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

FORM 10-Q

(Mark one)

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

For the quarterly period ended March 31, 2018

☐ **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 ☐
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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 May 1, 2018, there were 11,786,416 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended March 31, 2018
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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, acquisitions, contract manufacturing arrangements, 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, 2017, including the factors described in "Item 1A. Risk Factors." 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®, Cortrophin® Gel, Cortrophin-Zinc®, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiary. Atacand® and Atacand HCT® are the property of AstraZeneca AB and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Arimidex® and Casodex® are the property of AstraZeneca UK Limited and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products.

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

	March 31, 2018	*December 31, 2017*
Assets		
Current Assets		
Cash and cash equivalents	$ 51,970	$ 31,144
Accounts receivable, net of $30,786 and $34,686 of adjustments for chargebacks and other allowances at March 31, 2018 and December 31, 2017, respectively	54,801	58,788
Inventories, net	34,294	37,727
Prepaid income taxes, net	62	1,162
Prepaid expenses and other current assets	2,267	2,784
Total Current Assets	143,394	131,605
Property and equipment, net	21,882	20,403
Restricted cash	5,002	5,006
Deferred tax asset, net of valuation allowance	23,163	22,667
Intangible assets, net	221,917	229,790
Goodwill	1,838	1,838
Other long-term assets	823	829
Total Assets	$ 418,019	$ 412,138
Liabilities and Stockholders' Equity		
Current Liabilities		
Accounts payable	$ 4,886	$ 3,630
Accrued expenses and other	2,612	1,571
Accrued royalties	11,361	12,164
Accrued compensation and related expenses	1,495	2,306
Accrued government rebates	6,471	7,930
Returned goods reserve	9,020	8,274
Current component of long-term borrowing, net of deferred financing costs	3,805	3,353
Total Current Liabilities	39,650	39,228
Long-term Liabilities		
Long-term borrowing, net of deferred financing costs and current borrowing component	68,569	69,946
Convertible notes, net of discount and deferred financing costs	130,156	128,208
Total Liabilities	$ 238,375	$ 237,382
Commitments and Contingencies (Note 10)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 11,729,981 shares issued and 11,725,692 shares outstanding at March 31, 2018; 11,655,768 shares issued and 11,650,565 outstanding at December 31, 2017	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	-	-
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at March 31, 2018 and December 31, 2017, respectively	-	-
Treasury stock, 4,289 shares of common stock, at cost, at March 31, 2018 and 5,203 shares of common stock, at cost, at December 31, 2017	(250)	(259)
Additional paid-in capital	181,649	179,020
Accumulated deficit	(1,756)	(4,006)
Total Stockholders' Equity	179,644	174,756
Total Liabilities and Stockholders' Equity	$ 418,019	$ 412,138

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 March 31,	
	2018	***2017***
Net Revenues	$ 46,483	$ 36,628
Operating Expenses:		
Cost of sales (excluding depreciation and amortization)	20,693	16,386
Research and development	2,102	1,618
Selling, general, and administrative	8,956	7,293
Depreciation and amortization	8,195	6,706
Total Operating Expenses	39,946	32,003
Operating Income	6,537	4,625
Other Expense, net		
Interest expense, net	(3,634)	(2,932)
Other expense, net	(61)	(18)
Income Before Provision for Income Taxes	2,842	1,675
Provision for income taxes	(592)	(523)
Net Income	$ 2,250	$ 1,152
Basic and Diluted Earnings Per Share:		
Basic Earnings Per Share	$ 0.19	$ 0.10
Diluted Earnings Per Share	$ 0.19	$ 0.10
Basic Weighted-Average Shares Outstanding	11,589	11,527
Diluted Weighted-Average Shares Outstanding	11,706	11,653

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

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

	Three Months Ended March 31,	
	2018	***2017***
Cash Flows From Operating Activities		
Net income	$ 2,250	$ 1,152
Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	1,377	1,386
Deferred taxes	(496)	(735)
Depreciation and amortization	8,195	6,706
Non-cash interest relating to convertible notes and loan cost amortization	2,107	1,882
Changes in operating assets and liabilities:		
Accounts receivable, net	3,987	(802)
Inventories, net	3,433	(2,810)
Prepaid expenses and other current assets	530	(25)
Accounts payable	1,705	1,318
Accrued royalties	(803)	(2,250)
Accrued compensation and related expenses	(811)	(496)
Current income taxes, net	1,100	1,258
Accrued government rebates	(1,459)	(1,236)
Returned goods reserve	746	20
Accrued expenses and other	1,069	1,161
Net Cash and Cash Equivalents Provided by Operating Activities	22,930	6,529
Cash Flows From Investing Activities		
Acquisition of product rights and other related assets	-	(50,956)
Acquisition of property and equipment, net	(2,278)	(2,138)
Net Cash and Cash Equivalents Used in Investing Activities	(2,278)	(53,094)
Cash Flows From Financing Activities		
Payment of debt issuance costs	(153)	-
Payments on term loan agreement	(938)	-
Net borrowings under line of credit agreement	-	30,000
Proceeds from stock option exercises	1,511	25
Treasury stock purchases for restricted stock vestings	(250)	-
Net Cash and Cash Equivalents Provided by Financing Activities	170	30,025
Change in Cash, Cash Equivalents, and Restricted Cash	20,822	(16,540)
Cash, cash equivalents, and restricted cash, beginning of period	36,150	32,367
Cash, cash equivalents, and restricted cash, end of period	$ 56,972	$ 15,827
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	31,144	27,365
Restricted cash	5,006	5,002
Cash, cash equivalents, and restricted cash, beginning of period	36,150	32,367
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	51,970	10,826
Restricted cash	5,002	5,001
Cash, cash equivalents, and restricted cash, end of period	56,972	15,827
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 453	$ -
Cash paid for income taxes	$ -	$ 4
Supplemental non-cash investing and financing activities:		
Property and equipment purchased and included in accounts payable	$ 36	$ 78

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

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

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiary, ANIP Acquisition Company (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations. Our two pharmaceutical manufacturing facilities located in Baudette, Minnesota are capable of producing oral solid dose products, as well as liquids and topicals, controlled substances, 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 our 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 consolidated balance sheet at December 31, 2017, has been derived from audited financial statements of that date. The unaudited 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, 2017.

Principles of Consolidation

The unaudited interim condensed consolidated financial statements include the accounts of ANI Pharmaceuticals, Inc. and its subsidiary. All 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, administrative fees and rebates, government rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, deferred tax valuation allowance, purchase price allocations, and the depreciable lives of long-lived assets. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

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

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In June 2016, the Financial Accounting Standards Board ("FASB") issued guidance with respect to measuring credit losses on financial instruments, including trade receivables. The guidance eliminates the probable initial recognition threshold that was previously required prior to recognizing a credit loss on financial instruments. The credit loss estimate can now reflect an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. The guidance is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. The adoption of certain amendments of this guidance must be applied on a modified retrospective basis and the adoption of the remaining amendments must be applied on a prospective basis. We currently expect that the adoption of this guidance will likely change the way we assess the collectability of our receivables and recoverability of other financial instruments. We have not yet begun to evaluate the specific impacts of this guidance nor have we determined the manner in which we will adopt this guidance.

