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

# FORM 10-Q

**(Mark one)**

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

**For the quarterly period ended March 31, 2020**

☐ **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 56623**
(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 every Interactive Data File required to be submitted 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 such files). YES ☒ NO ☐

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

| | |
|---|---|
| Large accelerated filer ☐ | Accelerated filer ☒ |
| Non-accelerated filer ☐ | 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 April 30, 2020, there were 12,329,884 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

Securities registered pursuant to Section 12(b) of the Act:

| **Title of each class:** | **Trading Symbol(s)** | **Name of each exchange on which registered:** |
|---|---|---|
| Common Stock | ANIP | NASDAQ Global Market |

**ANI PHARMACEUTICALS, INC.**
**FORM 10-Q — Quarterly Report**
**For the Quarterly Period Ended March 31, 2020**
**TABLE OF CONTENTS**

**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, 2019, 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 subsidiaries. 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 SUBSIDIARIES**
**Condensed Consolidated Balance Sheets**
*(in thousands, except share and per share amounts)*
*(unaudited)*

| | *March 31, 2020* | *December 31, 2019* |
|---|---|---|
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | $ 20,414 | $ 62,332 |
| Accounts receivable, net of $104,711 and $59,946 of adjustments for chargebacks and other allowances at March 31, 2020 and December 31, 2019, respectively | 82,379 | 72,129 |
| Inventories, net | 52,902 | 48,163 |
| Prepaid income taxes | - | 1,076 |
| Prepaid expenses and other current assets | 2,967 | 3,995 |
| Total Current Assets | 158,662 | 187,695 |
| Property and equipment, net | 40,353 | 40,551 |
| Restricted cash | 5,002 | 5,029 |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | 57,906 | 38,326 |
| Intangible assets, net | 215,619 | 180,388 |
| Goodwill | 3,580 | 3,580 |
| Other non-current assets | 1,110 | 1,220 |
| Total Assets | $ 482,232 | $ 456,789 |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities | | |
| Current debt, net of deferred financing costs | $ 11,872 | $ 9,941 |
| Accounts payable | 12,485 | 14,606 |
| Accrued expenses and other | 4,378 | 2,362 |
| Accrued royalties | 6,285 | 5,084 |
| Accrued compensation and related expenses | 3,151 | 3,736 |
| Current income taxes payable, net | 15,223 | - |
| Accrued government rebates | 8,030 | 8,901 |
| Returned goods reserve | 17,614 | 16,595 |
| Deferred revenue | 318 | 451 |
| Total Current Liabilities | 79,356 | 61,676 |
| Non-current Liabilities | | |
| Non-current debt, net of deferred financing costs and current component | 188,094 | 175,808 |
| Other non-current liabilities | 13,611 | 6,514 |
| Total Liabilities | $ 281,061 | $ 243,998 |
| Commitments and Contingencies (Note 11) | | |
| Stockholders' Equity | | |
| Common Stock, $0.0001 par value, 33,333,334 shares authorized; 12,111,833 shares issued and 12,083,963 outstanding at March 31, 2020; 12,104,875 shares issued and 12,089,565 shares outstanding at December 31, 2019 | 1 | 1 |
| Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively | - | - |
| Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively | - | - |
| Treasury stock, 27,870 shares of common stock, at cost, at March 31, 2020 and 15,310 shares of common stock, at cost, at December 31, 2019 | (1,211) | (723) |
| Additional paid-in capital | 203,505 | 200,800 |
| Retained earnings | 10,565 | 17,584 |
| Accumulated other comprehensive loss, net of tax | (11,689) | (4,871) |
| Total Stockholders' Equity | 201,171 | 212,791 |
| Total Liabilities and Stockholders' Equity | $ 482,232 | $ 456,789 |

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

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

| | *Three Months Ended March 31,* | |
|---|---|---|
| | *2020* | *2019* |
| Net Revenues | $ 49,774 | $ 52,887 |
| Operating Expenses: | | |
| Cost of sales (excluding depreciation and amortization) | 21,804 | 14,725 |
| Research and development | 6,344 | 4,373 |
| Selling, general, and administrative | 13,683 | 13,284 |
| Depreciation and amortization | 11,183 | 16,103 |
| Cortrophin pre-launch charges | 4,602 | - |
| Total Operating Expenses | 57,616 | 48,485 |
| Operating (Loss)/Income | (7,842) | 4,402 |
| Other Expense, net | | |
| Interest expense, net | (2,032) | (3,354) |
| Other income/(expense), net | 10 | (130) |
| (Loss)/Income Before Benefit/(Provision) for Income Taxes | (9,864) | 918 |
| Benefit/(provision) for income taxes | 2,853 | (469) |
| Net (Loss)/Income | $ (7,011) | $ 449 |
| **Basic and Diluted (Loss)/Earnings Per Share:** | | |
| Basic (Loss)/Earnings Per Share | $ (0.59) | $ 0.04 |
| Diluted (Loss)/Earnings Per Share | $ (0.59) | $ 0.04 |
| Basic Weighted-Average Shares Outstanding | 11,902 | 11,747 |
| Diluted Weighted-Average Shares Outstanding | 11,902 | 11,823 |

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

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES**
**Condensed Consolidated Statements of Comprehensive (Loss)/Income**
*(in thousands)*
*(unaudited)*

| | *Three Months Ended March 31,* | |
|---|---|---|
| | *2020* | *2019* |
| Net (Loss)/Income | $ (7,011) | $ 449 |
| Other comprehensive loss, net of tax: | | |
| Change in fair value of interest rate swap, net of tax | (6,818) | (1,820) |
| Total other comprehensive loss, net of tax | (6,818) | (1,820) |
| Total comprehensive loss, net of tax | $ (13,829) | $ (1,371) |

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

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES**
**Condensed Consolidated Statements of Changes in Stockholders' Equity**
**For the Three Months Ended March 31, 2020 and 2019**
*(in thousands)*
*(unaudited)*

| | Common Stock Par Value | Common Stock Shares | Class C Special Stock | Additional Paid-in Capital | Treasury Stock Shares | Treasury Stock | Accumulated Other Comprehensive Loss, Net of Tax | Retained Earnings | Total |
|---|---|---|---|---|---|---|---|---|---|
| Balance, December 31, 2018 | $ 1 | 11,863 | $ - | $ 186,812 | 11 | $ (659) | $ (379) | $ 11,488 | $ 197,263 |
| Cumulative-effect of change in accounting principle | - | - | - | - | - | - | - | 2 | 2 |
| Stock-based Compensation Expense | - | - | - | 1,710 | - | - | - | - | 1,710 |
| Changes in Treasury Stock Related to Stock-based Compensation Arrangements | - | - | - | - | 6 | (308) | - | - | (308) |
| Issuance of Common Shares upon Stock Option and ESPP Exercise | - | 55 | - | 2,416 | - | - | - | - | 2,416 |
| Issuance of Restricted Stock Awards | - | 106 | - | (967) | (15) | 967 | - | - | - |
| Change in Fair Value of Interest Rate Swap, Net of Tax | - | - | - | - | - | - | (1,820) | - | (1,820) |
| Net Income | - | - | - | - | - | - | - | 449 | 449 |
| Balance, March 31, 2019 | $ 1 | 12,024 | $ - | $ 189,971 | 2 | $ - | $ (2,199) | $ 11,939 | $ 199,712 |
| | | | | | | | | | |
| Balance, December 31, 2019 | $ 1 | 12,105 | $ - | $ 200,800 | 15 | $ (723) | $ (4,871) | $ 17,584 | $ 212,791 |
| Cumulative-effect of change in accounting principle | - | - | - | - | - | - | - | (8) | (8) |
| Stock-based Compensation Expense | - | - | - | 2,424 | - | - | - | - | 2,424 |
| Changes in Treasury Stock Related to Stock-based Compensation Arrangements | - | - | - | - | 13 | (488) | - | - | (488) |
| Issuance of Common Shares upon Stock Option and ESPP Exercise | - | 7 | - | 281 | - | - | - | - | 281 |
| Change in Fair Value of Interest Rate Swap, Net of Tax | - | - | - | - | - | - | (6,818) | - | (6,818) |
| Net Loss | - | - | - | - | - | - | - | (7,011) | (7,011) |
| Balance, March 31, 2020 | $ 1 | 12,112 | $ - | $ 203,505 | 28 | $ (1,211) | $ (11,689) | $ 10,565 | $ 201,171 |

