ANI PHARMACEUTICALS INC
Form 10-Q
November 06, 2018

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-Q**

**(Mark one)**

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

**For the quarterly period ended September 30, 2018**

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

**For the transition period from to .**

**Commission File Number 001-31812**

**ANI PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

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

**210 Main Street West**

**Baudette, Minnesota**

(Address of principal executive offices)

**(218) 634-3500**

(Registrant's telephone number including area code)

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES x 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 x NO ¨

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

| | |
|---|---|
| Large accelerated filer ¨ | Accelerated filer x |
| Non-accelerated filer ¨ | 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 x

As of October 30, 2018, there were 11,846,735 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

**ANI PHARMACEUTICALS, INC.**

**FORM 10-Q — Quarterly Report**

**For the Quarterly Period Ended September 30, 2018**

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**CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS**

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

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

*These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2017, including the factors described in "Item 1A. Risk Factors." Other risks may be described from time to time in our filings made under the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.*

**NOTE REGARDING TRADEMARKS**

Cortenema®, Cortrophin® Gel, Cortrophin-Zinc®, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated 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)*

| | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | $ 44,136 | $ 31,144 |
| Accounts receivable, net of $50,603 and $34,686 of adjustments for chargebacks and other allowances at September 30, 2018 and December 31, 2017, respectively | 67,647 | 58,788 |
| Inventories, net | 40,006 | 37,727 |
| Prepaid income taxes, net | - | 1,162 |
| Prepaid expenses and other current assets | 5,004 | 2,784 |
| Total Current Assets | 156,793 | 131,605 |
| Property and equipment, net | 37,418 | 20,403 |
| Restricted cash | 5,014 | 5,006 |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | 25,082 | 22,667 |
| Intangible assets, net | 209,544 | 229,790 |
| Goodwill | 4,180 | 1,838 |
| Other long-term assets | 1,412 | 829 |
| Total Assets | $ 439,443 | $ 412,138 |
| Liabilities and Stockholders' Equity | | |
| Current Liabilities | | |
| Current component of long-term borrowing, net of deferred financing costs | $ 5,692 | $ 3,353 |
| Accounts payable | 7,257 | 3,630 |
| Accrued expenses and other | 2,818 | 1,571 |
| Accrued royalties | 7,455 | 12,164 |
| Accrued compensation and related expenses | 2,773 | 2,306 |
| Current income taxes payable, net | 318 | - |
| Accrued government rebates | 9,014 | 7,930 |
| Returned goods reserve | 10,840 | 8,274 |
| Deferred revenue | 735 | - |
| Total Current Liabilities | 46,902 | 39,228 |
| Long-term Liabilities | | |
| Long-term borrowing, net of deferred financing costs and current borrowing component | 65,954 | 69,946 |
| Convertible notes, net of discount and deferred financing costs | 134,122 | 128,208 |
| Total Liabilities | $ 246,978 | $ 237,382 |

| | | |
|---|---|---|
| Commitments and Contingencies (Note 12) | | |
| Stockholders' Equity | | |
| Common Stock, $0.0001 par value, 33,333,334 shares authorized; 11,857,914 shares issued and 11,846,735 shares outstanding at September 30, 2018; 11,655,768 shares issued and 11,650,565 outstanding at December 31, 2017 | 1 | 1 |
| Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | - | - |
| Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2018 and December 31, 2017, respectively | - | - |
| Treasury stock, 11,179 shares of common stock, at cost, at September 30, 2018 and 5,203 shares of common stock, at cost, at December 31, 2017 | (659) | (259) |
| Additional paid-in capital | 186,532 | 179,020 |
| Retained earnings/(accumulated deficit) | 6,058 | (4,006) |
| Accumulated other comprehensive income, net of tax | 533 | - |
| Total Stockholders' Equity | 192,465 | 174,756 |
| Total Liabilities and Stockholders' Equity | $ 439,443 | $ 412,138 |