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We will adopt this guidance as of January 1, 2019. We are currently reviewing our leases and other contracts to determine if the adoption of this guidance will have a material impact on our consolidated financial statements. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording the future benefits of those leases and the related minimum lease payments on our consolidated balance sheets.

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 condensed consolidated statements of operations, balance sheets, or cash flows.

Recently Adopted Accounting Pronouncements

In August 2017, the FASB issued guidance improving accounting for hedging activities. The guidance is intended to simplify hedge accounting by better aligning how an entity's risk management activities and hedging relationships are presented in its financial statements. The guidance also simplifies the application of hedge accounting guidance in certain situations. The guidance is effective for the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. The guidance with respect to the cash flow and net investment hedge relationships existing on the date of adoption must be applied on a modified retrospective basis and the new disclosure requirements must be applied on a prospective basis. We adopted this guidance as of January 1, 2018. The adoption of this guidance did not have a material impact on our consolidated financial statements.

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

In May 2017, the FASB issued guidance clarifying when modification accounting should be used for changes to the terms or conditions of a share-based payment award. The guidance does not change the accounting for modifications, but clarifies that modification accounting guidance should only be applied if there is a change to the value, vesting conditions, or award classification and would not be required if the changes are considered non-substantive. The guidance is effective for the fiscal years beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. We adopted this guidance as of January 1, 2018 on a prospective basis. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. 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. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. In September 2017, the FASB issued guidance amending and rescinding prior SEC staff announcements and observer comments related to revenue recognition, pursuant to the SEC Staff Announcement at the July 20, 2017 Emerging Issues Task Force meeting.

We performed a comprehensive review of our existing revenue arrangements as of January 1, 2018 following the five-step model. Our analysis indicated that there were no significant changes to how the amount and timing of revenue is recognized under the new guidance as compared to existing guidance. Additionally, our analysis indicated that there were no significant changes to how costs to obtain and fulfill our customer contracts are recognized under the new guidance as compared to existing guidance. We adopted this guidance as of January 1, 2018 using the modified retrospective method and the impact of adoption on our consolidated balance sheet, statement of operations, and statement of cash flows was not material. The adoption of the new guidance impacted the way we analyze, document, and disclose revenue recognition under customer contracts beginning on January 1, 2018 and resulted in additional disclosures in our financial statements.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

As of January 1, 2018, we adopted guidance for revenue recognition for contracts, using the modified retrospective method. The implementation of the guidance had no material impact on the measurement or recognition of revenue from customer contracts of prior periods. For our revenue recognition policies prior to adopting the guidance for revenue recognition for contracts, please see 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, 2017.

Upon adoption of this new guidance, we recognize revenue using the following steps:

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;
- Determination of the transaction price, including the identification and estimation of variable consideration;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when we satisfy a performance obligation.

We derive our revenues primarily from sales of generic and branded pharmaceutical products. Revenue is recognized when our obligations under the terms of our contracts with customers are satisfied, which generally occurs when control of the products we sell is transferred to the customer. We estimate variable consideration after considering applicable information that is reasonably available. We generally do not have incremental costs to obtain contracts that would otherwise not have been incurred. We do not adjust revenue for the promised amount of consideration for the effects of a significant financing component because our customers generally pay us within 100 days.

All revenue recognized in the accompanying unaudited interim condensed consolidated statements of operations is considered to be revenue from contracts with customers. The following table depicts the disaggregation of revenue according to contract type as of:

	Three Months Ended	
(in thousands)	**March 31, 2018**	**March 31, 2017**
Sales of generic pharmaceutical products	$ 23,227	$ 26,572
Sales of branded pharmaceutical products	16,595	8,039
Sales of contract manufactured products	945	1,793
Royalties on sales of pharmaceutical products	5,382	-
Other[(1)]	334	224
Total net revenues	$ 46,483	$ 36,628

[(1)] Primarily includes laboratory services and royalties on sales of contract manufactured products

In the three months ended March 31, 2018, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts. We recognized $3.3 million of net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2018, consisting primarily of royalties on sales of pharmaceutical products and revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

Revenue from Sales of Generic and Branded Pharmaceutical Products

Product sales consists of sales of our generic and brand pharmaceutical products. Our sole performance obligation in our contracts is to provide pharmaceutical products to customers. Our products are sold at pre-determined standalone selling prices and our performance obligation is considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer upon delivery of the product to the customer, as our pharmaceutical products are sold on an FOB destination basis and because inventory risk and risk of ownership passes to the customer upon delivery. Payment terms for these sales are generally less than 100 days.

Sales of our pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative and other rebates, and cash discounts. Estimates for these elements of variable consideration require significant judgment.

Chargebacks

Chargebacks, primarily from wholesalers, result from arrangements we have with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost ("WAC").
Chargeback credits are calculated as follows:

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

- A change in customer mix
- A change in negotiated terms with customers
- A change in the volume of off-contract purchases
- Changes in WAC

As necessary, we adjust ASPs based on anticipated changes in the factors above.

The difference between ASP and WAC is recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets, at the time we recognize revenue from the product sale.

To evaluate the adequacy of our chargeback accruals, we obtain on-hand inventory counts from the wholesalers. This inventory is multiplied by the chargeback amount, the difference between ASP and WAC, to arrive at total expected future chargebacks, which is then compared to the chargeback accruals. We continually monitor chargeback activity and adjust ASPs when we believe that actual selling prices will differ from current ASPs.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

Government Rebates

Our government rebates reserve consists of estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. The two largest government programs that impact our net revenue and our government rebates reserve are federal and state Medicaid rebate programs and Medicare.

We participate in certain qualifying federal and state Medicaid rebate programs whereby discounts and rebates are provided to participating programs after the final dispensing of the product by a pharmacy to a Medicaid plan participant. Medicaid rebates are typically billed up to 120 days after the product is shipped. Medicaid rebate amounts per product unit are established by law, based on the Average Manufacturer Price ("AMP"), which is reported on a monthly and quarterly basis, and, in the case of branded products, best price, which is reported on a quarterly basis. Our Medicaid reserves are based on expected claims from state Medicaid programs. Estimates for expected claims are driven by patient usage, sales mix, calculated AMP or best price, as well as inventory in the distribution channel that will be subject to a Medicaid rebate. As a result of the delay between selling the products and rebate billing, our Medicaid rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants.

Many of our products are also covered under Medicare. We, like all pharmaceutical companies, must provide a discount for any products sold under New Drug Applications ("NDAs") to Medicare Part D participants. This applies to all products sold under NDAs, regardless of whether the products are marketed as branded or generic. Our estimates for these discounts are based on historical experience with Medicare rebates for our products. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future rebates. Medicare rebates are typically billed up to 120 days after the product is shipped. As a result of the delay between selling the products and rebate billing, our Medicare rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to Medicare Part D participants.

To evaluate the adequacy of our government rebate reserves, we review the reserves on a quarterly basis against actual claims data to ensure the liability is fairly stated. We continually monitor our government rebate reserve and adjust our estimates if we believe that actual government rebates may differ from our established accruals. Accruals for government rebates are recorded as a reduction to gross revenues in the consolidated statements of operations and as an increase to accrued government rebates in the consolidated balance sheets.