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

| | *Three Months Ended March 31,* | |
|---|---|---|
| | *2020* | *2019* |
| Cash Flows From Operating Activities | | |
| Net (loss)/income | $ (7,011) | $ 449 |
| Adjustments to reconcile net loss to net cash and cash equivalents provided by operating activities: | | |
| Stock-based compensation | 2,424 | 1,710 |
| Deferred taxes | (19,243) | (165) |
| Depreciation and amortization | 11,183 | 16,103 |
| Acquired in-process research and development (“IPR&D”) | 3,753 | - |
| Non-cash interest relating to convertible notes and loan cost amortization | 182 | 1,873 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (10,250) | (2,568) |
| Inventories, net | 3,693 | (1,529) |
| Prepaid expenses and other current assets | 1,028 | 358 |
| Accounts payable | (1,332) | 2,005 |
| Accrued royalties | 1,201 | (3,016) |
| Current income taxes, net | 16,299 | (1,569) |
| Accrued government rebates | (871) | (422) |
| Returned goods reserve | 1,019 | 1,007 |
| Accrued expenses, accrued compensation, and other | (365) | 55 |
| Net Cash and Cash Equivalents Provided by Operating Activities | 1,710 | 14,291 |
| Cash Flows From Investing Activities | | |
| Acquisition of product rights, IPR&D, and other related assets | (56,007) | (18,510) |
| Acquisition of property and equipment, net | (1,539) | (1,775) |
| Net Cash and Cash Equivalents Used in Investing Activities | (57,546) | (20,285) |
| Cash Flows From Financing Activities | | |
| Borrowings under Revolver agreement | 15,000 | - |
| Payments on Term Loan agreement | (902) | (902) |
| Proceeds from stock option exercises | 281 | 2,416 |
| Treasury stock purchases for restricted stock vests | (488) | (308) |
| Net Cash and Cash Equivalents Provided by Financing Activities | 13,891 | 1,206 |
| Change in Cash, Cash Equivalents, and Restricted Cash | (41,945) | (4,788) |
| Cash, cash equivalents, and restricted cash, beginning of period | 67,361 | 48,029 |
| Cash, cash equivalents, and restricted cash, end of period | $ 25,416 | $ 43,241 |
| Reconciliation of cash, cash equivalents, and restricted cash, beginning of period | | |
| Cash and cash equivalents | 62,332 | 43,008 |
| Restricted cash | 5,029 | 5,021 |
| Cash, cash equivalents, and restricted cash, beginning of period | 67,361 | 48,029 |
| Reconciliation of cash, cash equivalents, and restricted cash, end of period | | |
| Cash and cash equivalents | 20,414 | 38,233 |
| Restricted cash | 5,002 | 5,008 |
| Cash, cash equivalents, and restricted cash, end of period | 25,416 | 43,241 |
| **Supplemental disclosure for cash flow information:** | | |
| Cash paid for interest, net of amounts capitalized | $ 1,848 | $ 449 |
| Cash paid for income taxes | $ 95 | $ - |
| **Supplemental non-cash investing and financing activities:** | | |
| Acquisition of product rights, IPR&D, and other related assets included in accounts payable or accrued expenses | $ 1,940 | $ - |
| Property and equipment purchased and included in accounts payable | $ 138 | $ 170 |

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

## 1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

### Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (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 three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, 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, comprehensive income, and cash flows. The consolidated balance sheet at December 31, 2019, 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, 2019.

### Principles of Consolidation

The unaudited interim condensed consolidated financial statements include the accounts of ANI Pharmaceuticals, Inc. and its subsidiaries. All intercompany accounts and transactions are eliminated in consolidation.

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

**Foreign Currency**

We have a subsidiary located in Canada. The subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar. The results of any non-U.S. dollar transactions are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. Our gain or loss on transactions denominated in foreign currencies was immaterial for the three months ended March 31, 2020 and 2019. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

**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 consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, revenue recognition, allowance for credit losses, variable consideration determined based on 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, income tax provision, deferred taxes and valuation allowance, determination of right-of-use assets and lease liabilities, 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.

We are closely monitoring the impact of the novel coronavirus ("COVID-19") pandemic on our business. While we did not incur significant disruptions during the three months ended March 31, 2020 from the COVID-19 pandemic, we are unable to predict the impact that the COVID-19 pandemic will have on our future business, financial condition and results of operations due to numerous uncertainties. These uncertainties include the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. We considered the potential impact of the COVID-19 pandemic on our estimates and assumptions and there was not a material impact to our condensed consolidated financial statements as of and for the three months ended March 31, 2020. Actual results could differ from those estimates, which may change our estimates in future periods.

**Accounts Receivable**

We extend credit to customers on an unsecured basis. We measure expected credit losses on our financial assets measured at amortized cost, including trade and unbilled receivables, on a collective basis, based on their similar risk characteristics. Expected credits losses are based on historical credit loss experience, review of the current aging or status of accounts receivable and current and forward-looking views from an economic and industry perspective. We determine trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. Our allowance for credit losses was immaterial as of March 31, 2020. Our allowance for doubtful accounts as of December 31, 2019, as accounted for and reported under previously applicable U.S. GAAP, was also immaterial.

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

**Geographic Information**

Based on the distinct nature of our operations, our internal management structure, and the financial information that is evaluated regularly by our Chief Operating Decision Maker, we determined that we operate in one reportable segment. Our operations are located in the United States and Canada.

The following table depicts the Company's revenue by geographic operations during the following periods:

| (in thousands) | Three Months Ended | |
|---|---|---|
| **Location of Operations** | **March 31, 2020** | **March 31, 2019** |
| United States | $ 48,231 | $ 50,900 |
| Canada | 1,543 | 1,987 |
| Total Revenue | $ 49,774 | $ 52,887 |

The following table depicts the Company's property and equipment, net according to geographic location as of:

| (in thousands) | **March 31, 2020** | **December 31, 2019** |
|---|---|---|
| United States | $ 26,507 | $ 26,708 |
| Canada | $ 13,846 | 13,843 |
| Total property and equipment, net | $ 40,353 | $ 40,551 |

**Recent Accounting Pronouncements**

***Recent Accounting Pronouncements Not Yet Adopted***

In November 2019, the Financial Accounting Standards Board ("FASB") issued guidance simplifying the accounting for income taxes by removing the following exceptions: 1) exception to the incremental approach for intraperiod tax allocation when there is a loss from continuing operations and income or a gain from other items, 2) exception requirement to recognize a deferred tax liability for equity method investments when a foreign subsidiary becomes and equity method investment, 3) exception to the ability not to recognize a deferred tax liability for a foreign subsidiary when a foreign equity method investment becomes a subsidiary, and 4) exception to the general methodology for calculating income taxes in an interim period when a year-to-date loss exceeds the anticipated loss the year. The amendments also simplify accounting for income taxes by doing the following: 1) requiring that an entity recognize a franchise tax or similar tax that is partially based on income as an income-based tax and account for any incremental amount incurred as a non-income-based tax, 2) requiring that an entity evaluate when a step up in the tax basis of goodwill should be considered part of the business combination in which the book goodwill was originally recognized and when it should be considered a separate transaction, 3) specifying that an entity is not required to allocate the consolidated amount of current and deferred tax expense to a legal entity that is not subject to tax in its separate financial statements, 4) requiring that an entity reflect the effect of an enacted change in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date, and 5) making minor Codification improvements for income taxes related to employee stock ownership plans and investments in qualified affordable housing projects accounted for using the equity method. The guidance is effective for reporting periods beginning after December 15, 2020, including interim periods within that fiscal year. Early adoption is permitted, including adoption in an interim period. We are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

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

We have evaluated all 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, comprehensive income, balance sheets, or cash flows.

***Recently Adopted Accounting Pronouncements***

In November 2018, the FASB issued guidance clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under Accounting Standards Codification Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account. The guidance was effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2020. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In August 2018, the FASB issued guidance amending the disclosure requirements on fair value measurements. The amendments add, modify, and eliminate certain disclosure requirements on fair value measurements. The guidance was effective for reporting periods beginning after December 15, 2019, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2020. The adoption of this guidance did not have a material impact on our consolidated financial statements.

In June 2016, the FASB issued guidance under 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 now reflects an entity's current estimate of all future expected credit losses. Under the previous guidance, an entity only considered past events and current conditions. In April 2019, the FASB further clarified the scope of the credit losses standard and addressed issues related to accrued interest receivable balances, recoveries, variable interest rates, and prepayment. In May 2019, the FASB issued further guidance to provide entities with an option to irrevocably elect the fair value option applied on an instrument-by-instrument basis for eligible financial instruments. We adopted this guidance as of January 1, 2020 using the modified retrospective method for all financial assets measured at amortized cost. Results for reporting periods beginning after January 1, 2020 are presented under the new guidance while prior period amounts continue to be reported in accordance with previously applicable GAAP. We recognized an $8 thousand decrease to retained earnings as of January 1, 2020 for the cumulative effect of adopting the new guidance.

## 2. REVENUE RECOGNITION AND RELATED ALLOWANCES

### Revenue Recognition

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:

| **Products and Services** | **Three Months Ended** | |
|---|---|---|
| (in thousands) | **March 31, 2020** | **March 31, 2019** |
| Sales of generic pharmaceutical products | $ 37,495 | $ 31,599 |
| Sales of branded pharmaceutical products | 9,157 | 17,543 |
| Sales of contract manufactured products | 1,974 | 2,437 |
| Royalties from licensing agreements | 290 | 577 |
| Product development services | 577 | 320 |
| Other[(1)] | 281 | 411 |
| Total net revenues | $ 49,774 | $ 52,887 |

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

The following table depicts revenue recognized during the following periods:

| **Timing of Revenue Recognition** | **Three Months Ended** | |
|---|---|---|
| (in thousands) | **March 31, 2020** | **March 31, 2019** |
| Performance obligations transferred at a point in time | $ 49,197 | $ 52,567 |
| Performance obligations transferred over time | 577 | 320 |
| Total | $ 49,774 | $ 52,887 |

**2. REVENUE RECOGNITION AND RELATED ALLOWANCES – continued**

In the three months ended March 31, 2020 and 2019, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts. We recognized a decrease of $2.4 million to net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2020, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales, partially offset by royalties from licensing agreements. We recognized a decrease of $0.6 million of net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2019, consisting primarily of royalties from licensing agreements and revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We provide technical transfer services to customers, for which services are transferred over time. As a result, we had $0.1 million of contract assets related to revenue recognized based on a percentage of completion but not yet billed at both March 31, 2020 and December 31, 2019 and $0.3 million and $0.5 million of deferred revenue at March 31, 2020 and December 31, 2019, respectively. For the three months ended March 31, 2020, we recognized $0.1 million of revenue that was included in deferred revenue as of December 31, 2019.

