Module 1.3.1.2 Change in Contact/Agent**).

Responsible Official	
Name:	Ellen Camos
Title:	Director, Regulatory Affairs
Phone :	919.449.4033
Alt. Phone:	218.634.3638
Fax :	888.519.0459
Email :	ellen.camos@anipharmaceuticals.com

The electronic submission is in the Electronic Common Technical Document format (eCTD) and sent via the FDA Gateway; sequence 0000. The approximate size of the electronic submission is displayed in the window of the gateway. This electronic submission is virus free.

During your review of this application, if there are any questions concerning this submission, please contact me at the information provided under my signature.

Sincerely,

Ellen Camos
Director, Regulatory Affairs
[name of subsidiary]
Phone : 919.449.4033
Alt. Phone: 218.634.3638
Fax : 888.519.0459
Email: ellen.camos@anipharmaceuticals.com

EXHIBIT B-2
BUYER FDA TRANSFER LETTERS

ani Pharmaceuticals, Inc.

_____ __, 2016

Jean-Marc Guettier, M.D., Director
Division of Metabolism and
Endocrinology Products (DMEP)
Center for Drug Evaluation and Research
Food and Drug Administration
5901-B Ammendale Road
Beltsville, MD 20705-1266

ACCEPTANCE OF OF NDA OWNERSHIP

SUBJECT: **NDA 09854**
Cortrophin-Zinc (Corticotropin zinc hydroxide) Injection, 40 Units/mL

Dear Dr. Guettier:

In accordance with 21 CFR § 314.72(a)(2),[[name of subsidiary], a wholly owned subsidiary of ANI Pharmaceuticals, Inc.], is accepting the transfer of ownership, including all rights to the New Drug Application (NDA) 09854: Cortrophin-Zinc (Corticotropin zinc hydroxide) Injection, 40 Units/mL from Merck Sharp & Dohme Corp. (Please refer to **Module 1.3.1.5 Change in Ownership of an Application).**

Merck Sharp & Dohme Corp. (Merck), a subsidiary of Merck & Co., Inc., notified the agency of the transfer on behalf of Organon, USA Inc., which is also a subsidiary of Merck & Co., Inc. of this ownership in the Transfer of NDA Ownership letter dated _____ __, 2016. The effective date of the change of ownership is _____ __, 2016.

New Owner of NDA	Previous Owner of NDA
[name of subsidiary] 210 Main Street West Baudette, MN 56623	[Merck]

By accepting the ownership of this NDA 09854, [name of subsidiary] commits to all agreements, promises and conditions made by the former owner (Merck) and contained in the application. [name of subsidiary] has received a copy of the approved application, including supplements and records that are required to be kept under 21 CFR § 314.81. If at any time during the review of the transferred records [name of subsidiary] becomes aware of absent documents that are required, we commit to making a request from the FDA's files under the fee schedule in 21 CFR § 20.45 of FDA's public information regulations.

In accordance with 21 CFR § 314.72(b), [name of subsidiary] will advise the FDA about any change in the conditions in the approved applications under 21 CFR § 314.70. Additionally, [name of subsidiary] will include in the subsequent annual report any changes to the drug product's label or labeling to change the product's brand or the name of the manufacturer, packer, or distributor.

Please note the contact information for the Responsible official at ANI Pharmaceuticals, Inc. for all regulatory inquiries: (Refer to **Module 1.3.1.2 Change in Contact/Agent**).

Responsible Official	
Name:	Ellen Camos
Title:	Director, Regulatory Affairs
Phone :	919.449.4033
Alt. Phone:	218.634.3638
Fax :	888.519.0459
Email :	ellen.camos@anipharmaceuticals.com

The electronic submission is in the Electronic Common Technical Document format (eCTD) and sent via the FDA Gateway; sequence 0000. The approximate size of the electronic submission is displayed in the window of the gateway. This electronic submission is virus free.

During your review of this application, if there are any questions concerning this submission, please contact me at the information provided under my signature.

Sincerely,

Ellen Camos
Director, Regulatory Affairs
[name of subsidiary]
Phone : 919.449.4033
Alt. Phone: 218.634.3638
Fax : 888.519.0459
Email: ellen.camos@anipharmaceuticals.com

EXHIBIT C-1

SELLER FDA TRANSFER LETTERS

[MERCK LETTERHEAD]

_____ __, 2016

Jean-Marc Guettier, M.D., Acting Director
Division of Metabolism and Endocrinology Products (DMEP)
Center for Drug Evaluation and Research
Food and Drug Administration

NDA 08-975: Corticotrophin
General Correspondence – Transfer of Ownership

Dear Dr. Guettier:

Merck Sharp & Dohme Corp. (Merck), a subsidiary of Merck & Co., Inc. is filing this submission on behalf of Organon, USA Inc., which is also a subsidiary of Merck & Co., Inc.