Returns

We maintain a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. Our product returns are settled through the issuance of a credit to the customer. Our estimate for returns is based upon historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. We continually monitor our estimates for returns and make adjustments when we believe that actual product returns may differ from the established accruals. Accruals for returns are recorded as a reduction to gross revenues in the consolidated statements of operations and as an increase to the return goods reserve in the consolidated balance sheets.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

Administrative Fees and Other Rebates

Administrative fees or rebates are offered to wholesalers, group purchasing organizations and indirect customers. We accrue for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of our administrative fee accruals, we obtain on-hand inventory counts from the wholesalers. This inventory is multiplied by the ASPs to arrive at total expected future sales, which is then multiplied by contracted rates. The result is then compared to the administrative fee accruals. We continually monitor administrative fee activity and adjust our accruals when we believe that actual administrative fees will differ from the accruals. Accruals for administrative fees and other rebates are recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets.

Prompt Payment Discounts

We often grant sales discounts for prompt payment. The reserve for prompt payment discounts is based on invoices outstanding. We assume, based on past experience, that all available discounts will be taken. Accruals for prompt payment discounts are recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the three months ended March 31, 2018 and 2017, respectively:

	Accruals for Chargebacks, Rebates, Returns, and Other Allowances				
(in thousands)	**Chargebacks**	**Government Rebates**	**Returns**	**Administrative Fees and Other Rebates**	**Prompt Payment Discounts**
Balance at December 31, 2016	$ 26,785	$ 5,891	$ 5,756	$ 3,550	$ 1,554
Accruals/Adjustments	38,191	1,821	1,855	5,030	1,662
Credits Taken Against Reserve	(40,442)	(3,057)	(1,835)	(4,755)	(1,737)
Balance at March 31, 2017	$ 24,534	$ 4,655	$ 5,776	$ 3,825	$ 1,479
Balance at December 31, 2017	$ 28,230	$ 7,930	$ 8,274	$ 5,226	$ 1,834
Accruals/Adjustments	38,217	1,795	3,644	7,584	1,890
Credits Taken Against Reserve	(42,696)	(3,254)	(2,898)	(6,792)	(2,142)
Balance at March 31, 2018	$ 23,751	$ 6,471	$ 9,020	$ 6,018	$ 1,582

2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consists of agreements in which we manufacture a pharmaceutical product on behalf of third party. Our performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The contract manufactured products are sold at pre-determined standalone selling prices and our performance obligations are considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves our dock to be shipped to the customer, as our pharmaceutical products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally less than two months. We estimate returns based on historical experience. Historically, we have not had material returns for contract manufactured products.

As of March 31, 2018, the value of our unsatisfied performance obligations (or backlog) was $2.3 million, which consists of firm orders for contract manufactured products, for which our performance obligations remain unsatisfied and for which the related revenue has yet to be recognized. We anticipate satisfying these performance obligations within five months.

Royalties on Sales of Pharmaceutical Products

From time to time, we enter into transition agreements with the sellers of products we acquire, under which we license to the seller the right to sell the acquired products. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the sellers. Upon full transition of the products and upon launching the products under our own labels, we recognize revenue for the products as sales of generic or branded pharmaceutical products, as described above.

Credit Concentration

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

During the three months ended March 31, 2018, three customers represented 34%, 25%, and 20% of net revenues, respectively. As of March 31, 2018, accounts receivable from these customers totaled 79% of accounts receivable, net. During the three months ended March 31, 2017, three customers represented 31%, 25%, and 20% 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. The Notes pay 3.0% interest semi-annually in arrears starting on June 1, 2015 and are due December 1, 2019. The initial conversion price was $69.48 per share. Simultaneous with the issuance of the Notes, we entered into "bond hedge" (or purchased call) and "warrant" (or written call) transactions with an affiliate of one of the offering underwriters in order 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 Notes are convertible at the option of the holder under certain circumstances and upon conversion 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. Deferred financing costs are recorded as a reduction of long-term debt in the consolidated balance sheets and are being amortized as additional non-cash interest expense on a straight-line basis over the term of the debt, since this method was not significantly different from the effective interest method.

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

(in thousands)	**March 31, 2018**	**December 31, 2017**
Principal amount	$ 143,750	$ 143,750
Unamortized debt discount	(12,187)	(13,924)
Deferred financing costs	(1,407)	(1,618)
Net carrying value	$ 130,156	$ 128,208

We had accrued interest of $1.4 million and $0.4 million related to the Notes recorded in accrued expenses, other in our consolidated balance sheets at March 31, 2018 and December 31, 2017, respectively.

3. INDEBTEDNESS – continued

Credit Agreement

In December 2017, we entered into a five-year senior secured credit facility (the "Credit Agreement") with Citizens Bank, N.A. as a lender and administrative agent. As contemplated in the initial agreement, Citizens Bank, N.A. syndicated the facility to five additional lenders on February 5, 2018. The Credit Agreement is comprised of a $75.0 million five-year term loan (the "Term Loan") and a $50.0 million senior secured revolving credit facility (the "Revolving Credit Facility"), with availability subject to a borrowing base consisting of eligible accounts receivable and inventory and the satisfaction of conditions precedent specified in the agreement. We may repay borrowings under the Term Loan and Revolving Credit Facility without any premium or penalty, but must pay all borrowings thereunder by August 30, 2019 if we do not meet certain conditions relating to the repayment or refinance of our outstanding 3.0% Senior Convertible Notes due 2019, and in no event later than December 29, 2022.

The Term Loan includes a repayment schedule, pursuant to which $4.2 million of the loan will be paid in quarterly installments during the 12 months ended March 31, 2019. As a result, $4.2 million of the loan is recorded in current component of long-term borrowing, net of deferred financing in the accompanying unaudited interim condensed consolidated balance sheets. We deferred $2.9 million of total debt issuance costs related to the Credit Agreement, of which $1.8 million was allocated to the Term Loan and $1.1 million was allocated to the undrawn Revolving Credit Facility.

The carrying value of the current and long-term components of the Term Loan as of March 31, 2018 and December 31, 2017 are:

	Current	
(in thousands)	**March 31, 2018**	**December 31, 2017**
Current borrowing on secured term loan	$ 4,219	$ 3,750
Unamortized deferred financing costs	(414)	(397)
Current component of long-term borrowing, net of unamortized deferred financing costs	$ 3,805	$ 3,353

	Long-Term	
(in thousands)	**March 31, 2018**	**December 31, 2017**
Long-term borrowing on secured term loan	$ 69,844	$ 71,250
Unamortized deferred financing costs	(1,275)	(1,304)
Long-term borrowing, net of unamortized deferred financing costs and current borrowing component	$ 68,569	$ 69,946

3. INDEBTEDNESS – continued

The Term Loan was accounted for as a modification of our existing Line of Credit and consequently, the remaining balance of the deferred issuance costs related to the Line of Credit are included with the Term Loan issuance costs and amortized as interest expense over the life of the Term Loan using the effective interest method. The issuance costs allocated to the Revolving Credit Facility will be deferred and amortized as interest expense on a straight-line basis over the term of the Revolving Credit Facility.