***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. A comprehensive discussion of variable consideration 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, 2019.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the three months ended March 31, 2020 and 2019, respectively:

| (in thousands) | Accruals for Chargebacks, Rebates, Returns, and Other Allowances | | | | |
|---|---|---|---|---|---|
| | Chargebacks | Government Rebates | Returns | Administrative Fees and Other Rebates | Prompt Payment Discounts |
| Balance at December 31, 2018 | $ 39,007 | $ 8,974 | $ 12,552 | $ 7,353 | $ 2,009 |
| Accruals/Adjustments | 55,831 | 2,381 | 3,620 | 8,207 | 2,433 |
| Credits Taken Against Reserve | (54,614) | (2,803) | (2,613) | (8,272) | (2,333) |
| Balance at March 31, 2019 | $ 40,224 | $ 8,552 | $ 13,559 | $ 7,288 | $ 2,109 |
| | | | | | |
| Balance at December 31, 2019 | $ 49,882 | $ 8,901 | $ 16,595 | $ 8,281 | $ 2,549 |
| Accruals/Adjustments | 95,393 | 3,567 | 5,937 | 8,922 | 3,361 |
| Credits Taken Against Reserve | (51,575) | (4,438) | (4,918) | (8,817) | (2,219) |
| Balance at March 31, 2020 | $ 93,700 | $ 8,030 | $ 17,614 | $ 8,386 | $ 3,691 |

**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, 2020, the value of our unsatisfied performance obligations was $7.9 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 six months.

***Royalties from Licensing Agreements***

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.

We receive royalties from a license for patent rights initially owned by Cell Genesys, Inc., which merged with BioSante in 2009. The royalties are the results of sales and milestones related to the Yescarta® product. We recognize revenue for sales-based royalties when the underlying sales occur. We estimate variable consideration related to milestones, which requires significant judgment.

***Product Development Services Revenue***

We provide product development services to customers, which are performed over time. These services primarily relate to the technical transfer of product development to our facility in Oakville, Ontario. The duration of these technical transfer projects can be up to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a percentage of completion basis, which results in contract assets on our balance sheet. As of March 31, 2020, the value of our unsatisfied performance obligations for product development services contracts was $1.5 million. We expect to satisfy these performance obligations in the next 6 to 15 months.

**Credit Concentration**

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

During the three months ended March 31, 2020, three customers represented 31%, 23%, and 18% of net revenues, respectively. As of March 31, 2020, accounts receivable from these customers totaled 90% of accounts receivable, net. During the three months ended March 31, 2019, three customers represented 35%, 23%, and 23% of net revenues, respectively.

## 3. INDEBTEDNESS

***Credit Facility***

On December 27, 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to $265.2 million. The principal new feature of the Credit Facility was a $118.0 million Delayed Draw Term Loan (the "DDTL"), which could only be drawn on in order to pay down the Company's 3.0% Convertible Senior Notes (the "Notes"), which matured on December 1, 2019. The Credit Facility has a subjective acceleration clause in case of a material adverse event. The Credit Facility also extended the maturity of the $72.2 million secured term loan balance (the "Term Loan") to December 2023 and increased the previous $50.0 million line of credit (the "Revolver") to $75.0 million. The Term Loan includes a repayment schedule, pursuant to which $5.0 million of the loan will be paid in quarterly installments during the 12 months ended March 31, 2021. As of March 31, 2020, $5.0 million of the loan is recorded as current borrowings in the unaudited condensed consolidated balance sheets. On November 29, 2019, we exercised our option to borrow $118.0 million pursuant to the DDTL feature and used the proceeds to repay the outstanding Notes. The DDTL matures in December 2023 and includes a repayment schedule, pursuant to which $7.4 million will be paid in quarterly installments during the 12 months ended March 31, 2021. As of March 31, 2020, $7.4 million of the loan is recorded as current borrowings in the unaudited condensed consolidated balance sheets. In March 2020, we drew $15.0 million under the Revolver. Borrowings under the Revolver mature in December 2023. As of March 31, 2020, $60.0 million remains available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.75% 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 1.75%, depending our total leverage ratio. On the Revolver, we incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio.

The Credit Facility is secured by a lien on substantially all of ANI Pharmaceuticals, Inc.'s and its principal domestic subsidiary's assets and any future domestic subsidiary guarantors' assets. The Credit Facility imposes financial covenants consisting of a maximum total leverage ratio, which is, as of March 31, 2020, no greater than 3.50 to 1.00 and a minimum fixed charge coverage ratio, which shall be greater than or equal to 1.25 to 1.00. The primary non-financial covenants under the Credit Facility limit, subject to various exceptions, our ability to incur future indebtedness, to place liens on assets, to pay dividends or make other distributions on our capital stock, to repurchase our capital stock, to conduct acquisitions, to alter our capital structure, and to dispose of assets.

**3. INDEBTEDNESS – continued**

The carrying value of the current and non-current components of the Term Loan and DDTL as of March 31, 2020 and December 31, 2019 are:

| | Current | |
|---|---|---|
| (in thousands) | March 31, 2020 | December 31, 2019 |
| Current borrowing on debt | $ 12,338 | $ 10,412 |
| Deferred financing costs | (466) | (471) |
| Current debt, net of deferred financing costs | $ 11,872 | $ 9,941 |

| | Non-current | |
|---|---|---|
| (in thousands) | March 31, 2020 | December 31, 2019 |
| Non-current borrowing on debt | $ 174,240 | $ 177,069 |
| Deferred financing costs | (1,146) | (1,261) |
| Non-current debt, net of deferred financing costs and current component | $ 173,094 | $ 175,808 |

The refinancing of the Term Loan was accounted for as a modification of our previous term loan and consequently, the remaining balance of the deferred issuance costs related to the previous term loan are included with the lenders fees associated with the refinance of the Term Loan and amortized as interest expense over the life of the Term Loan using the effective interest method. Fees to third parties associated with the refinance of the Term Loan were recognized as other (expense)/income, net in the accompanying consolidated statements of operations. The refinancing of the Revolver was accounted for as a modification of our previous revolving credit facility and consequently, the remaining balance of the deferred issuance costs related to the previous revolving credit facility are included with the lenders fees and fees to third parties associated with the refinance of the Revolver and amortized as interest expense on a straight-line basis over the life of the Revolver. All issuance costs allocated to the DDTL were deferred and will be amortized as interest expense on a straight-line basis over the five-year term of the DDTL.

As of March 31, 2020, we had a $68.6 million balance on the Term Loan, a $118.0 million balance on the DDTL, and a $15.0 million balance on the Revolver. Of the $0.9 million of deferred debt issuance costs allocated to the Revolving Credit Facility, $0.7 million is included in other non-current assets in the 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. Of the $0.4 million of deferred debt issuance costs allocated to the DDTL, $0.1 million is classified as a direct deduction to the current portion of the DDTL in the unaudited condensed consolidated balance sheets and $0.3 million is classified as a direct reduction to the non-current portion of the DDTL in the unaudited condensed consolidated balance sheets. Of the $1.2 million of deferred debt issuance costs allocated to the Term Loan, $0.4 million is classified as a direct deduction to the current portion of the Term Loan in the unaudited condensed consolidated balance sheets and $0.8 million is classified as a direct deduction to the non-current portion of the Term Loan in the unaudited condensed consolidated balance sheets.

**3. INDEBTEDNESS – continued**

The contractual maturity of our Term Loan, DDTL, and Revolver is as follows for the years ending December 31:

| (in thousands) | Term Loan | DDTL | Revolver |
|---|---|---|---|
| 2020 | $ 3,609 | $ 5,900 | $ - |
| 2021 | 5,414 | 5,900 | - |
| 2022 | 5,414 | 8,850 | - |
| 2023 | 54,141 | 97,350 | 15,000 |
| Total | $ 68,578 | $ 118,000 | $ 15,000 |

The following table sets forth the components of total interest expense related to the Term Loan, DDTL, and Revolver recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three months ended March 31, 2020 and 2019:

| | Three Months Ended | |
|---|---|---|
| (in thousands) | March 31, 2020 | March 31, 2019 |
| Contractual coupon | $ 1,893 | $ 1,631 |
| Amortization of debt discount | - | 1,513 |
| Amortization of deferred financing costs | 182 | 360 |
| Capitalized interest | (25) | (75) |
| | $ 2,050 | $ 3,429 |

## 4. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

At times we use derivative financial instruments to hedge our exposure to interest rate risks. All derivative financial instruments are recognized as either assets or liabilities at fair value on the consolidated balance sheet and are classified as current or non-current based on the scheduled maturity of the instrument.

When we enter into a hedge arrangement and intend to apply hedge accounting, we formally document the hedge relationship and designate the instrument for financial reporting purposes as a fair value hedge, a cash flow hedge, or a net investment hedge. When we determine that a derivative financial instrument qualifies as a cash flow hedge and is effective, the changes in fair value of the instrument are recorded in accumulated other comprehensive loss, net of tax in our consolidated balance sheets and will be reclassified to earnings when the hedged item affects earnings.

In December 2018, we refinanced our previous Credit Agreement and, as part of that refinancing, extended the maturity of our $72.2 million secured term loan balance to December 2023. At the same time, we terminated an interest rate swap on the previous loan and entered into a new interest rate swap arrangement, which is also considered a derivative financial instrument, with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our Term Loan. The interest rate swap hedges the variable cash flows associated with the borrowings under our Term Loan (Note 3), effectively providing a fixed rate of interest throughout the life of our Term Loan.