This is to inform you that as of _____ __, 2016, Merck, holder of NDA **08-975** for **Corticotrophin** has transferred the NDA **08-975** to XXXX. XXXXX has assumed the ownership and all rights and responsibilities of the referenced NDA and will also notify the Division of Metabolism and Endocrinology Products of the transfer of NDA **08-975**.

All future correspondence and regulatory communications concerning NDA **08-975** for **Corticotrophin**, should be directed to the XXXX:

XXXXXXXXX
Name
Address
Telephone
Fax
DUNS number:

E-mail

This submission is being submitted in accordance with the current FDA Guidance Documents for the electronic common technical document. This submission is being transmitted through the FDA's electronic submission gateway. Merck has taken precautions to ensure that the contents are free of computer viruses (McAfee Agent, McAfee, Inc.), and Merck authorizes the use of anti-virus software, as appropriate.

Merck considers the information included in this submission to be a confidential matter, and request that the Food and Drug Administration not make its content, public without first obtaining the written permission of Merck.

For further information or questions, please contact me by phone at [Tel. number] or email, [email]. In my absence, questions concerning the content of this submission should be directed to [name] ([Tel. number, email]).

Sincerely,

[name]
Manager, Regulatory Affairs International
Global Regulatory Affairs

EXHIBIT C-2

SELLER FDA TRANSFER LETTERS

[MERCK LETTERHEAD]

_____ __, 2016

Jean-Marc Guettier, M.D., Acting Director
Division of Metabolism and Endocrinology Products (DMEP)
Center for Drug Evaluation and Research
Food and Drug Administration

NDA 09-854: Corticotrophin zinc hydroxide suspension
General Correspondence – Transfer of Ownership

Dear Dr. Guettier:

Merck Sharp & Dohme Corp. (Merck), a subsidiary of Merck & Co., Inc. is filing this submission on behalf of Organon, USA Inc., which is also a subsidiary of Merck & Co., Inc.

This is to inform you that as of _____ __, 2016, Merck, holder of NDA 09-854 for **Corticotrophin zinc hydroxide suspension** has transferred the NDA 09-854 to XXXX. XXXXX has assumed the ownership and all rights and responsibilities of the referenced NDA and will also notify the Division of Metabolism and Endocrinology Products of the transfer of NDA 09-854.

All future correspondence and regulatory communications concerning NDA 09-854 for **Corticotrophin zinc hydroxide suspension**, should be directed to the XXXX:

XXXXXXXXX
Name
Address
Telephone
Fax
DUNS number:

E-mail

This submission is being submitted in accordance with the current FDA Guidance Documents for the electronic common technical document. This submission is being transmitted through the FDA's electronic submission gateway. Merck has taken precautions to ensure that the contents are free of computer viruses (McAfee Agent, McAfee, Inc.), and Merck authorizes the use of anti-virus software, as appropriate.

Merck considers the information included in this submission to be a confidential matter, and request that the Food and Drug Administration not make its content, public without first obtaining the written permission of Merck.

For further information or questions, please contact me by phone at [Tel. number] or email, [email]. In my absence, questions concerning the content of this submission should be directed to [name] ([Tel. number, email]).

Sincerely,

[name]
Manager, Regulatory Affairs International
Global Regulatory Affairs

EXHIBIT D

TRADEMARK ASSIGNMENT

This Trademark Assignment (this "**Trademark Assignment**") is made as of this [•] day of _____, 2016, by and between Merck Sharp & Dohme Corp., a New Jersey corporation ("**MSD Corp.**"), and [ANI Pharmaceuticals, Inc., a Delaware corporation] ("**Buyer**"). Each of MSD Corp. and Buyer is sometimes referred to herein individually as a "**Party**" and are referred to herein collectively as the "**Parties**."

RECITALS

WHEREAS, MSD Corp. is the owner in the United States of the Trademark applications set forth on Schedule A attached hereto and made part hereof (collectively, the "**Purchased Trademarks**");

WHEREAS, Merck Sharp & Dohme B.V. ("**Seller**"), an Affiliate of MSD Corp., and Buyer have entered into that certain Asset Purchase Agreement, dated as of September 18, 2015 (the "**Asset Purchase Agreement**"); and

WHEREAS, pursuant to the Asset Purchase Agreement, Buyer has agreed to acquire from Seller or its Affiliates, and Seller has agreed to, or to cause its Affiliates to, sell, transfer, convey, assign and deliver to Buyer all of Seller's or its Affiliates' rights, title and interest in and to the Purchased Trademarks and the goodwill of the business associated with and symbolized by the Purchased Trademarks.