As of March 31, 2018, we had a $74.1 million balance on the Term Loan. As of March 31, 2018, we had not drawn on the Revolving Credit Facility. As of March 31, 2018, $0.8 million of unamortized deferred debt issuance costs is included in other long-term assets in the accompanying unaudited interim condensed consolidated balance sheets and $0.2 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets.

The following table sets forth the components of total interest expense related to the Notes and Term Loan recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three months ended March 31, 2018 and 2017:

	Three Months Ended	
(in thousands)	**March 31, 2018**	**March 31, 2017**
Contractual coupon	$ 1,724	$ 1,078
Amortization of debt discount	1,737	1,647
Amortization of finance fees	370	211
Capitalized interest	(192)	(90)
	$ 3,639	$ 2,846

As of March 31, 2018, the combined effective interest rate on the Notes and Term Loan was 6.7%, 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, shares to be purchased under our Employee Stock Purchase Plan ("ESPP"), unvested restricted stock awards, stock purchase warrants, and any conversion gain on our Notes (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.

For purposes of determining diluted earnings per share, we have elected a policy to assume that the principal portion of the Notes (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 (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 months ended March 31, 2018 and 2017 are calculated for basic and diluted earnings per share as follows:

	Basic		Diluted	
	Three Months Ended March 31,		Three Months Ended March 31,	
(in thousands, except per share amounts)	**2018**	**2017**	**2018**	**2017**
Net income	$ 2,250	$ 1,152	$ 2,250	$ 1,152
Net income allocated to restricted stock	(13)	(11)	(13)	(11)
Net income allocated to common shares	$ 2,237	$ 1,141	$ 2,237	$ 1,141
Basic Weighted-Average Shares Outstanding	11,589	11,527	11,589	11,527
Dilutive effect of stock options and ESPP			117	126
Diluted Weighted-Average Shares Outstanding			11,706	11,653
Earnings Per Share	$ 0.19	$ 0.10	$ 0.19	$ 0.10

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 4.6 million for each of the three months ended March 31, 2018 and 2017. 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, underlying shares related to out-of-the-money bonds issued as convertible debt, and out-of-the-money warrants exercisable for common stock.

5. INVENTORIES

Inventories consist of the following as of:

(in thousands)	March 31, 2018	December 31, 2017
Raw materials	$ 23,518	$ 22,139
Packaging materials	1,623	1,527
Work-in-progress	746	510
Finished goods	8,914	13,901[1]
	34,801	38,077
Reserve for excess/obsolete inventories	(507)	(350)
Inventories, net	$ 34,294	$ 37,727

[1] Includes finished goods acquired in asset purchases (Note 11).

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 cost 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 March 31, 2018, we purchased approximately 29% of our inventory from two suppliers. As of March 31, 2018, the amounts payable to these suppliers was $2.1 million. During the three months ended March 31, 2017, we purchased approximately 33% of our inventory (exclusive of inventory acquired in asset purchases (Note 11)) from two suppliers.

6. PROPERTY, PLANT, AND EQUIPMENT

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

(in thousands)	March 31, 2018	December 31, 2017
Land	$ 160	$ 160
Buildings	3,835	3,835
Machinery, furniture, and equipment	12,766	12,334
Construction in progress	11,779	10,663
	28,540	26,992
Less: accumulated depreciation	(6,658)	(6,589)
Property, Plant, and Equipment, net	$ 21,882	$ 20,403

Depreciation expense was $0.3 million for the three months ended March 31, 2018 and 2017. During the three months ended March 31, 2018 and 2017, there was $0.2 million and $0.1 million of interest capitalized into construction in progress, respectively. Construction in progress consists of multiple projects, primarily related to new equipment to expand our manufacturing capability as our product lines continue to grow.

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 31st 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 during the three months ended March 31, 2018. No impairment losses were recognized during the three months ended March 31, 2018 or 2017.

Definite-lived Intangible Assets

Acquisition of New Drug Applications and Product Rights

In December 2017, we entered into an agreement with AstraZeneca AB and AstraZeneca UK Limited to purchase the right, title, and interest in the NDAs and the U.S. rights to market Atacand, Atacand HCT, Arimidex, and Casodex, for $46.5 million in cash. We also entered into a license agreement for use of these trademarks in the U.S. We made the $46.5 million cash payment with funds from our Term Loan (Note 3). We also capitalized $0.2 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $46.7 million product rights assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 11 for further details regarding the transaction.

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark, and certain finished goods inventory for Inderal XL for $20.2 million in cash. We made the $20.2 million cash payment using cash on hand. We accounted for this transaction as an asset purchase. We also capitalized $40 thousand of costs directly related to the transaction. The $15.1 million product rights intangible asset acquired in the asset purchase is being amortized in full over its estimated useful life of 10 years. Please see Note 11 for further details regarding the transaction.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for $30.6 million in cash. We made the $30.6 million cash payment using $30.0 million of funds from our former Line of Credit and $0.6 million of cash on hand. We accounted for this transaction as an asset purchase. We also capitalized $0.1 million of costs directly related to the transaction. The $19.0 million product rights intangible asset acquired in the asset purchase is being amortized in full over its estimated useful life of 10 years. Please see Note 11 for further details regarding the transaction.

7. GOODWILL AND INTANGIBLE ASSETS – continued

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

(in thousands)	March 31, 2018 Gross Carrying Amount	March 31, 2018 Accumulated Amortization	December 31, 2017 Gross Carrying Amount	December 31, 2017 Accumulated Amortization	Weighted Average Amortization Period
Acquired ANDA intangible assets	$ 42,076	$ (13,642)	$ 42,076	$ (12,592)	10.0 years
NDAs and product rights	230,974	(43,374)	230,974	(37,091)	10.0 years
Marketing and distribution rights	11,042	(5,605)	11,042	(5,087)	4.7 years
Non-compete agreement	624	(178)	624	(156)	7.0 years
	$ 284,716	$ (62,799)	$ 284,716	$ (54,926)	

Definite-lived intangible assets are stated at cost, net of amortization, generally using the straight-line method over the expected useful lives of the intangible assets. In the case of the Inderal XL and InnoPran XL asset purchases, because we anticipate that the acquired assets will provide a greater economic benefit in the earlier years, we are amortizing 80% of the value of the intangible assets over the first five years of useful lives of the assets and amortizing the remaining 20% of the value of the intangible assets over the second five years of useful lives of the assets. Amortization expense was $7.9 million and $6.4 million for the three months ended March 31, 2018 and 2017, respectively.

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three months ended March 31, 2018 and 2017 and therefore no impairment loss was recognized in the three months ended March 31, 2018 or 2017.

Expected future amortization expense is as follows:

(in thousands)	
2018 (remainder of the year)	$ 23,619
2019	31,492
2020	31,010
2021	29,564
2022	26,099
2023 and thereafter	80,133
Total	$ 221,917

8. STOCK-BASED COMPENSATION

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of March 31, 2018, we have 0.2 million shares of common stock available under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount. In the three months ended March 31, 2018, we recognized $2 thousand, $2 thousand, and $14 thousand of stock-based compensation expense related to the ESPP in cost of sales, research and development, and sales, general, and administrative expense in our accompanying unaudited interim condensed consolidated statements of operations, respectively. In the three months ended March 31, 2017, we recognized $1 thousand and $14 thousand of stock-based compensation expense related to the ESPP in cost of sales and sales, general, and administrative expense in our accompanying unaudited interim condensed consolidated statement of operations, respectively.