The interest rate swap arrangement with Citizens Bank, N.A became effective on December 27, 2018, with a maturity date of December 27, 2023. The notional amount of the swap agreement at inception was $72.2 million and decreases in line with our Term Loan. As of March 31, 2020, the notional amount of the interest rate swap was $68.6 million. The interest rate swap has a weighted average fixed rate of 2.60% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of March 31, 2020, the fair value of the interest rate swap liability was valued at $5.0 million and was recorded in other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of March 31, 2020, $4.4 million, the fair value of the interest rate swap net of tax, was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets. During the three months ended March 31, 2020, changes in the fair value of the interest rate swap of $2.5 million, net of tax, was recorded in accumulated other comprehensive (loss), net of tax in our unaudited interim condensed consolidated statements of comprehensive income. Differences between the hedged LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Loan based on the LIBOR rate. In the three months ended March 31, 2020, $0.2 million of interest expense was recognized in relation to the interest rate swap.

## 4. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY – continued

In February 2019, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our DDTL. As of March 31, 2020, the notional amount of the interest rate swap was $118.0 million and decreases in line with our DDTL. The interest rate swap provides an effective fixed rate of 2.47% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. The interest rate swap hedges the variable cash flows associated with the borrowings under our DDTL (Note 3), effectively providing a fixed rate of interest throughout the life of our DDTL. As of March 31, 2020, the fair value of the interest rate swap liability was valued at $8.4 million and was recorded in other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of March 31, 2020, $7.3 million, the fair value of the interest rate swap net of tax, was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets. During the three months ended March 31, 2020, changes in the fair value of the interest rate swap of $4.4 million, net of tax, were recorded in accumulated other comprehensive loss, net of tax in our unaudited interim condensed consolidated statements of comprehensive income. Differences between the hedged LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the DDTL based on the LIBOR rate. In the three months ended March 31, 2020, $0.2 million of interest expense was recognized in relation to the February 2019 interest rate swap.

## 5. EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing net income (loss) 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 (loss) 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, and stock purchase warrants, 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 (loss) per share excludes from the numerator net income (but not net loss) attributable to the unvested restricted shares, and excludes the impact of those shares from the denominator.

For purposes of determining diluted earnings (loss) per share in 2019, we elected a policy to settle the principal portion of the Notes in cash. As such, the principal portion of the Notes had no effect on either the numerator or denominator when determining diluted earnings (loss) per share. Any conversion gain was assumed to be settled in shares and was incorporated in diluted earnings per share using the treasury method. The warrants issued in conjunction with the issuance of the Notes 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 was always considered to be anti-dilutive.

## 5. EARNINGS (LOSS) PER SHARE – continued

Earnings (loss) per share for the three months ended March 31, 2020 and 2019 are calculated for basic and diluted earnings (loss) per share as follows:

| (in thousands, except per share amounts) | Basic | | Diluted | |
|---|---|---|---|---|
| | Three Months Ended March 31, | | Three Months Ended March 31, | |
| | 2020 | 2019 | 2020 | 2019 |
| Net (loss)/income | $ (7,011) | $ 449 | $ (7,011) | $ 449 |
| Net income allocated to restricted stock | - | (9) | - | (9) |
| Net (loss)/income allocated to common shares | $ (7,011) | $ 440 | $ (7,011) | $ 440 |
| Basic Weighted-Average Shares Outstanding | 11,902 | 11,747 | 11,902 | 11,747 |
| Dilutive effect of stock options and ESPP | | | - | 76 |
| Diluted Weighted-Average Shares Outstanding | | | 11,902 | 11,823 |
| (Loss)/Earnings Per Share | $ (0.59) | $ 0.04 | $ (0.59) | $ 0.04 |

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share was 1.8 million and 4.1 million for the three months ended March 31, 2020 and 2019, respectively. Anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the treasury stock method, underlying shares related to out-of-the-money bonds issued as convertible debt (for 2019 only) and out-of-the-money warrants exercisable for common stock.

## 6. INVENTORIES

Inventories consist of the following as of:

| (in thousands) | March 31, 2020[(1)] | December 31, 2019 |
|---|---|---|
| Raw materials | $ 35,340 | $ 34,881 |
| Packaging materials | 2,878 | 2,902 |
| Work-in-progress | 646 | 361 |
| Finished goods | 20,835 | 16,750 |
| | 59,699 | 54,894 |
| Reserve for excess/obsolete inventories | (6,797) | (6,731) |
| Inventories, net | $ 52,902 | $ 48,163 |

(1) Includes fair value of inventory acquired in Amerigen Pharmaceuticals, Ltd. asset acquisition and unsold as of March 31, 2020. See Note 12 for more details.

### 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 on-going product manufacturing. During the three months ended March 31, 2020, we purchased approximately 13% of our inventory from one supplier. As of March 31, 2020, our amount payable to this supplier was $0.7 million. During the three months ended March 31, 2019, we purchased approximately 55% of our inventory from three suppliers.

## 7. PROPERTY, PLANT, AND EQUIPMENT

Property and equipment consist of the following as of:

| (in thousands) | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Land | $ 4,566 | $ 4,566 |
| Buildings | 10,289 | 10,275 |
| Machinery, furniture, and equipment | 35,845 | 34,984 |
| Construction in progress | 3,575 | 3,496 |
| | 54,275 | 53,321 |
| Less: accumulated depreciation | (13,922) | (12,770) |
| Property and equipment, net | $ 40,353 | $ 40,551 |

Depreciation expense was $1.2 million for both the three months ended March 31, 2020 and 2019. During the three months ended March 31, 2020 and 2019, there was $25 thousand 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.

## 8. GOODWILL AND INTANGIBLE ASSETS

### Goodwill

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. (“BioSante”), we recorded goodwill of $1.8 million. As a result of our acquisition of WellSpring, we recorded additional goodwill of $1.7 million in 2018. We assess the recoverability of the carrying value of goodwill as of October 31$^{st}$ 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, 2020. No impairment losses were recognized during the three months ended March 31, 2020 and 2019.

### Definite-lived Intangible Assets

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

| (in thousands) | March 31, 2020 | | December 31, 2019 | | Weighted Average |
|---|---|---|---|---|---|
| | Gross Carrying Amount | Accumulated Amortization | Gross Carrying Amount | Accumulated Amortization | Amortization Period |
| Acquired ANDA intangible assets | $ 103,234 | $ (33,162) | $ 64,704 | $ (30,169) | 8.9 years |
| NDAs and product rights | 230,974 | (93,635) | 230,974 | (87,352) | 10.0 years |
| Marketing and distribution rights | 17,657 | (9,716) | 10,923 | (8,982) | 5.7 years |
| Non-compete agreement | 624 | (357) | 624 | (334) | 7.0 years |
| | $ 352,489 | $ (136,870) | $ 307,225 | $ (126,837) | |

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 certain New Drug Application (“NDA”) and product rights assets, we use an accelerated amortization method to better match the anticipated economic benefits expected to be provided. Amortization expense was $10.0 million and $15.0 million for the three months ended March 31, 2020 and 2019, respectively. Refer to Note 12 for more details on acquired definite-lived intangible assets.

## 8. GOODWILL AND INTANGIBLE ASSETS – continued

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, 2020 and 2019 and therefore no impairment loss was recognized in the three months ended March 31, 2020 and 2019.

Expected future amortization expense is as follows:

| (in thousands) | |
|---|---|
| 2020 (remainder of the year) | $ 29,614 |
| 2021 | 38,201 |
| 2022 | 34,795 |
| 2023 | 34,047 |
| 2024 | 31,070 |
| 2025 and thereafter | 47,892 |
| Total | $ 215,619 |

## 9. STOCK-BASED COMPENSATION

**Employee Stock Purchase Plan**

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of March 31, 2020, 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.

The following table summarizes ESPP expense incurred under the 2016 Employee Stock Purchase Plan and included in our accompanying unaudited interim condensed consolidated statements of operations:

| (in thousands) | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Cost of sales | $ 4 | $ 3 |
| Research and development | 7 | 5 |
| Selling, general, and administrative | 18 | 22 |
| | $ 29 | $ 30 |

**Stock Incentive Plan**

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, 2020, 0.3 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:

| (in thousands) | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Cost of sales | $ 26 | $ 21 |
| Research and development | 187 | 113 |
| Selling, general, and administrative | 2,182 | 1,546 |
| | $ 2,395 | $ 1,680 |

**9. STOCK-BASED COMPENSATION – continued**

A summary of stock option and restricted stock activity under the 2008 Plan during the three months ended March 31, 2020 and 2019 is presented below:

| (in thousands) | Options | RSAs |
|---|---|---|
| Outstanding December 31, 2018 | 759 | 117 |
| Granted | 157 | 122 |
| Options Exercised/RSAs Vested | (58) | (11) |
| Forfeited | (18) | (2) |
| Expired | (1) | - |
| Outstanding March 31, 2019 | 839 | 226 |
| | | |
| Outstanding December 31, 2019 | 757 | 192 |
| Granted | 8 | - |
| Options Exercised/RSAs Vested | (7) | (49) |
| Forfeited | (3) | - |
| Expired | - | - |
| Outstanding March 31, 2020 | 755 | 143 |

(1) Includes 13 thousand shares purchased from employees to cover employee income taxes related to income earned upon vesting of restricted stock. The shares purchased are held in treasury and the $488 thousand total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

On January 17, 2020, we entered into employment agreements with our Named Executive Officers (“NEOs”), (i)President and Chief Executive Officer, Arthur S. Przybyl, (ii) Vice President of Finance and Chief Financial Officer, Stephen P. Carey, (iii) Senior Vice President of Business Development and Specialty Sales, Robert Schrepfer and (iv) Senior Vice President of Operations and Product Development, James G. Marken. As part of the employment agreements, the NEOs’ Non-Statutory Stock Option, Incentive Option and Restricted Stock Grant agreements (“NEO Stock Agreements”) were modified to provide for accelerated vesting of unvested non-statutory stock options and restricted stock awards in the event of a termination for any reason other than “cause” as defined in the employment agreements or by the NEOs for “good reason” as defined in the employment agreements. Additionally, any vested incentive or non-statutory stock options and unvested non-statutory stock options subject to acceleration and held unexercised by the NEOs at the time of such termination at the time will retain their normal term, which is generally 10 years from grant date. We did not recognize any incremental share-based compensation expense associated with these modifications, as no assumptions regarding the assumed probability of these awards’ future vests were changed on the modification date.