*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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Net Revenues | $ 50,703 | $ 48,164 | $ 144,454 | $ 129,556 |
| Operating Expenses: | | | | |
| Cost of sales (excluding depreciation and amortization) | 15,605 | 21,078 | 52,891 | 58,586 |
| Research and development | 4,667 | 2,634 | 11,906 | 6,419 |
| Selling, general, and administrative | 11,769 | 8,022 | 30,687 | 22,695 |
| Depreciation and amortization | 8,548 | 7,099 | 25,056 | 20,906 |
| Total Operating Expenses | 40,589 | 38,833 | 120,540 | 108,606 |
| Operating Income | 10,114 | 9,331 | 23,914 | 20,950 |
| Other Expense, net | | | | |
| Interest expense, net | (3,768) | (3,052) | (11,132) | (9,009) |
| Other income/(expense), net | 20 | 95 | (71) | 58 |
| Income Before Provision for Income Taxes | 6,366 | 6,374 | 12,711 | 11,999 |
| Provision for income taxes | (1,329) | (1,654) | (2,647) | (3,446) |
| Net Income | $ 5,037 | $ 4,720 | $ 10,064 | $ 8,553 |
| Basic and Diluted Earnings Per Share: | | | | |
| Basic Earnings Per Share | $ 0.43 | $ 0.41 | $ 0.85 | $ 0.74 |
| Diluted Earnings Per Share | $ 0.42 | $ 0.40 | $ 0.85 | $ 0.73 |
| Basic Weighted-Average Shares Outstanding | 11,706 | 11,553 | 11,659 | 11,542 |
| Diluted Weighted-Average Shares Outstanding | 11,804 | 11,677 | 11,767 | 11,666 |

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

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

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Net income | $ 5,037 | $ 4,720 | $ 10,064 | $ 8,553 |
| Other comprehensive income, net of tax: | | | | |
| Change in fair value of interest rate swap, net of tax | 317 | - | 533 | - |
| Total other comprehensive income, net of tax | 317 | - | 533 | - |
| Total comprehensive income, net of tax | $ 5,354 | $ 4,720 | $ 10,597 | $ 8,553 |

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

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

| | Nine Months Ended September 30, | |
|---|---|---|
| | **2018** | **2017** |
| Cash Flows From Operating Activities | | |
| Net income | $ 10,064 | $ 8,553 |
| Adjustments to reconcile net income to net cash and cash equivalents provided by operating activities: | | |
| Stock-based compensation | 4,954 | 4,668 |
| Deferred taxes | (2,581) | (4,602) |
| Depreciation and amortization | 25,056 | 20,906 |
| Acquired in-process research and development ("IPR&D") | 1,335 | - |
| Non-cash interest relating to convertible notes and loan cost amortization | 6,392 | 5,723 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable, net | (7,548) | (16,279) |
| Inventories, net | 118 | 4,605 |
| Prepaid expenses and other current assets | (1,769) | (1,365) |
| Accounts payable | 2,250 | 2,078 |
| Accrued royalties | (4,709) | (840) |
| Accrued compensation and related expenses | (194) | 378 |
| Current income taxes, net | 1,480 | (4,450) |
| Accrued government rebates | 1,084 | (136) |
| Returned goods reserve | 2,566 | 2,561 |
| Accrued expenses and other | 1,344 | 1,814 |
| Net Cash and Cash Equivalents Provided by Operating Activities | 39,842 | 23,614 |
| Cash Flows From Investing Activities | | |
| Acquisition of WellSpring Pharma Services Inc., net of cash acquired | (17,067) | - |
| Acquisition of product rights, IPR&D, and other related assets | (5,169) | (50,956) |
| Acquisition of property and equipment, net | (4,736) | (6,922) |
| Net Cash and Cash Equivalents Used in Investing Activities | (26,972) | (57,878) |
| Cash Flows From Financing Activities | | |
| Payment of debt issuance costs | (153) | - |
| Payments on term loan agreement | (1,875) | - |
| Net borrowings under line of credit agreement | - | 25,000 |
| Proceeds from stock option exercises | 2,817 | 191 |
| Treasury stock purchases for restricted stock vestings | (659) | (259) |