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the “2008 Plan”). As of March 31, 2018, 0.8 million shares of our common stock remained available for issuance under the 2008 Plan.

The following table summarizes stock-based compensation expense incurred under the 2008 Plan and included in our accompanying unaudited interim condensed consolidated statements of operations:

	Three Months Ended March 31,	
(in thousands)	**2018**	**2017**
Cost of sales	$ 18	$ 23
Research and development	160	139
Selling, general, and adminstrative	1,182	1,209
	$ 1,360	$ 1,371

A summary of stock option and restricted stock activity under the 2008 Plan during the three months ended March 31, 2018 and 2017 is presented below:

(in thousands)	**Options**	**RSAs**
Outstanding December 31, 2016	578	63
Granted	182	50
Options Exercised/RSAs Vested	(1)	(4)
Forfeited	(2)	-
Outstanding March 31, 2017	757	109
Outstanding December 31, 2017	767	86
Granted	5	-
Options Exercised/RSAs Vested	(79)	(16)
Forfeited	(11)	-
Outstanding March 31, 2018	682	70

9. 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. The utilization of our NOL carryforwards will be limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code. As of both March 31, 2018 and December 31, 2017, we had provided a valuation allowance against certain state net operating loss ("NOL") carryforwards of $0.3 million.

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. 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 consolidated financial statements. 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 March 31, 2018 and December 31, 2017. 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.

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate expected for the entire year. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and estimated permanent differences, and excludes certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discrete items result in variances to the effective tax rate from period to period. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. Our estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discrete items occur.

The estimated consolidated effective tax rate for the three months ended March 31, 2018 was 20.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in the first quarter. Our effective tax rate for the three months ended March 31, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

The 31.2% effective tax rate for the three months ended March 31, 2017 was impacted primarily by the Domestic Production Activities Deduction (which deduction was repealed effective January 1, 2018 as part of the Tax Cuts and Jobs Act of 2017), as well as the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options.

10. COMMITMENTS AND CONTINGENCIES

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies. The 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 ("EEMT") and Opium Tincture, are marketed without approved NDAs or Abbreviated New Drug Applications ("ANDAs"). During the three months ended March 31, 2018 and 2017, net revenues for these products totaled $5.6 million and $6.2 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.

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 March 31, 2018 and 2017 were $0.4 million and $0.6 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 the three months ended March 31, 2018 and 2017 were less than 1% of total revenues.

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.

10. COMMITMENTS AND CONTINGENCIES – continued

Civil Action

In November of 2017, we were served with a complaint filed by Arbor Pharmaceuticals, LLC, in the United States District Court, District of Minnesota. The complaint alleges false advertising and unfair competition in violation of Section 43(a) of the Lanham Act, Section 1125(a) of Title 15 of the United States Code, and Minnesota State law, and seeks injunctive relief and damages. In December of 2017, we filed a motion to dismiss, which is currently pending before the Court. We intend to defend this action vigorously.

Other Commitments and Contingencies

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, have faced 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 complaints. In August 2016, we settled the outstanding California short form complaints and in February 2018, we settled the remaining four complaints that were not captured in the 2016 settlement. 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 and paid all losses in settlement of the California cases. 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 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.

We launched Erythromycin Ethylsuccinate (“EES”) on September 27, 2016 under a previously approved ANDA. In August 2016, we filed with the FDA to reintroduce this product under a Changes Being Effected in 30 Days submission (a “CBE-30 submission”). Under a CBE-30 submission, certain defined changes to an ANDA can be made if the FDA does not object in writing within 30 days. The FDA’s regulations, guidance documents, and historic actions support the filing of a CBE-30 for the types of changes that we proposed for our EES ANDA. We received no formal written letter from the FDA within 30 days of the CBE-30 submission date, and as such, launched the product in accordance with FDA regulations. On December 16, 2016, and nearly four months after our CBE-30 submission, the FDA sent us a formal written notice that a Prior Approval Supplement (“PAS”) was required for this ANDA. Under a PAS, proposed changes to an ANDA cannot be implemented without prior review and approval by the FDA. Because we did not receive this notice in the timeframe prescribed by the FDA’s regulations, we believe that our supplemental ANDA is valid, and as such continue to market the product. In addition, we filed a PAS which was accepted by the FDA and was originally assigned action date of June 2017. This date was later revised to October 2017 due to the election by the FDA to perform a Pre-Approval Inspection (“PAI”) of our Baudette manufacturing facilities. The FDA conducted its PAI between May 15, 2017 and May 18, 2017. On July 31, 2017, we received an Establishment Inspection Report from the FDA documenting that no objectionable conditions resulted from the inspection and that no FDA-483 or verbal observations were issued. On September 21, 2017, we received a Major CR Letter (Complete Response Letter). In February 2018, we submitted our response to the letter. In March 2018, we received notification from the FDA that our response to the letter had received priority review status. We continue to reserve all of our legal options in this matter.

10. COMMITMENTS AND CONTINGENCIES – continued

On or about September 20, 2017, the Company and certain of its employees were served with search warrants and/or grand jury subpoenas to produce documents and possibly testify relating to a federal investigation of the generic pharmaceutical industry. The Company has been cooperating and intends to continue cooperating with the investigation. However, no assurance can be given as to the timing or outcome of the investigation.

11. FAIR VALUE DISCLOSURES

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. 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 accompanying unaudited interim condensed consolidated balance sheets at their net carrying value of $130.2 million as of March 31, 2018, the Notes are being traded on the bond market and their fair value is $156.6 million, based on their closing price on March 31, 2018, 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 and expire in June 2023, 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 March 31, 2018 and December 31, 2017. We also determined that the changes in such fair value were immaterial as of March 31, 2018 and December 31, 2017.

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

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

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 months ended March 31, 2018 and 2017.

11. FAIR VALUE DISCLOSURES – continued

Acquired Non-Financial Assets Measured at Fair Value

In December 2017, we entered into an agreement with AstraZeneca AB and AstraZeneca UK Limited to purchase the right, title, and interest in the NDAs and the U.S. right to market Atacand, Atacand HCT, Arimidex, and Casodex, for $46.5 million in cash (Note 7). We also licensed these trademarks for use in the U.S. We made the $46.5 million cash payment with funds from our Term Loan (Note 3) and capitalized $0.2 million of costs directly related to the asset purchase. The agreement included a $3.0 million contingent payment due in early 2023 if the annual net sales of the Atacand and Atacand HCT products equals or exceeds certain threshold amounts in 2020, 2021, and 2022. Because we believe that the likelihood of meeting or exceeding the threshold amounts is not probable, we did not record a contingent liability in relation to the agreement. We accounted for this transaction as an asset purchase. The $46.7 million product rights intangible assets were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible assets, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over their 10-year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to March 31, 2018 and therefore no impairment loss was recognized for the three months ended March 31, 2018.