As noted in our Form 8-K, Item 5.02 filed on April 14, 2020 with a report date of April 10, 2020, Arthur S. Przybyl will depart as President and Chief Executive Officer on May 10, 2020. Mr. Przybyl’s departure will constitute a Termination Without Good Cause as defined in his employment agreement, which agreement has previously been disclosed, and he will receive separation payments and benefits under his employment agreement in respect of a termination without good cause, including those related to his incentive stock options, non-statutory stock options and restricted stock awards as discussed above.

## 10. INCOME TAXES

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of March 31, 2020, we have provided a valuation allowance against consolidated net deferred tax assets of $0.4 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

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, 2020 and December 31, 2019. We are subject to taxation in various U.S. 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, calculated on a worldwide consolidated basis, expected for the entire year. If we project taxable losses in any specific taxing jurisdiction, those losses are excluded from the calculation of the worldwide estimated annual effective tax rate and a resulting tax benefit is not recognized. 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. During periods when we incur net losses before income taxes, our annual estimated effective tax rate may be adjusted based on the “loss limitation” requirements applicable to interim tax provisions, resulting in a limited income tax benefit recognized in that period. 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. Global Intangible Low-Taxed Income (“GILTI”), as defined in the Tax Cuts and Jobs Act of 2017, generated from our Canadian operations is subject to U.S. taxes, with certain defined exemptions, thresholds and credits. For financial reporting purposes we have elected to treat GILTI inclusions as a period cost.

**10. INCOME TAXES – continued**

For the three months ended March 31, 2020, we recognized an income tax benefit of $2.9 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 29.7% to pre-tax consolidated loss of $9.9 million reported during the period, reduced by the net effects of certain discrete items occurring in 2020 which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended March 31, 2020.

The estimated consolidated effective tax rate for the three months ended March 31, 2019, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit could be recognized, was 22.0% of pre-tax income reported in our U.S. operations in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2019 plus the effects of certain discrete items occurring in the third quarter. Our effective tax rate for the three months ended March 31, 2019 was impacted primarily 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.

## 11. COMMITMENTS AND CONTINGENCIES

### Operating Leases

All our existing leases as of March 31, 2020 are classified as operating leases. As of March 31, 2020, we have eleven material operating leases for facilities and office equipment with remaining terms expiring from 2021 through 2024 and a weighted average remaining lease term of 2.2 years. Many of our existing leases have fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. Discount rates used in the calculation of our lease liability ranged between 4.02% and 8.95%.

Rent expense for the three months ended March 31, 2020 and 2019 consisted of the following:

| | Three Months Ended March 31, | |
|---|---|---|
| (in thousands) | March 31, 2020 | March 31, 2019 |
| Operating lease costs | $ 52 | $ 44 |
| Variable lease costs | 15 | 13 |
| Total lease costs | $ 67 | $ 57 |

A maturity analysis of our operating leases follows:

| (in thousands) | |
|---|---|
| Future payments: | |
| 2020 (remainder of the year) | $ 160 |
| 2021 | 151 |
| 2022 | 111 |
| 2023 | 40 |
| 2024 | 3 |
| 2025 and thereafter | - |
| Total | $ 465 |
| | |
| Discount | (25) |
| Lease liability | 440 |
| Current lease liability | (199) |
| Non-current lease liability | $ 241 |

### Government Regulation

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

**11. COMMITMENTS AND CONTINGENCIES – continued**

**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, 2020 and 2019, net revenues for these products totaled $4.4 million and $5.4 million, respectively.

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

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, 2020 and 2019 were $1.0 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.

**Legal proceedings**

We are involved, and from time to time may become involved, in various disputes, governmental and/or regulatory inquiries, investigations, and litigation matters, some of which could result in losses, including damages, fines, and/or civil or criminal penalties against us. These matters are often complex and have outcomes that we are unable to predict.

We intend to vigorously defend ourselves in these matters and believe that we have strong defenses regarding the claims currently asserted against us. However, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations, and legal proceedings, individually or in the aggregate, could have a material adverse effect on our results of operations and/or cash flows in any given accounting period or on our overall financial condition.

Some of these matters with which we are involved are described below, and unless otherwise disclosed, we are unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. We record accruals for loss contingencies to the extent we conclude it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated. From time to time, we are also involved in other pending proceedings for which, in our opinion based upon facts and circumstances known at the time, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to our results. If and when any reasonably possible losses associated with the resolution of such other pending proceedings, in our opinion, become material, we will disclose such matters.

**11. COMMITMENTS AND CONTINGENCIES – continued**

**Louisiana Medicaid Lawsuit**

On September 11, 2013, the Attorney General of the State of Louisiana filed a lawsuit in Louisiana state court against numerous pharmaceutical companies, including us, under various state laws, alleging that each defendant caused the state's Medicaid agency to provide reimbursement for drug products that allegedly were not approved by the FDA and therefore allegedly not reimbursable under the federal Medicaid program. The lawsuit relates to three cough and cold prescription products manufactured and sold by our former Gulfport, Mississippi operation, which was sold in September 2010. Through its lawsuit, the state seeks unspecified damages, statutory fines, penalties, attorneys' fees, and costs. 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.

**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. Discovery in this action closed on March 31, 2019. Trial has been scheduled for October 2020. We continue 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 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 ("legacy claims"). All these original legacy claims were settled or closed out, including a series of claims in California that were resolved by coordinated proceeding and settlement. At the end of March 2019, we were served with a lawsuit in the Superior Court of California, County of Riverside, adding us as a defendant in a complaint filed in July 2017 that is alleged not to have been part of the original settled legacy claims. This new claim as well as the impact of the prior settlements on this claim is currently being evaluated by the Company, its insurers, and its legal counsel.

At the present time, we are unable to assess the likely outcome of the case. Our insurance company had assumed the defense of the legacy claims and paid all losses in settlement of the California cases. We cannot provide assurances that the outcome of this new matter 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.

Our ANDA for Erythromycin Ethylsuccinate ("EES") was originally approved by the FDA on November 27$^{th}$, 1978. We purchased the EES ANDA from Teva on July 10, 2015. 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 our 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 September 27, 2016. 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 reserved our legal right to an internal Agency appeal. We believe that our supplemental ANDA is valid, and as such continued to market the product. In addition, we filed a PAS which was approved by the FDA on November 2, 2018 with no FDA objection to our prior actions.

**11. 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.

**12. FAIR VALUE DISCLOSURES**

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Loan, DDTL, and Revolver bear an interest rate that fluctuates with the changes in LIBOR and, because the variable interest rates approximate market borrowing rates available to us, we believe the carrying values of these borrowings approximated their fair values at March 31, 2020.

**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 was immaterial as of March 31, 2020 and December 31, 2019. We also determined that the changes in such fair value were immaterial in the three months ended March 31, 2020 and 2019.

In December 2018, we refinanced our previous Credit Agreement and, as part of that refinancing, extended the maturity of our $72.2 million secured term loan balance to December 2023. At the same time, we closed out the original interest rate swap and entered into a new interest rate swap arrangement (Note 4) to manage our exposure to the variable interest rate on our Term Loan (Note 3). The notional amount of our interest rate swap was set to match the balance of our Term Loan. The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 4, the fair value of the interest rate swap was a $5.0 million liability at March 31, 2020.

In February 2019, we entered into an interest rate swap arrangement (Note 4), with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying our DDTL (Note 3). The fair value of our interest rate swap was estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap included inputs of readily observable market data, a Level 2 input. As described in detail in Note 4, the fair value of the interest rate swap was a $8.4 million liability at March 31, 2020.

**12. FAIR VALUE DISCLOSURES – continued**

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of March 31, 2020 and December 31, 2019, by level within the fair value hierarch

(in thousands)

| Description | Fair Value at March 31, 2020 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Liabilities | | | | |
| Interest rate swap | $ 13,370 | $ - | $ 13,370 | $ - |

| Description | Fair Value at December 31, 2019 | Level 1 | Level 2 | Level 3 |
|---|---|---|---|---|
| Liabilities | | | | |
| Interest rate swap | $ 6,215 | $ - | $ 6,215 | $ - |

**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, ROU assets, 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, 2020 and 2019.

**12. FAIR VALUE DISCLOSURES – continued**

***Acquired Non-Financial Assets Measured at Fair Value***

In January 2020, we completed the acquisition of the U.S. portfolio of 23 generic products and API and finished goods related to certain of those products from Amerigen Pharmaceuticals, Ltd. ("Amerigen") for a purchase consideration of $56.8 million and up to $25.0 million in contingent payments over the next four years. The product portfolio included ten commercial products, three approved products with launches pending, four filed products and four in-development products as well as a license to commercialize two approved products. Payments of $48.9 million were made using cash on hand. We also incurred and paid $0.7 million in transaction costs directly related to the acquisition. We accounted for the transaction as an asset acquisition and capitalized the transactions costs directly related to the acquisition. We recognized $38.5 million as acquired ANDA intangible assets and $6.7 million as acquired marketing and distribution rights related to the licensed products, which will be amortized over their useful lives of seven years. We also recognized $3.8 million of the purchase price as research and development expense because certain of the generic products have significant remaining work required in order to be commercialized and the products do not have an alternative future use. The payment was allocated to the two asset categories and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. To determine the fair value of the acquired intangible assets and in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 8%. We also recognized $8.4 million in inventory at fair value, including $1.7 million of API and $6.7 million of finished goods. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. Contingent liabilities are accrued when they are both estimable and probable. As of March 31, 2020, the Company accrued $0.1 million in contingent payments due to Amerigen. The intangible assets 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, 2020 and therefore no impairment loss was recognized for the three months ended March 31, 2020.