| | | |
|---|---|---|
| Net Cash and Cash Equivalents Provided by Financing Activities | 130 | 24,932 |
| Change in Cash, Cash Equivalents, and Restricted Cash | 13,000 | (9,332) |
| Cash, cash equivalents, and restricted cash, beginning of period | 36,150 | 32,367 |
| Cash, cash equivalents, and restricted cash, end of period | $ 49,150 | $ 23,035 |
| Reconciliation of cash, cash equivalents, and restricted cash, beginning of period | | |
| Cash and cash equivalents | 31,144 | 27,365 |
| Restricted cash | 5,006 | 5,002 |
| Cash, cash equivalents, and restricted cash, beginning of period | 36,150 | 32,367 |
| Reconciliation of cash, cash equivalents, and restricted cash, end of period | | |
| Cash and cash equivalents | 44,136 | 18,031 |
| Restricted cash | 5,014 | 5,004 |
| Cash, cash equivalents, and restricted cash, end of period | 49,150 | 23,035 |
| Supplemental disclosure for cash flow information: | | |
| Cash paid for interest, net of amounts capitalized | $ 3,763 | $ 2,197 |
| Cash paid for income taxes | $ 3,890 | $ 12,493 |
| Supplemental non-cash investing and financing activities: | | |
| Property and equipment purchased and included in accounts payable | $ 110 | $ 354 |

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

## 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 focuse 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, Canada are 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.

On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. ("ANI Canada"), acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc. ("WellSpring"), a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Subject to further adjustments, the estimated consideration was $17.3 million. The consideration was paid entirely from cash on hand. In conjunction with the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity's name being ANI Pharmaceuticals Canada Inc.

### 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/(loss), and cash flows. The consolidated balance sheet at December 31, 2017, has been derived from audited financial statements of that date. The unaudited interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our Annual Report on Form 10-K for the year ended December 31, 2017.

**Principles of Consolidation**

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

**Foreign Currency**

The company has 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 average exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. 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 unaudited interim condensed consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, income tax provision, deferred taxes and valuation allowance, purchase price allocations, and the depreciable lives of long-lived assets. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

**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 ("CODM"), 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** | | **Nine Months Ended** | |
|---|---|---|---|---|
| **Location of Operations** | **September 30, 2018** | **September 30, 2017** | **September 30, 2018** | **September 30, 2017** |
| United States | $ 48,961 | $ 48,164 | $ 142,712 | $ 129,556 |
| Canada | 1,742 | - | 1,742 | - |
| Total Revenue | $ 50,703 | $ 48,164 | $ 144,454 | $ 129,556 |

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

| **(in thousands)** | **September 30, 2018** | **December 31, 2017** |
|---|---|---|
| United States | $ 23,645 | $ 20,403 |
| Canada | 13,773 | - |
| Total Property, Plant, and Equipment, net | $ 37,418 | $ 20,403 |

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

**Recent Accounting Pronouncements**

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

In October 2018, the Financial Accounting Standards Board (“FASB”) issued guidance for accounting for derivatives and hedging. The guidance provides for the inclusion of the Secured Overnight Financing Rate (“SOFR”) Overnight Index swap rate as a benchmark interest rate for hedge accounting purposes. In July 2017, the Financial Conduct Authority in the United Kingdom announced that it would phase out London Interbank Offered Rate (“LIBOR”) as a benchmark by the end of 2021. As a result, the U.S. Federal Reserve identified the SOFR as its preferred alternative reference rate, calculated with a broad set of short-term repurchase agreements backed by treasury securities. Amounts drawn under our five-year senior secured credit facility bear interest rates in relation to LIBOR, and our interest rate swap is designated in LIBOR. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We will adopt this guidance as of January 1, 2019.