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark, and certain finished goods inventory for Inderal XL for $20.2 million in cash (Note 7). We made the $20.2 million cash payment using cash on hand and capitalized $40 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $15.1 million product rights intangible asset was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible asset, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over its 10-year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to March 31, 2018 and therefore no impairment loss was recognized for the three months ended March 31. 2018. We also recorded $5.0 million of finished goods inventory. The fair value of the finished goods inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for $30.6 million in cash (Note 7). We made the $30.6 million cash payment using $30.0 million of funds from our former Line of Credit and $0.6 million of cash on hand. We also capitalized $0.1 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $19.0 million product rights intangible asset was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible asset, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over its 10-year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to March 31, 2018 and therefore no impairment loss was recognized for the three months ended March 31, 2018. We also recorded $11.6 million of finished goods inventory. The fair value of the finished goods inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin.

12. SUBSEQUENT EVENTS

In April 2018, we entered into an agreement with IDT Australia, Limited to purchase the ANDAs for 23 previously-marketed generic drug products and API of one of the acquired products for $2.7 million in cash and a single-digit royalty on net profits from sales of one of the products. The transaction closed in April 2018 and we made the $2.7 million payment using cash on hand.

In April 2018, we entered into an interest rate swap with Citizens Bank, N.A. to hedge the variable rate on our Term Loan balance with a fixed rate.

In April 2018, we entered into an agreement with Impax Laboratories, Inc. to purchase the approved ANDAs for five generic drug products, the development package for one generic drug product, and a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval. We also purchased certain manufacturing equipment required to manufacture one of the products. The transaction closed in May 2018 and we paid $2.3 million of up-front consideration using cash on hand.

At the same time, we entered into a supply agreement with Amneal Pharmaceuticals, LLC (“Amneal”) under which we may elect to purchase the finished goods for one of the products for up to 17 months beginning October 1, 2019, under certain conditions. If we do elect to purchase the finished goods from Amneal for this period, we may be required to pay a milestone payment of up to $10.0 million upon launch, depending on the number of competitors selling the product at the time of launch.

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, 2017.

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its consolidated subsidiary, ANIP Acquisition Company (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations. We have two pharmaceutical manufacturing facilities located in Baudette, Minnesota, which are capable of producing oral solid dose products, as well as liquids and topicals, controlled substances, 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 our business, expand and diversify our product portfolio, and create long-term value for our investors.

As of March 31, 2018, our products include both branded and generic pharmaceuticals, specifically:

Generic Products	Branded Products
Diphenoxylate Hydrochloride and Atropine Sulfate	Cortenema
Erythromycin Ethylsuccinate	Inderal LA
Esterified Estrogen with Methyltestosterone	Inderal XL
Etodolac	InnoPran XL
Fenofibrate	Lithobid
Flecainide	Reglan
Fluvoxamine	Vancocin
Hydrocortisone Enema	
Hydrocortisone Rectal Cream (1% and 2.5%)	
Indapamide	
Lithium Carbonate ER	
Mesalamine Enema	
Methazolamide	
Metoclopramide Syrup	
Nilutamide	
Nimodipine	
Opium Tincture	
Oxycodone Capsules	
Oxycodone Hydrochloride Oral Solution (5 mg/5 mL)	
Oxycodone Hydrochloride Oral Solution (100 mg/5 mL)	
Pindolol	
Propafenone	
Propranolol ER	
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 products 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, including the 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 optimize the utilization of our facilities, ensure quality control in our products, and maximize profit potential.
- ***Competition.*** When determining whether to develop or acquire a product, we research existing and expected competition. We seek to develop products for which we can obtain sufficient market share, and may decline to develop a product if we anticipate significant competition. Our specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies are able to compete.

Recent Developments

In April 2018, we entered into an agreement with Impax Laboratories, Inc. to purchase the approved Abbreviated New Drug Applications (“ANDAs”) for five generic drug products, the development package for one generic drug product, and a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval. We also purchased certain manufacturing equipment required to manufacture one of the products. The transaction closed in May 2018 and we paid $2.3 million of up-front consideration using cash on hand.

At the same time, we entered into a supply agreement with Amneal Pharmaceuticals, LLC (“Amneal”) under which we may elect to purchase the finished goods for one of the products for up to 17 months beginning October 1, 2019, under certain conditions. If we do elect to purchase the finished goods from Amneal for this period, we may be required to pay a milestone payment of up to $10.0 million upon launch, depending on the number of competitors selling the product at the time of launch.

In April 2018, we entered into an agreement with IDT Australia, Limited to purchase the ANDAs for 23 previously-marketed generic drug products and active pharmaceutical ingredient (“API”) of one of the acquired products for $2.7 million in cash and a single-digit royalty on net profits from sales of one of the products. The transaction closed in April 2018 and we made the $2.7 million payment using cash on hand.

In April 2018, we received approval from the Food and Drug Administration (“FDA”) for our ANDA for Morphine Sulfate Oral Solution 10mg/5mL, 20mg/5mL and 100mg/5mL. Morphine Sulfate Oral Solution is indicated for the management of acute and chronic pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL) is indicated for the relief of acute and chronic pain in opioid-tolerant patients.

Cortrophin Gel Re-commercialization Update

In the first quarter of 2018, we continued to advance the manufacture of Corticotropin API. We ordered and are in the process of installing and qualifying the capital equipment necessary for commercial scale API manufacturing. We plan to initiate commercial-scale API manufacturing in the second quarter of 2018 and are still on track to initiate API process validation and registration batch manufacturing by the end of 2018. We have continued to manufacture batches of Cortrophin gel drug product and are still on track to manufacture commercial scale drug product batches before the end of 2018.

We requested a Type C meeting with the FDA in the fourth quarter of 2017 to provide the regulatory plan for re-commercialization of Cortrophin gel. The FDA granted the Type C meeting and provided an initial response in March 2018, with further communications expected during the second quarter of 2018.

Vancocin Oral Solution Update

We are currently advancing a commercialization effort for Vancocin oral solution. Following completion of ongoing formulation and manufacturing optimization, we intend to file a prior approval supplement (“PAS”) in the second half of 2018. This product will be manufactured at our site in Baudette, Minnesota.