In June 2019, we acquired from Coeptis Pharmaceuticals, Inc. seven development stage generic products, as well as API and reference-listed drug inventory related to certain of the products for a payment of $2.3 million. The entire payment, and $24 thousand of transaction costs directly related to the acquisition, was recorded as research and development expense because the potential generic products have significant remaining work required in order to commercialize the products and do not have an alternative future use. In addition, we could make up to $12.0 million in payments for certain development and commercial milestones. These milestones were determined to be contingent liabilities and will be accrued when they are both estimable and probable.

In April 2019, we entered into an agreement with PII and BAS, under which a previously-commercialized product will be developed and marketed. Per the agreement, we may pay PII a series of licensing fees in conjunction with the achievement of certain development and commercial milestones. In the fourth quarter of 2019, the product was launched, triggering a $0.5 million payment due to PII. The payment due was capitalized as an intangible asset and will be amortized in full over its useful life of 10 years.

In March 2019, we entered into an agreement with Teva Pharmaceutical Industries Ltd. to purchase a basket of ANDAs for 35 previously-marketed generic drug products for $2.5 million in cash. We made the $2.5 million cash payment using cash on hand and capitalized $10 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $2.5 million of ANDAs 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 15%. The ANDAs 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, 2020 and therefore no impairment loss was recognized for the three months ended March 31, 2020.

**12. FAIR VALUE DISCLOSURES – continued**

In January 2019, we entered into an amendment to asset purchase agreements with Teva related to three purchases of baskets of ANDAs. Under the terms of the Asset Purchase Agreement Amendment, all royalty obligations of the Company owed to Teva with respect to products associated with ten ANDAs under the original asset purchase agreements ceased being effective as of December 31, 2018. As consideration for the termination of such future royalty obligations, we paid Teva a sum of $16.0 million in cash. Upon payment of $16.0 million, the purchase price of each basket of ANDAs was increased to reflect the subsequent payment as if that payment had been made on the initial acquisition date. As a result, in addition to increasing the carrying value of the acquired ANDA intangible assets by $9.2 million, we recognized cumulative amortization expense of $6.8 million. The payment was allocated to the three ANDA baskets based on the relative fair value of the ANDA baskets, which were determined using Level 3 unobservable inputs. In order to determine the fair value of the acquired ANDA intangible assets, we used the present value of the estimated cash flows related to the ANDAs, using a discount rate of 12%. The additional carrying value will be amortized over the remaining useful lives of the three ANDA baskets 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, 2020 and therefore no impairment loss was recognized for the three months ended March 31, 2020.

In April 2018, we entered into an agreement with Impax Laboratories, Inc. (now Amneal) to purchase the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have not yet been commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for $2.3 million in cash. At the same time, we entered into a supply agreement with 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 elected to purchase the finished goods from Amneal for this period, we could have been 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. The payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. The launch of one of the acquired products had the potential to trigger a milestone payment of $25.0 million to Teva, depending on the number of competitors selling the product at the time of launch. We launched this product in 2019 and the payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. Additionally, depending on the number of competitors selling the product one year after the launch date, we could have been required to pay a second milestone of $15.0 million to Teva. The one-year anniversary of the launch occurred during the three months ended March 31, 2020 and the payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. We made the $2.3 million cash payment using cash on hand and capitalized $0.1 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $1.0 million acquired ANDA intangible assets were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the acquired ANDA intangible assets, we used the present value of the estimated cash flows related to the approved ANDAs, using discount rates of 10 to 15%. The acquired ANDAs 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 assets may not be recoverable. The $58 thousand of manufacturing equipment used to manufacture one of the products was recorded at its relative fair value, based on the estimated net book value of the equipment purchased. The equipment will be amortized in full over its 5-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, 2020 and therefore no impairment loss was recognized for the three months ended March 31, 2020. The $1.3 million of in-process research and development related to products with significant further work required in order to commercialize the products, and for which there is no alternative future use. The in-process research and development was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 75%, reflective of the higher risk associated with these products. As the transaction was accounted for as an asset purchase, the $1.3 million of in-process research and development was immediately recognized as research and development expense.

**12. FAIR VALUE DISCLOSURES – continued**

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 for four 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. We made the $2.7 million cash payment using cash on hand and capitalized $18 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $2.5 million acquired ANDA 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 discount rates of 10% to 15%. The acquired ANDA intangible assets 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, 2020 and therefore no impairment loss was recognized for the three months ended March 31, 2020. We also recorded $0.2 million of raw materials inventory, measured at fair value. The fair value of the raw materials inventory was determined based on the estimated replacement cost.

In March 2018, we entered into an agreement with Appco, in which a potential generic product, Ranitidine, was to be developed and marketed. Per the agreement, we paid Appco a series of licensing fees in conjunction with certain development milestones. Ranitidine was launched in the third quarter of 2019, resulting in the final milestone payment of $80 thousand. The $80 thousand milestone payment was capitalized as an intangible asset and determined to have estimated useful life of eight years. In September 2019, the FDA issued a public statement that some ranitidine medicines contain a nitrosamine impurity referred to as NDMA at low levels. NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests and the cause of the presence of this impurity in the ranitidine products is not yet fully understood at this time. During the fourth quarter of 2019, testing of the API used in our ranitidine drug product, as well as testing of the drug product itself, indicated a level of NDMA above acceptable thresholds and Appco initiated a voluntary recall. We elected to exit the market for Ranitidine and determined that the carrying value of the asset has been impaired. During the fourth quarter of 2019, we recognized a full impairment of the remaining $75 thousand carrying value of the asset.

**13. CORTROPHIN PRE-LAUNCH CHARGES**

In January 2016, we acquired the right, title and interest in the NDAs for Cortrophin Gel and Cortrophin-Zinc. Subsequently, we have assembled a Cortrophin re-commercialization team of scientists, executed a long-term supply agreement with a supplier of pig pituitary glands, our primary raw material for corticotrophin API, executed a long-term supply agreement with an API manufacturer, with whom we have advanced the manufacture of corticotropin API via manufacture of commercial-scale batches, and executed a long-term commercial supply agreement with a current good manufacturing practice (“cGMP”) aseptic fill contract manufacturer.

Prior to the third quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts have been consumed in research and development activities and recognized as research and development expense in the period in which they were incurred. In the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. Under U.S. GAAP, we cannot capitalize these pre-launch purchases of materials as inventory prior to FDA approval, and accordingly, they are charged to expense in the period in which they are incurred. We expect these pre-launch purchases of material to increase significantly in the future as we build raw materials, API and finished goods for the expected launch of this product. During the three months ended March 31, 2020, we incurred related charges for the purchase of materials of $4.6 million. We currently expect to incur expense related to this activity of approximately $14.0-$16.0 million for 2020. In the future, we also expect to incur other charges directly related to the Cortrophin pre-launch commercialization efforts, including, but not limited to, sales and marketing and consulting expenses, which will vary in frequency and impact on our results of operations.

## 14. SUBSEQUENT EVENT

In April 2020, we terminated our two existing interest rate swaps entered into in December 2018 and February 2019 underlying our Term Loan and DDTL with Citizens, Bank N. A., respectively. At the same time, we entered into a new interest rate swap with Citizens Bank, N.A. to continue managing our exposures to variable rates underlying the total borrowing under the Term Loan and DDTL. The hedge matures in December 2026, has an initial notional amount of $184.2 million and provides an effective fixed rate of 1.99%.

As previously announced, Arthur S. Przybyl will depart as President and Chief Executive Officer on May 10, 2020. Our Board of Directors has retained an executive search firm to lead the search for a new President and Chief Executive Officer, and has appointed Patrick D. Walsh interim President and CEO, effective May 11, 2020, until such time that Mr. Przybyl’s permanent replacement is identified.

**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, 2019.*

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (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 three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, 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.

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**

***Product Launches***

In April 2020, we launched Omega-3-Acid Ethyl Esters Capsules, 1 gram. Omega-3-Acid Ethyl Esters Capsules are indicated as an adjunct to diet to reduce triglyceride levels in adult patients with severe (greater than or equal to 500mg per dL) hypertriglyceridemia.

In April 2020, we launched Polyethylene Glycol 3350, 17g/Packet (PEG-3350). Polyethylene Glycol 3350 is indicated for the treatment of occasional constipation.

In February 2020, we launched Sulfamethoxazole and Trimethoprim Oral Suspension USP 200 mg/40 mg per 5 mL. Sulfamethoxazole and Trimethoprim Oral Suspension is indicated in the treatment and prevention of various infections proven or strongly suspected to be caused by susceptible bacteria which include urinary tract infections, acute otitis media, bronchitis, shigellosis, Pneumocystis jiroveci pneumonia, and traveler's diarrhea.

In January 2020, we launched Tolterodine Extended-Release Capsules, 2mg and 4 mg. Tolterodine Tartrate Extended-Release Capsules are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency.