In August 2018, the Securities and Exchange Commission (“SEC”) adopted the final rule amending certain disclosure requirements that have become redundant, duplicative, overlapping, outdated, or superseded. In addition, the amendments expand the disclosure requirements on the analysis of stockholders' equity for interim financial statements. Under the amendments, an analysis of changes in each caption of stockholders' equity presented in the balance sheet must be provided in a note or separate statement. The rule was effective on November 5, 2018 and will be effective for the quarter that begins after the effective date. The adoption of this guidance will result in the inclusion of the statement of stockholder’s equity in our interim financial statement filings.

In August 2018, the FASB issued guidance modifying the disclosure requirements on fair value measurements. The amendments add, modify, and eliminate certain disclosure requirements on fair value measurements. The guidance is effective for reporting periods beginning after December 15, 2019, 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.

In June 2018, the FASB issued guidance simplifying the accounting for nonemployee stock-based compensation awards. The guidance aligns the measurement and classification for employee stock-based compensation awards to nonemployee stock-based compensation awards. Under the guidance, nonemployee awards will be measured at their grant date fair value. Upon transition, the existing nonemployee awards will be measured at fair value as of the adoption date. The guidance is effective for reporting periods beginning after December 15, 2018, 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.

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

In February 2016, the FASB issued guidance for accounting for leases. The guidance requires lessees to recognize assets and liabilities related to long-term leases on the balance sheet and expands disclosure requirements regarding leasing arrangements. In July 2018, the FASB issued additional guidance, which offers a transition option to entities adopting the new lease standards. Under the transition option, entities can elect to apply the new guidance using a modified retrospective approach at the beginning of the year in which the new lease standard is adopted, rather than to the earliest comparative period presented in their financial statements. The guidance is effective for reporting periods beginning after December 15, 2018 and early adoption is permitted. The guidance must be adopted on a modified retrospective basis and provides for certain practical expedients. We will elect to use the transition option and adopt the guidance using the modified retrospective approach as of January 1, 2019. We are currently reviewing our leases and other contracts to determine the impact the adoption of this guidance will have on our consolidated financial statements, and we will continue to assess any new lease arrangements entered into during 2018. We currently expect that the adoption of this guidance will likely change the way we account for our operating leases and will likely result in recording right-of-use assets and liabilities in our consolidated balance sheets and result in additional lease-related disclosures in the footnotes to our consolidated financial statements.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

We have evaluated all other issued and unadopted Accounting Standards Updates and believe the adoption of these standards will not have a material impact on our condensed consolidated statements of operations, balance sheets, or cash flows.

***Recently Adopted Accounting Pronouncements***

In August 2017, the FASB issued guidance improving accounting for hedging activities. The guidance is intended to simplify hedge accounting by better aligning how an entity's risk management activities and hedging relationships are presented in its financial statements. The guidance also simplifies the application of hedge accounting guidance in certain situations. The guidance is effective for the fiscal years beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption was permitted, including adoption in an interim period. The guidance with respect to the cash flow and net investment hedge relationships existing on the date of adoption must be applied on a modified retrospective basis and the new disclosure requirements must be applied on a prospective basis. We adopted this guidance as of January 1, 2018. The adoption of this guidance did not have a material impact on our consolidated financial statements. However, the adoption of this guidance did impact how we accounted for the interest rate swap we entered into in April 2018. See Note 5 for further details regarding the interest rate swap.

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

In May 2014, the FASB issued guidance for revenue recognition for contracts, superseding the previous revenue recognition requirements, along with most existing industry-specific guidance. The guidance requires an entity to