GENERAL

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

(in thousands)	Three Months Ended March 31, 2018	2017
Net revenues	$ 46,483	$ 36,628
Operating expenses		
Cost of sales (exclusive of depreciation and amortization)	20,693	16,386
Research and development	2,102	1,618
Selling, general, and administrative	8,956	7,293
Depreciation and amortization	8,195	6,706
Operating income	6,537	4,625
Interest expense, net	(3,634)	(2,932)
Other expense, net	(61)	(18)
Income before provision for income taxes	2,842	1,675
Provision for income taxes	(592)	(523)
Net income	$ 2,250	$ 1,152

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

	Three Months Ended March 31, 2018	2017
Net revenues	100.0%	100.0%
Operating expenses		
Cost of sales (exclusive of depreciation and amortization)	44.5%	44.7%
Research and development	4.5%	4.4%
Selling, general, and administrative	19.3%	19.9%
Depreciation and amortization	17.6%	18.3%
Operating income	14.1%	12.7%
Interest expense, net	(7.9)%	(8.1)%
Other expense, net	(0.1)%	-%
Income before provision for income taxes	6.1%	4.6%
Provision for income taxes	(1.3)%	(1.4)%
Net income	4.8%	3.2%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2018 AND 2017

Net Revenues

(in thousands)	Three Months Ended March 31, 2018	2017	Change	% Change
Generic pharmaceutical products	$ 23,227	$ 26,572	$ (3,345)	(12.6)%
Branded pharmaceutical products	16,595	8,039	8,556	106.4%
Contract manufacturing	945	1,793	(848)	(47.3)%
Royalty and other income	5,716	224	5,492	NM(1)
Total net revenues	$ 46,483	$ 36,628	$ 9,855	26.9%

(1) Not Meaningful

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. We adopted the Financial Accounting Standards Boards ("FASB's") guidance for revenue recognition for contracts on January 1, 2018, using the modified retrospective method. The adoption of this guidance did not have a material impact on our net revenues.

Net revenues for the three months ended March 31, 2018 were $46.5 million compared to $36.6 million for the same period in 2017, an increase of $9.9 million, or 26.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $23.2 million during the three months ended March 31, 2018, a decrease of 12.6% compared to $26.6 million for the same period in 2017. The primary reason for the decrease was volume decreases for Fenofibrate and sales decreases for Propranolol ER driven by price, tempered by the impact of the second quarter 2017 launch of Diphenoxylate Hydrochloride and Atropine Sulfate.

  As described in Note 10, *Commitments and Contingencies*, in the unaudited interim 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 March 31, 2018 and 2017 were $5.6 million and $6.2 million, respectively.

- Net revenues for branded pharmaceutical products were $16.6 million during the three months ended March 31, 2018, an increase of 106.4% compared to $8.0 million for the same period in 2017. The primary reason for the increase was sales of Inderal XL and InnoPran XL, both of which were acquired in the first quarter of 2017, and which were re-launched under our label in the first quarter of 2018, as well as increased sales of Inderal LA.

- Contract manufacturing revenues were $0.9 million during the three months ended March 31, 2018, a decrease of 47.3% compared to $1.8 million for the same period in 2017, due to timing of orders from contract manufacturing customers in the period. As described in Note 10, *Commitments and Contingencies*, in the unaudited interim 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 March 31, 2018 and 2017 were $0.4 million and $0.6 million, respectively.

- Royalty and other income were $5.7 million during the three months ended March 31, 2018, an increase of $5.5 million from $0.2 million for the same period in 2017, due primarily to royalties on sales of Atacand, Atacand HCT, Casodex, and Arimidex. We acquired the right, title, and interest in the NDAs and the U.S. right to market these products in December 2017.

  As described in Note 10, *Commitments and Contingencies*, in the unaudited interim 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 less than 1% of total revenues for the three months ended March 31, 2018 and 2017.

Cost of Sales (Excluding Depreciation and Amortization)

	Three Months Ended March 31,			
(in thousands)	**2018**	**2017**	**Change**	**% Change**
Cost of sales (excl. depreciation and amortization)	$ 20,693	$ 16,386	$ 4,307	26.3%

Cost of sales consists of direct labor, including manufacturing and packaging, active and inactive pharmaceutical ingredients, freight costs, packaging components, and royalties related to profit-sharing arrangements. 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 March 31, 2018, cost of sales increased to $20.7 million from $16.4 million for the same period in 2017, an increase of $4.3 million or 26.3%, primarily due to $5.6 million of costs of sales related to the excess of fair value over cost on Inderal XL and InnoPran XL inventory and the write-off of remaining inventory acquired as part of the acquisition when we re-launched the products under our own label during the first quarter of 2018. Cost of sales as a percentage of net revenues decreased to 44.5% during the three months ended March 31, 2018, from 44.7% during same period in 2017, primarily as a result of increased royalty income, change in product mix toward higher-margin brand products, and lower sales of products subject to profit-sharing arrangements, tempered by the $5.6 million net impact on cost of sales (12.1% as a percent of net revenues) of the excess of fair value over cost for Inderal XL and InnoPran XL inventory sold and written off during the period. During the three months ended March 31, 2018, we began selling the Inderal XL and InnoPran XL products under our own label and stopped selling the Inderal XL and InnoPran XL inventory acquired through asset purchase transactions.

We source the raw materials for our products, including APIs from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the 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 March 31, 2018, we purchased 29% of our inventory from two suppliers. As of March 31, 2018, the amounts payable to these suppliers was $2.1 million. In the three months ended March 31, 2017, we purchased approximately 33% of our inventory (exclusive of inventory acquired in asset purchases as described in Note 11, *Fair Value Disclosures*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report) from two suppliers.

In order to manufacture Opium Tincture, Oxycodone capsules, and Oxycodone oral solution, we must receive approval from the Drug Enforcement Agency ("DEA") for a quota to purchase the amount of opium and oxycodone needed to manufacture the respective products. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are dependent upon the DEA to annually approve a sufficient quota of API to support our continued manufacture of Opium Tincture, Oxycodone capsules, and Oxycodone oral solution.

Other Operating Expenses

	Three Months Ended March 31,			
(in thousands)	**2018**	**2017**	**Change**	**% Change**
Research and development	$ 2,102	$ 1,618	$ 484	29.9%
Selling, general, and administrative	8,956	7,293	1,663	22.8%
Depreciation and amortization	8,195	6,706	1,489	22.2%
Total other operating expenses	$ 19,253	$ 15,617	$ 3,636	23.3%

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

For the three months ended March 31, 2018, other operating expenses increased to $19.3 million from $15.6 million for the same period in 2017, an increase of $3.6 million, or 23.3%, primarily as a result of the following factors:

- Research and development expenses increased from $1.6 million to $2.1 million, an increase of 29.9%, due to timing of work on development projects, primarily the Cortrophin gel re-commercialization project and work on the ANDAs purchased in 2014 and 2015. We anticipate that research and development costs will continue to be greater in 2018 than in 2017, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Cortrophin product.

- Selling, general, and administrative expenses increased from $7.3 million to $9.0 million, an increase of 22.8%, primarily due to increases in personnel and related costs. We anticipate that selling, general, and administrative expenses will continue to be greater in 2018 than in 2017 as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $6.7 million to $8.2 million, an increase of 22.2%, primarily due to the amortization of the rights, title, and interest in the NDAs for Atacand, Atacand HCT, Arimidex, and Casodex, which were acquired in December 2017. We anticipate that depreciation and amortization expense will continue to be greater in 2018 than in 2017 as a result of our amortization of the NDAs for Atacand, Atacand HCT, Arimidex, and Casodex, acquired in late December 2017.

Other Expense, net

(in thousands)	Three Months Ended March 31, 2018	2017	Change	% Change
Interest expense, net	$ (3,634)	$ (2,932)	$ (702)	23.9%
Other expense, net	(61)	(18)	(43)	238.9%
Total other expense, net	$ (3,695)	$ (2,950)	$ (745)	25.3%

For the three months ended March 31, 2018, we recognized other expense of $3.7 million versus other expense of $3.0 million for the same period in 2017, a change of $0.7 million. Interest expense, net for 2018 consists primarily of interest expense on our convertible debt and interest expense on borrowings under our term loan. Interest expense, net for 2017 consisted primarily of interest expense on our convertible debt and interest expense on borrowings under our former line of credit. For the three months ended March 31, 2018 and 2017, there was $0.2 million and $0.1 million of interest capitalized into construction in progress, respectively.