In January 2020, we launched Paliperidone Extended-Release Tablets, 1.5 mg, 3 mg, 6 mg, and 9 mg. Paliperidone Extended-Release Tablets is an atypical antipsychotic agent indicated for the treatment of schizophrenia, the treatment of schizoaffective disorder as monotherapy, and as an adjunct to mood stabilizers and/or antidepressants.

***Cortrophin Gel Re-commercialization Update***

We successfully filed the Supplemental New Drug Application ("sNDA") for Cortrophin Gel re-commercialization on March 23, 2020, on track with our long-standing publicly projected Q1 2020 target filing date. The Food and Drug Administration ("FDA") initially set a Prescription Drug User Fee Act ("PDUFA") goal date of July 23, 2020, however, as announced on April 29, 2020, subsequently issued a Refusal to File ("RTF") letter. We will request a Type-A meeting with the FDA in order to discuss the deficiencies identified in the RTF letter and our plan to address each of them. In addition, significant accomplishments since the February 27, 2020 annual report on Form 10-K include:

- We successfully completed manufacturing for a sixth commercial scale batch of Corticotropin active pharmaceutical ingredient ("API"). All six commercial scale batches have been analytically consistent with each other and have met all API release specifications.

- We obtained 6 months accelerated and real-time stability on all API registration batches which facilitated sNDA filing by the end of first quarter 2020.

- We successfully completed three media fill simulations demonstrating sterility assurance for our Cortrophin Gel manufacturing process.

- We obtained six months accelerated and real-time stability on all drug product registration batches which also facilitated sNDA filing by the end of first quarter 2020.

- We successfully completed full shipping validation which confirmed that the integrity of Cortrophin Gel is fully maintained to support our commercial launch and distribution plan.

- In preparation for a future launch, we have continued to stockpile porcine pituitaries and corticotropin API to ensure that it can satisfy market demand.

***CEO Departure***

As previously announced, Arthur S. Przybyl will depart as President and Chief Executive Officer on May 10, 2020. Our Board of Directors has retained an executive search firm to lead the search for a new President and Chief Executive Officer, and has appointed Patrick D. Walsh interim President and CEO, effective May 11, 2020, until such time that Mr. Przybyl's permanent replacement is identified.

***COVID-19***

We are closely monitoring the impact of the novel coronavirus ("COVID-19") pandemic on our business and the geographic regions where we operate. While we did not incur significant disruptions during the three months ended March 31, 2020 from the COVID-19 pandemic, we are unable to predict the impact that the COVID-19 pandemic will have on our future financial condition, results of operations and cash flows due to numerous uncertainties. These uncertainties include the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. The outbreak of COVID-19 in many countries, including the United States, has significantly adversely impacted global economic activity and has contributed to significant volatility and negative pressure in financial markets. Certain states, including Minnesota, where our principal place of business is located, have reacted by instituting quarantines, restrictions on travel, "shelter in place" rules, and restrictions on types of business that may continue to operate. As a result, the COVID-19 pandemic is negatively impacting almost every industry directly or indirectly. Further, the impacts of a potential worsening of global economic conditions and the continued disruptions to, and volatility in, the credit and financial markets, pharmaceutical supply chains, patient access to healthcare as well as other unanticipated consequences remain unknown.

GENERAL

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

| (in thousands) | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Net revenues | $ 49,774 | $ 52,887 |
| Operating expenses | | |
| Cost of sales (exclusive of depreciation and amortization) | 21,804 | 14,725 |
| Research and development | 6,344 | 4,373 |
| Selling, general, and administrative | 13,683 | 13,284 |
| Depreciation and amortization | 11,183 | 16,103 |
| Cortrophin pre-launch charges | 4,602 | - |
| Operating (loss)/income | (7,842) | 4,402 |
| Interest expense, net | (2,032) | (3,354) |
| Other income/(expense), net | 10 | (130) |
| (Loss)/Income before benefit/(provision) for income taxes | (9,864) | 918 |
| Benefit/(provision) for income taxes | 2,853 | (469) |
| Net (loss)/income | $ (7,011) | $ 449 |

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 30, | |
|---|---|---|
| | 2020 | 2019 |
| Net revenues | 100.0% | 100.0% |
| Operating expenses | | |
| Cost of sales (exclusive of depreciation and amortization) | 43.8% | 27.8% |
| Research and development | 12.7% | 8.3% |
| Selling, general, and administrative | 27.5% | 25.1% |
| Depreciation and amortization | 22.5% | 30.4% |
| Cortrophin pre-launch charges | 9.2% | -% |
| Operating (loss)/income | (15.7)% | 8.3% |
| Interest expense, net | (4.1)% | (6.3)% |
| Other income/(expense), net | -% | (0.2)% |
| (Loss)/Income before benefit/(provision) for income taxes | (19.8)% | 1.7% |
| Benefit/(provision) for income taxes | 5.7% | (0.9)% |
| Net (loss)/income | (14.1)% | 0.8% |

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2020 AND 2019

**Net Revenues**

| (in thousands) | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % Change |
| Generic pharmaceutical products | $ 37,495 | $ 31,599 | $ 5,896 | 18.7% |
| Branded pharmaceutical products | 9,157 | 17,543 | (8,386) | (47.8)% |
| Contract manufacturing | 1,974 | 2,437 | (463) | (19.0)% |
| Royalty and other | 1,148 | 1,308 | (160) | (12.2)% |
| Total net revenues | $ 49,774 | $ 52,887 | $ (3,113) | (5.9)% |

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

Net revenues for the three months ended March 31, 2020 were $49.8 million compared to $52.9 million for the same period in 2019, a decrease of $3.1 million, or 5.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $37.5 million during the three months ended March 31, 2020, an increase of 18.7% compared to $31.6 million for the same period in 2019. The primary drivers of the increase are the September 2019 launch of Vancomycin Oral Solution and the January 2020 launch of Miglustat, Mixed Amphetamine Salts, Penicillamine, and Paliperidone, all products acquired from Amerigen Pharmaceuticals, Ltd. (“Amerigen”). These increases were tempered by decreases in sales of Vancomycin capsules, Esterified Estrogen with Methyltestosterone (“EEMT”), Erythromycin Ethylsuccinate (“EES”), and Ezetimibe Simvastatin.

- Net revenues for branded pharmaceutical products were $9.2 million during the three months ended March 31, 2020, a decrease of 47.8% compared to $17.5 million for the same period in 2019. The primary reasons for the decrease were lower unit sales of Inderal XL, Inderal LA, and Atacand as well as decreased sales of Arimidex.

- Contract manufacturing revenues were $2.0 million during the three months ended March 31, 2020, a decrease of 19.0% compared to $2.4 million for the same period in 2019, due to the timing and volume of orders from contract manufacturing customers in the period.

- Royalty and other were $1.1 million during the three months ended March 31, 2020, a decrease of $0.2 million from $1.3 million for the same period in 2019, primarily due to a decrease in royalty and laboratory service revenues, tempered by increases in product development revenues earned by ANI Canada during the three months ended March 31, 2020.

**Cost of Sales (Excluding Depreciation and Amortization)**

| (in thousands) | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % Change |
| Cost of sales (excl. depreciation and amortization) | $ 21,804 | $ 14,725 | $ 7,079 | 48.1% |

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, 2020, cost of sales increased to $21.8 million from $14.7 million for the same period in 2019, an increase of $7.1 million or 48.1%, primarily as a result of $2.7 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the period, increased volumes related to a shift in product mix toward generic products, inventory reserve charges during the current quarter related to excess inventory on hand as well as increased sales of products subject to profit-sharing arrangements, partially offset by the lack of the impact of the January 2019 royalty buy out from the Asset Purchase Agreement Amendment with Teva Pharmaceuticals USA, Inc. Cost of sales, exclusive of the $2.7 million net impact related to excess of fair value over the cost of inventory sold during the period, as a percentage of net revenues increased to 38.4% during the three months ended March 30, 2020, from 27.8% during same period in 2019, primarily as a result of a shift in product mix to an increased volume of generic products, which have lower average selling prices, inventory reserve charges in the current quarter as well as increased sales of products subject to profit-sharing arrangements during the current quarter.

During the three months ended March 31, 2020, we purchased approximately 13% of our inventory from one supplier. As of March 31, 2020, our amount payable to this supplier was $0.7 million. In the three months ended March 31, 2019, we purchased 55% of our inventory from three suppliers.

**Other Operating Expenses**

| (in thousands) | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % Change |
| Research and development | $ 6,344 | $ 4,373 | $ 1,971 | 45.1% |
| Selling, general, and administrative | 13,683 | 13,284 | 399 | 3.0% |
| Depreciation and amortization | 11,183 | 16,103 | (4,920) | (30.6)% |
| Cortrophin pre-launch charges | 4,602 | - | 4,602 | NM(1) |
| Total other operating expenses | $ 35,812 | $ 33,760 | $ 2,052 | 6.1% |

(1) Not Meaningful

Other operating expenses consist of research and development costs, selling, general, administrative expenses, and depreciation and amortization, and Cortrophin pre-launch charges.

For the three months ended March 31, 2020, other operating expenses increased to $35.8 million from $33.8 million for the same period in 2019, an increase of $2.1 million, or 6.1%, primarily as a result of the following factors:

- Research and development expenses increased from $4.4 million to $6.3 million, an increase of 45.1%, primarily due to $3.8 million in-process research and development expense from the Amerigen acquisition, partially offset by a decrease in expense related to the Cortrophin re-commercialization project as we begin to complete our development efforts. We anticipate that research and development costs will be lower in 2020 as compared to 2019, as we anticipate the completion of our Cortrophin re-development efforts.