NOW, THEREFORE, in consideration of the mutual benefits to be derived from this Trademark Assignment and of the representations, warranties, conditions, agreements and promises contained in the Asset Purchase Agreement, this Trademark Assignment and the other Ancillary Agreements, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, hereby agree as follows:

1. **Defined Terms.** Unless otherwise specifically provided herein, capitalized terms used in this Trademark Assignment and not otherwise defined herein shall have the respective meanings ascribed thereto in the Asset Purchase Agreement.

2. **Conveyance and Acceptance of Purchased Trademarks.** In accordance with the provisions of the Asset Purchase Agreement, (a) MSD Corp. hereby sells, transfers, conveys, assigns and delivers to Buyer, free and clear of any Liens other than Permitted Liens, all of its right, title and interest in and to the Purchased Trademarks in the United States and (b) Buyer hereby accepts such sale, transfer, conveyance, assignment and delivery.

3. **Recordation.** MSD Corp. hereby authorizes Buyer to record this Trademark Assignment with the U.S. Patent and Trademark Office. All costs and expenses, including Third Party filing and recordation fees and other disbursements, associated with the conveyance of the Purchased Trademarks and with the recordation of this Trademark Assignment shall be borne solely by Buyer.

4. **Asset Purchase Agreement Controls**. Notwithstanding any other provision of this Trademark Assignment to the contrary, nothing contained herein (other than in Section 3 above) shall in any way supersede, modify, replace, amend, change, rescind, waive, exceed, expand, enlarge or in any way affect the provisions, including warranties, covenants, agreements, conditions, representations or, in general any of the rights and remedies, or any of the obligations of Buyer or Seller set forth in the Asset Purchase Agreement. This Trademark Assignment is subject to, and governed entirely in accordance with, the terms and conditions of the Asset Purchase Agreement. Except as set forth in Section 3 above, nothing contained herein is intended to modify or supersede any of the provisions of the Asset Purchase Agreement.

5. **Further Assurances.** MSD Corp. agrees, at Buyer's expense, to take such further action and to execute and deliver such additional instruments and documents as Buyer may reasonably request to carry out and fulfill the purposes and intent of this Trademark Assignment.

6. **Counterparts.** This Trademark Assignment may be executed in any number of counterparts, and each such counterpart hereof shall be deemed to be an original instrument, but all such counterparts together shall constitute but one agreement. Delivery of an executed counterpart of a signature page of this Trademark Assignment by facsimile or other electronic transmission shall be effective as delivery of a manually executed original counterpart of this Trademark Assignment.

[*Signature page follows*]

IN WITNESS WHEREOF, the Parties have executed this Trademark Assignment as of the date first above written.

MERCK SHARP & DOHME CORP.

By: _____
Name:
Title:

[ANI PHARMACEUTICALS, INC.]

By: _____
Name:
Title:

[Signature Page to Trademark Assignment Agreement]

STATE OF _____}
} ss
COUNTY OF _____}

On this ____ day of _____, 2016, before me personally appeared _____, to me personally known, who, being duly sworn, did say that he/she is the _____ of Merck Sharp & Dohme Corp. and that he/she duly executed the foregoing instrument for and on behalf of Merck Sharp & Dohme Corp. being duly authorized to do so and that said individual acknowledged said instrument to be the free act and deed of said company.

_____
Notary Public
Expiration Date:_____

STATE OF _____}
} ss
COUNTY OF _____}

On this ____ day of _____, 2016, before me personally appeared _____, to me personally known, who, being duly sworn, did say that he/she is the _____ of [ANI Pharmaceuticals, Inc.] and that he/she duly executed the foregoing instrument for and on behalf of [ANI Pharmaceuticals, Inc.] being duly authorized to do so and that said individual acknowledged said instrument to be the free act and deed of said company.

_____
Notary Public
Expiration Date:_____

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: [***]

SCHEDULE A

PURCHASED TRADEMARKS

1. U.S. Trademark application for the Trademark CORTROPHIN, U.S. Serial No. 86534100, for “medicinal hormone preparation.”

2. U.S. Trademark application for the Trademark CORTROPHIN-ZINC, U.S. Serial No. 86534102, for “medicinal hormone preparation.”

Exhibit 31.1

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 3, 2015

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

Exhibit 31.2

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

I, Charlotte C. Arnold, 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 3, 2015

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

Exhibit 32.1

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, 2015 (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 3, 2015

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

Dated: November 3, 2015

/s/ Charlotte C. Arnold
Charlotte C. Arnold
Vice President, Finance 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.