Provision for Income Taxes

(in thousands)	Three Months Ended March 31, 2018	2017	Change	% Change
Provision for income taxes	$ (592)	$ (523)	$ (69)	13.2%

Our provision for income taxes consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance.

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate expected for the entire year plus the effects of certain discrete items occurring in the quarter. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and estimated permanent differences, and excludes certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discrete items result in variances to the effective tax rate from period to period. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. Our estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discrete items occur.

For the three months ended March 31, 2018, we recognized income tax expense of $0.6 million, versus $0.5 million for the same period in 2017, an increase of $0.1 million. The effective tax rate for the three months ended March 31, 2018 was 20.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in the first quarter. Our effective tax rate for the three months ended March 31, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

The 31.2% effective tax rate for the three months ended March 31, 2017 was impacted primarily by the Domestic Production Activities Deduction (which deduction was repealed effective January 1, 2018 as part of the Tax Cuts and Jobs Act of 2017), as well as the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	March 31, 2018	December 31, 2017
Cash and cash equivalents	$ 51,970	$ 31,144
Accounts receivable, net	54,801	58,788
Inventories, net	34,294	37,727
Prepaid income taxes	62	1,162
Prepaid expenses and other current assets	2,267	2,784
Total current assets	$ 143,394	$ 131,605
Accounts payable	$ 4,886	$ 3,630
Accrued expenses and other	2,612	1,571
Accrued royalties	11,361	12,164
Accrued compensation and related expenses	1,495	2,306
Accrued government rebates	6,471	7,930
Returned goods reserve	9,020	8,274
Current component of long-term borrowing, net of deferred financing costs	3,805	3,353
Total current liabilities	$ 39,650	$ 39,228

At March 31, 2018, we had $52.0 million in unrestricted cash and cash equivalents. At December 31, 2017, we had $31.1 million in unrestricted cash and cash equivalents. We generated $22.9 million of cash from operations in the three months ended March 31, 2018. In December 2017, we entered into a Credit Agreement with Citizens Bank, N.A. that includes a $75.0 million five-year Term Loan, as well as a $50.0 million Revolving Credit Facility, which remains undrawn at March 31, 2018. In April 2018, we entered into an interest rate swap with Citizens Bank, N.A. to hedge the variable rate on our Term Loan balance with a fixed rate.

The Tax Cuts and Jobs Act, which was enacted on December 22, 2017, includes a number of changes to existing U.S. tax laws, most notably the reduction of the U.S. corporate income tax rate from 35% to 21%, beginning in 2018. We anticipate that our cash tax payments will decrease in 2018 as a result of this reduction in income tax rate.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue, and our revolving line of credit facility, 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:

	Three Months Ended March 31,	
(in thousands)	**2018**	**2017**
Operating Activities	$ 22,930	$ 6,529
Investing Activities	$ (2,278)	$ (53,094)
Financing Activities	$ 170	$ 30,025

Net Cash Provided By Operations

Net cash provided by operating activities was $22.9 million for the three months ended March 31, 2018, compared to $6.5 million during the same period in 2017, an increase of $16.4 million. This increase was principally due to changes in working capital, as well as increased sales volume and corresponding gross profit dollars.

Net Cash Used In Investing Activities

Net cash used in investing activities for the three months ended March 31, 2018 was $2.3 million, principally due to capital expenditures during the period. Net cash used in investing activities for the three months ended March 31, 2017 was $53.1 million, principally due to the February 2017 payment of $20.2 million for the asset acquisition of the product rights for Inderal XL, the February 2017 payment of $30.6 million for the asset acquisition of the product rights for InnoPran XL, and $2.1 million of capital expenditures during the period.

Net Cash Provided By Financing Activities

Net cash provided by financing activities was $0.2 million for the three months ended March 31, 2018, principally due to $1.5 million of proceeds from stock option exercises, partially offset by our $0.9 million first quarterly payment on the Term Loan and $0.2 million of debt issuance fees paid in relation to the Term Loan. Net cash provided by financing activities was $30.0 million for the three months ended March 31, 2017, principally due to the $30.0 million draw on the Citizens Agreement Line of Credit.

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 interim condensed consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, administrative fees and rebates, 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, purchase price allocations, 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, 2017. 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, 2017.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

A discussion of the recently issued accounting pronouncements is described in Note 1, *Business, Presentation, and Recent Accounting Pronouncements*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report and is incorporate herein by reference.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of March 31, 2018 and December 31, 2017, 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

Market risks include interest rate risk, equity risk, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, interest rate risk and equity risk could have a significant impact on our results of operations.

As of March 31, 2018, our largest 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 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 change accordingly. As a result, we face equity risk in relation to our Notes.

On December 29, 2017, we entered into our five-year Credit Agreement with Citizens Bank, N.A. The Credit Agreement is comprised of a $75.0 million five-year Term Loan and a $50.0 million Revolving Credit Facility. Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.25% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.25%, depending our total leverage ratio. We will incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.35%, depending on our leverage ratio. As of March 31, 2018, we had a $74.1 million outstanding balance on the Term Loan. A 100 basis-point adverse movement (increase) in short-term interest rates would increase the interest expense on our Term Loan in the three months ended March 31, 2018 by approximately $32 thousand. In April 2018, we entered into an interest rate swap with Citizens Bank, N.A. to hedge the variable rate on our Term Loan balance with a fixed rate.

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 months ended March 31, 2018 by approximately $1 thousand.

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 March 31, 2018. 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 March 31, 2018 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 10, *Commitments and Contingencies*, in the unaudited interim 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, 2017 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. Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities

The following table contains information for shares of common stock repurchased and acquired from employees in lieu of amounts required to satisfy tax withholding requirements upon vesting of the employees' restricted stock during the three months ended March 31, 2018:

(in thousands, except per share data)

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Maximum Number (or approximate dollar value) of Shares (or units) that May Yet be Purchased Under the Plans or Programs
January 1 - January 31, 2018	-	$ -	-	$ -
February 1 - February 28, 2018	-	$ -	-	$ -
March 1 - March 31, 2018	4	$ 58.22	-	$ -
Total	4	$ 58.22	-	

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.

INDEX TO EXHIBITS

Exhibit No.	Description
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

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: May 8, 2018

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

Date: May 8, 2018

By: /s/ Stephen P. Carey
Stephen P. Carey
Vice President, Finance and
Chief Financial Officer
(principal financial officer)

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 subsidiary, 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: May 8, 2018

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

Exhibit 31.2

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

I, Stephen P. Carey, 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 subsidiary, 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: May 8, 2018

/s/ Stephen P. Carey
Stephen P. Carey
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 March 31, 2018 (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: May 8, 2018

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

Dated: May 8, 2018

/s/ Stephen P. Carey
Stephen P. Carey
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.