review contracts in five steps: 1) identify the contract, 2) identify performance obligations, 3) determine the transaction price, 4) allocate the transaction price, and 5) recognize revenue. The new standard will result in enhanced disclosures regarding the nature, amount, timing, and uncertainty of revenue arising from contracts with customers. In August 2015, the FASB issued guidance approving a one-year deferral, making the standard effective for reporting periods beginning after December 15, 2017, with early adoption permitted only for reporting periods beginning after December 15, 2016. In March 2016, the FASB issued guidance to clarify the implementation guidance on principal versus agent considerations for reporting revenue gross rather than net, with the same deferred effective date. In April 2016, the FASB issued guidance to clarify the implementation guidance on identifying performance obligations and the accounting for licenses of intellectual property, with the same deferred effective date. In May 2016, the FASB issued guidance rescinding SEC paragraphs related to revenue recognition, pursuant to two SEC Staff Announcements at the March 3, 2016 Emerging Issues Task Force meeting. In May 2016, the FASB also issued guidance to clarify the implementation guidance on assessing collectability, presentation of sales tax, noncash consideration, and contracts and contract modifications at transition, with the same effective date. In September 2017, the FASB issued guidance amending and rescinding prior SEC staff announcements and observer comments related to revenue recognition, pursuant to the SEC Staff Announcement at the July 20, 2017 Emerging Issues Task Force meeting.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

We performed a comprehensive review of our existing revenue arrangements as of January 1, 2018 following the five-step model. Our analysis indicated that there were no significant changes to how the amount and timing of revenue is recognized under the new guidance as compared to existing guidance. Additionally, our analysis indicated that there were no significant changes to how costs to obtain and fulfill our customer contracts are recognized under the new guidance as compared to existing guidance. We adopted this guidance as of January 1, 2018 using the modified retrospective method and the impact of adoption on our consolidated balance sheet, statement of operations, and statement of cash flows was not material. The adoption of the new guidance impacted the way we analyze, document, and disclose revenue recognition under customer contracts beginning on January 1, 2018 and resulted in additional disclosures in our financial statements. ANI Canada adopted this guidance as of the acquisition date, August 6, 2018. The adoption of this guidance did not have a material impact on our consolidated financial statements.

**2. REVENUE RECOGNITION AND RELATED ALLOWANCES**

**Revenue Recognition**

As of January 1, 2018, we adopted guidance for revenue recognition for contracts, using the modified retrospective method. The implementation of the guidance had no material impact on the measurement or recognition of revenue from customer contracts of prior periods. For our revenue recognition policies prior to adopting the guidance for revenue recognition for contracts, please see Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2017.

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

- Identification of the contract, or contracts, with a customer;
- Identification of the performance obligations in the contract;

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

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

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

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:

| (in thousands) | Three Months Ended September 30, 2018 | September 30, 2017 | Nine Months Ended September 30, 2018 | September 30, 2017 |
|---|---|---|---|---|
| Sales of generic pharmaceutical products | $ 30,287 | $ 30,546 | $ 83,716 | $ 88,608 |
| Sales of branded pharmaceutical products | 14,589 | 15,688 | 41,714 | 35,398 |
| Sales of contract manufactured products | 2,826 | 1,829 | 5,450 | 5,151 |
| Royalties from licensing agreements | 2,409 | - | 12,560 | - |
| Product development services | 288 | - | 288 | - |
| Other[(1)] | 304 | 101 | 726 | 399 |
| Total net revenues | $ 50,703 | $ 48,164 | $ 144,454 | $ 129,556 |

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

The following table depicts revenue recognized during the following periods:

| (in thousands) | Three Months Ended September 30, 2018 | September 30, 2017 | Nine Months Ended September 30, 2018 | September 30, 2017 |
|---|---|---|---|---|
| Performance obligations transferred at a point in time | $ 50,415 | $ 48,164 | $ 144,166 | $ 129,556 |
| Performance obligations transferred over time | 288 | - | 288 | - |
| Total | $ 50,703 | $ 48,164 | $ 144,454 | $ 129,556 |

In the three and nine months ended September 30, 2018, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts. We recognized $6.4 million of net revenue from performance obligations satisfied in prior periods during the nine months ended September 30, 2018, 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. In August 2018, we acquired WellSpring (see Note 3), a contract manufacturing company that also provides technical transfer services to customers, for which services are transferred over time. As a result, we had $14 thousand of contract assets and $0.7 million of deferred revenue at September 30, 2018. We had no contract assets or deferred revenue at December 31, 2017 or June 30, 2018.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

***Revenue from Sales of Generic and Branded Pharmaceutical Products***

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

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

*Chargebacks*

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

Chargeback credits are calculated as follows:

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

· A change in customer mix

· A change in negotiated terms with customers

· A change in the volume of off-contract purchases

· Changes in WAC

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

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

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

*Government Rebates*

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

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

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

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

*Returns*

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

*Administrative Fees and Other Rebates*

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

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

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

*Prompt Payment Discounts*

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

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the nine months ended September 30, 2018 and 2017, 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, 2016 | $ 26,785 | $ 5,891 | $ 5,756 | $ 3,550 | $ 1,554 |
| Accruals/Adjustments | 133,849 | 7,807 | 8,949 | 16,840 | 5,960 |
| Credits Taken Against Reserve | (134,412) | (7,943) | (6,388) | (15,448) | (5,617) |
| Balance at September 30, 2017 | $ 26,222 | $ 5,755 | $ 8,317 | $ 4,942 | $ 1,897 |
| | | | | | |
| Balance at December 31, 2017 | $ 28,230 | $ 7,930 | $ 8,274 | $ 5,226 | $ 1,834 |
| Accruals/Adjustments | 170,533 | 8,097 | 10,942 | 23,148 | 6,744 |

| | | | | | |
|---|---|---|---|---|---|
| Credits Taken Against Reserve | (156,750) | (7,013) | (8,376) | (21,418) | (6,373) |
| Balance at September 30, 2018 | $ 42,013 | $ 9,014 | $ 10,840 | $ 6,956 | $ 2,205 |

***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.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

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

As of September 30, 2018, the value of our unsatisfied performance obligations (or backlog) was $5.7 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.

In addition, 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 products to our facility in Oakville, Canada. The duration of these technical transfer projects is generally 18 months 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 September 30, 2018, the value of our unsatisfied performance obligations for product development services contracts was $3.5 million. We expect to satisfy these performance obligations in the next 9 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 September 30, 2018, three customers represented 35%, 23%, and 20% of net revenues, respectively. During the nine months ended September 30, 2018, the same three customers represented 34%, 23%, and 20% of net revenues respectively. As of September 30, 2018, accounts receivable from these customers totaled 80% of accounts receivable, net. During the three months ended September 30, 2017, three customers represented 30%, 30%, and 19% of net revenues, respectively. During the nine months ended September 30, 2017, these same three customers represented 31%, 26%, and 21% of net revenues, respectively.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

## 3. BUSINESS COMBINATION

### Summary

On August 6, 2018, our subsidiary, ANI Canada, acquired all the issued and outstanding equity interests of WellSpring, a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Subject to further adjustments, the estimated consideration was $17.3 million. The consideration was paid entirely from cash on hand. In conjunction with the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity's name being ANI Pharmaceuticals Canada Inc.

We acquired WellSpring to provide an additional tech transfer site in order to accelerate the re-commercialization of the previously-approved ANDAs in our pipeline, to expand our contract manufacturing revenue base, and to broaden our manufacturing capabilities to three manufacturing facilities.

### Transaction Costs

In conjunction with the acquisition, we incurred approximately $1.0 million in transaction costs, all of which were expensed in 2018.

### Purchase Consideration and Net Assets Acquired

The business combination was accounted for using the acquisition method of accounting, with ANI as the accounting acquirer of WellSpring. The acquisition method requires that acquired assets and assumed liabilities be recorded at

their fair values as of the acquisition date.

The following presents the preliminary allocation of the preliminary purchase price to the assets acquired and liabilities assumed on August 6, 2018:

| | (in thousands) |
|---|---|
| Total Purchase Consideration | $ 17,287 |
| | |
| Cash and cash equivalents | 220 |
| Accounts receivable | 1,311 |
| Inventories | 2,197 |
| Prepaid expenses and other current assets | 361 |
| Property and equipment | 13,935 |
| Goodwill | 2,342 |
| Total assets acquired | 20,366 |
| | |
| Accounts payable and other current liabilities | 2,413 |
| Deferred revenue | 666 |
| Total liabilities assumed | 3,079 |
| Net assets acquired | $ 17,287 |

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

**3. BUSINESS COMBINATION – continued**

The net assets were recorded at their estimated fair value. In valuing acquired assets and liabilities, fair value estimates were based primarily on future expected cash flows, market rate assumptions for contractual obligations, and appropriate discount rates.