- Selling, general, and administrative expenses increased from $13.3 million to $13.7 million, an increase of 3.0%, driven by increased U.S. based headcount, increased pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, increased stock compensation expense, and increased sales and marketing related costs. We anticipate that selling, general, and administrative expenses will continue to be greater in 2020 than in 2019 as we support anticipated revenue growth and increased scope of our business.

- Depreciation and amortization decreased from $16.1 million to $11.2 million, a decrease of 30.6%, primarily due to the non-reoccurrence of amortization expense recorded in relation to the January 2019 royalty buy out, partially offset by the amortization of the Abbreviate New Drug Applications ("ANDAs") and marketing and distribution rights acquired in January 2020 from Amerigen.

- As described in Note 13, *Cortrophin Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we recognized Cortrophin pre-launch charges of $4.6 million in the three months ended March 31, 2020. No Cortrophin pre-launch charges were recognized in the three months ended March 31, 2019.

**Other Expense, net**

| (in thousands) | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % Change |
| Interest expense, net | $ (2,032) | $ (3,354) | $ 1,322 | (39.4)% |
| Other income/(expense), net | 10 | (130) | 140 | (107.7)% |
| Total other expense, net | $ (2,022) | $ (3,484) | $ 1,462 | (42.0)% |

For the three months ended March 31, 2020, we recognized other expense of $2.0 million versus other expense of $3.5 million for the same period in 2019, a decrease of $1.5 million. Interest expense, net for 2020 consists primarily of interest expense on borrowings under our secured term loan ("Term Loan") and delayed draw term loan ("DDTL"). Interest expense, net for 2019 consists primarily of interest expense on our convertible debt, including amortization of related debt discount, and interest expense on borrowings under our Term Loan. For the three months ended March 31, 2020 and 2019, there was $25 thousand and $0.1 million of interest capitalized into construction in progress, respectively.

**Benefit/(Provision) for Income Taxes**

| (in thousands) | Three Months Ended March 31, | | | |
|---|---|---|---|---|
| | 2020 | 2019 | Change | % Change |
| Benefit/(provision) for income taxes | $ 2,853 | $ (469) | $ 3,322 | (708.3)% |

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. During periods when we incur net losses before income taxes, our annual estimated effective tax rate may be adjusted based on the "loss limitation" requirements applicable to interim tax provisions, resulting in a limited income tax benefit recognized in that 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, 2020, we recognized an income tax benefit of $2.9 million. The income tax expense resulted from applying an estimated annual worldwide effective tax rate of 29.7% to pre-tax consolidated loss of $9.9 million reported during the period, reduced by the net effects of certain discrete items occurring in 2020 which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended March 31, 2020.

The estimated consolidated effective tax rate for the three months ended March 31, 2019, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit could be recognized, was 22.0% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2019 plus the effects of certain discrete items occurring in the first quarter. Our effective tax rate was 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.

LIQUIDITY AND CAPITAL RESOURCES

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

| (in thousands) | March 31, 2020 | December 31, 2019 |
|---|---|---|
| Cash and cash equivalents | $ 20,414 | $ 62,332 |
| Accounts receivable, net | 82,379 | 72,129 |
| Inventories, net | 52,902 | 48,163 |
| Prepaid income taxes | - | 1,076 |
| Prepaid expenses and other current assets | 2,967 | 3,995 |
| Total current assets | $ 158,662 | $ 187,695 |
| | | |
| Current debt, net of deferred financing costs | $ 11,872 | $ 9,941 |
| Accounts payable | 12,485 | 14,606 |
| Accrued expenses and other | 4,378 | 2,362 |
| Accrued royalties | 6,285 | 5,084 |
| Accrued compensation and related expenses | 3,151 | 3,736 |
| Current income taxes payable, net | 15,223 | - |
| Accrued government rebates | 8,030 | 8,901 |
| Returned goods reserve | 17,614 | 16,595 |
| Deferred revenue | 318 | 451 |
| Total current liabilities | $ 79,356 | $ 61,676 |

At March 31, 2020, we had $20.4 million in unrestricted cash and cash equivalents. At December 31, 2019, we had $62.3 million in unrestricted cash and cash equivalents. We generated $1.7 million of cash from operations in the three months ended March 31, 2020. In January 2020, we acquired the U.S. portfolio of 23 generic products and certain commercial and development inventory and materials from Amerigen Pharmaceuticals, Ltd. using $55.5 million in cash and up to $25.0 million in contingent profit share payments over the next four years. The contingent payments are earned if annual gross profit exceeds a minimum threshold and are earned on a subset of the acquired products. The acquired portfolio includes ten commercial products, three approved products with launches pending, four filed products, and four in-development products as well as a license to commercialize two approved products. The transaction was funded from cash on hand.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue, and our revolving line of credit facility, under which $60.0 million remains available for borrowing as of March 31, 2020, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months.

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

| (in thousands) | Three Months Ended March 31, | |
|---|---|---|
| | 2020 | 2019 |
| Operating Activities | $ 1,710 | $ 14,291 |
| Investing Activities | $ (57,546) | $ (20,285) |
| Financing Activities | $ 13,891 | $ 1,206 |

**Net Cash Provided by Operations**

Net cash provided by operating activities was $1.7 million for the three months ended March 31, 2020, compared to $14.3 million provided by operating activities during the same period in 2019, a decrease of $12.6 million. This decrease was principally due to changes in working capital in the first quarter 2020.

**Net Cash Used in Investing Activities**

Net cash used in investing activities for the three months ended March 31, 2020 was $57.5 million, principally due to the January 2020 acquisition 23 generic products and inventory and materials from Amerigen Pharmaceuticals, Ltd. for $55.5 million and $1.5 million of capital expenditures during the period. Net cash used in investing activities for the three months ended March 31, 2019 was $20.3 million, principally due to the March 2019 asset acquisition of ANDAs for $2.5 million, the January 2019 Asset Purchase Agreement Amendment for $16.0 million, and $1.8 million of capital expenditures during the period.

**Net Cash Provided by Financing Activities**

Net cash provided by financing activities was $13.9 million for the three months ended March 31, 2020, principally due to $15.0 million in borrowings on the Revolver and $0.3 million of proceeds from stock option exercises, partially offset by $0.9 million of payment on the Term Loan, and $0.5 million of treasury stock purchased in relation to restricted stock vests. Net cash provided by financing activities was $1.2 million for the three months ended March 31, 2019, principally due to $2.4 million of proceeds from stock option exercises, partially offset by $0.9 million of payments on the Term Loan and $0.3 million of treasury stock purchased in relation to restricted stock vests.

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 management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, 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, and the depreciable 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, 2019. 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, 2019.

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 incorporated herein by reference.

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of March 31, 2020 and December 31, 2019, 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, equity risk, and foreign currency exchange rate risk could have a significant impact on our results of operations.

On December 27, 2018, we refinanced our $125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to $265.2 million. The principal new feature of the Credit Facility was a $118.0 million Delayed Draw Term Loan (the "DDTL"), which could only be drawn on in order to pay down the Company's 3.0% Convertible Senior Notes (the "Notes"), which matured December 2019. The Credit Facility also extended the maturity of the $72.2 million secured Term Loan to December 2023 and increased the previous $50.0 million line of credit (the "Revolver") to $75.0 million. On November 29, 2019, we exercised our option to borrow $118.0 million pursuant to the DDTL feature and the proceeds were used to repay the outstanding Notes. In March 2020, we drew $15.0 million under the Revolver. Borrowings under the Revolver mature in December 2023. As of March 31, 2020, $60.0 million remains available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.75% 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 1.75%, depending our total leverage ratio. On the Revolver, we incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. As of March 31, 2020, we had a $186.6 million outstanding balance on the Credit Facility.

On December 27, 2018, we entered into an interest rate swap to manage our exposure to the variable interest rate on our refinanced secured Term Loan. The interest rate swap hedges the variable cash flows associated with the secured Term Loan borrowings under the secured Term Loan, effectively providing a fixed rate of interest throughout the life of the secured Term Loan. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

On February 7, 2019, we entered into an interest rate swap to manage our exposure to the variable interest rate on our DDTL. The interest rate swap hedges the variable cash flows associated with borrowings under the DDTL, effectively providing a fixed rate of interest throughout the life of the DDTL. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

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 year ended March 31, 2020 by approximately $2 thousand.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated transactions from our ANI Pharmaceuticals Canada Inc. subsidiary from the Canadian dollar to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the quarter ended March 31, 2020.

**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, 2020. 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, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Part II — OTHER INFORMATION**

**Item 1. Legal Proceedings**

Please refer to Note 11, *Commitments and Contingencies*, in the unaudited 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, 2019 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. The following is a new significant risk factor known to us after the filing of our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2019 that could materially harm our business, financial position, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report.

***The novel coronavirus ("COVID-19") pandemic has resulted in significant financial market volatility, and its impact on the global economy and our operations remains uncertain. A continuation or worsening of the pandemic could have a material adverse impact on our business, results of operations and financial condition and on the market price of our common stock.***

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada, and China, have imposed unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. Although our operations have not been materially affected at this point, significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations and on the global economy as a whole. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty in recent weeks. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

**Item 2. Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities**

(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, 2020 | - | $ - | - | $ - |
| February 1 - February 29, 2020 | - | $ - | - | $ - |
| March 1 - March 31, 2020 | 13 | $ 38.73 | - | $ - |
| Total | 13 | $ 38.73 | - | |

**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 7, 2020

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

Date: May 7, 2020

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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2020

/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 subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 7, 2020

/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, 2020 (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 7, 2020

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

Dated: May 7, 2020

/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.