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

Goodwill is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition, such as the assembled workforce and synergies between the entities. Goodwill established as a result of the acquisition is not tax deductible in any taxing jurisdiction. There was no value ascribed to any separately identifiable intangible assets.

Legacy WellSpring operations generated $1.7 million of revenue and recorded a net loss of $0.2 million from the acquisition date through September 30, 2018.

**Pro Forma Condensed Combined Financial Information (unaudited)**

The following unaudited pro forma condensed combined financial information summarizes the results of operations for the periods indicated as if the WellSpring acquisition had been completed as of January 1, 2017.

| | **Three Months Ended** | **Nine Months Ended** |
|---|---|---|

| (in thousands) | September 30, 2018 | September 30, 2017[1] | September 30, 2018 | September 30, 2017[1] |
|---|---|---|---|---|
| Net revenues | $ 51,384 | $ 51,676 | $ 151,091 | $ 137,884 |
| Net income | $ 4,456 | $ 8,683 | $ 7,812 | $ 10,108 |

(1) Net income for the three and nine months ended September 30, 2017 includes the impact to WellSpring of $4.4 million of related party debt forgiveness.

The pro forma amounts are not necessarily indicative of the results that would have been obtained if the transaction had occurred as of January 1, 2017 or that may be obtained in the future. The unaudited pro forma condensed consolidated financial information includes pro forma adjustments primarily relating to the following non-recurring items directly attributable to the business combination:

- Elimination of amortization expense related to the acquiree's historical intangible assets;
- Elimination of transaction costs;
- Elimination of profit on sales from WellSpring to ANI in the periods; and
- Tax impacts of the adjustments to the acquirer's net income, calculated as 23% in 2018 and 37% in 2017. As the acquiree has a loss in both years, there is no tax impact to adjustments to the acquiree's net income.

The pro forma financial information does not include the effects of any expected operational efficiencies or synergies resulting from the acquisition.

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## 4. INDEBTEDNESS

### Convertible Senior Notes

In December 2014, we issued $143.8 million of our Convertible Senior Notes due 2019 (the "Notes") in a registered public offering. The Notes pay 3.0% interest semi-annually in arrears starting on June 1, 2015 and are due December 1, 2019. The initial conversion price was $69.48 per share. Simultaneous with the issuance of the Notes, we entered into "bond hedge" (or purchased call) and "warrant" (or written call) transactions with an affiliate of one of the offering underwriters in order to synthetically raise the initial conversion price of the Notes to $96.21 per share and reduce the potential common stock dilution that may arise from the conversion of the Notes.

The Notes are convertible at the option of the holder under certain circumstances and upon conversion we may elect to settle such conversion in shares of our common stock, cash, or a combination thereof. As a result of our cash conversion option, we separately accounted for the value of the embedded conversion option as a debt discount (with an offset to Additional Paid in Capital ("APIC")) of $33.6 million. Deferred financing costs are recorded as a reduction of long-term debt in the consolidated balance sheets and are being amortized as additional non-cash interest expense on a straight-line basis over the term of the debt, since this method was not significantly different from the effective interest method.

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

| (in thousands) | September 30, 2018 | December 31, 2017 |
|---|---|---|
| Principal amount | $ 143,750 | $ 143,750 |
| Unamortized debt discount | (8,643) | (13,924) |
| Deferred financing costs | (985) | (1,618) |
| Net carrying value | $ 134,122 | $ 128,208 |

We had accrued interest of $1.4 million and $0.4 million related to the Notes recorded in accrued expenses, other in our consolidated balance sheets at September 30, 2018 and December 31, 2017, respectively.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

**4. INDEBTEDNESS – continued**

**Credit Agreement**

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

The Term Loan includes a repayment schedule, pursuant to which $6.1 million of the loan will be paid in quarterly installments during the 12 months ended September 30, 2019. As a result, $6.1 million of the loan is recorded in current component of long-term borrowing, net of deferred financing in the accompanying unaudited interim condensed consolidated balance sheets. We deferred $2.9 million of total debt issuance costs related to the Credit Agreement, of which $1.8 million was allocated to the Term Loan and $1.1 million was allocated to the undrawn Revolving Credit Facility. In April 2018, we entered into an interest rate swap with Citizens Bank, N.A. to hedge the variable rate on our Term Loan balance with a fixed rate (Note 5).

The carrying value of the current and long-term components of the Term Loan as of September 30, 2018 and December 31, 2017 are:

| **(in thousands)** | **Current September 30, 2018** | **December 31, 2017** |
|---|---|---|
| Current borrowing on secured term loan | $6,094 | $ 3,750 |

| | | |
|---|---|---|
| Unamortized deferred financing costs | (402 ) | (397 ) |
| Current component of long-term borrowing, net of unamortized deferred financing costs | $5,692 | $ 3,353 |

| **(in thousands)** | **Long-Term September 30, 2018** | **December 31, 2017** |
|---|---|---|
| Long-term borrowing on secured term loan | $67,031 | $ 71,250 |
| Unamortized deferred financing costs | (1,077 ) | (1,304 ) |
| Long-term borrowing, net of unamortized deferred financing costs and current borrowing component | $65,954 | $ 69,946 |

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**4. INDEBTEDNESS – continued**

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

As of September 30, 2018, we had a $73.1 million balance on the Term Loan. As of September 30, 2018, we had not drawn on the Revolving Credit Facility. As of September 30, 2018, $0.7 million of unamortized deferred debt issuance costs is included in other long-term assets in the accompanying unaudited interim condensed consolidated balance sheets and $0.2 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets.

The following table sets forth the components of total interest expense related to the Notes and Term Loan recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three and nine months ended September 30, 2018 and 2017:

| | Three Months Ended | | Nine Months Ended | |
|---|---|---|---|---|
| **(in thousands)** | **September 30, 2018** | **September 30, 2017** | **September 30, 2018** | **September 30, 2017** |
| Contractual coupon | $ 1,835 | $ 1,078 | $ 5,393 | $ 3,234 |
| Amortization of debt discount | 1,783 | 1,692 | 5,280 | 5,007 |
| Amortization of finance fees | 370 | 211 | 1,111 | 633 |
| Capitalized interest | (174) | (143) | (552) | (367) |
| | $ 3,814 | $ 2,838 | $ 11,232 | $ 8,507 |

As of September 30, 2018, the combined effective interest rate on the Notes and Term Loan was 6.8%, on an annualized basis.

**5. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY**

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 long-term 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 income/(loss), net of tax in our consolidated balance sheets and will be reclassified to earnings when the hedged item affects earnings.

In April 2018, we entered into an interest rate swap arrangement, which is 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 4), effectively providing a fixed rate of interest throughout the life of the Term Loan.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

**5. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY – continued**

The interest rate swap arrangement with Citizens Bank, N.A became effective on April 29, 2018, with a maturity date of December 29, 2022. The notional amount of the swap agreement at inception was $74.1 million and will decrease in line with our Term Loan. As of September 30, 2018, the notional amount of the interest rate swap was $72.2 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 September 30, 2018, the fair value of the interest rate swap asset was valued at $0.7 million and was recorded in other long-term assets in the accompanying unaudited condensed consolidated balance sheets. As of September 30, 2018, $0.5 million, the fair value of the interest rate swap net of tax, was recorded in accumulated other comprehensive income, net of tax in the accompanying unaudited condensed consolidated balance sheets. During the three and nine months ended September 30, 2018, changes in the fair value of the interest rate swap of $0.3 million, net of tax, and $0.5 million, net of tax, respectively, was recorded in accumulated other comprehensive income, net of tax in the accompanying unaudited condensed consolidated statements of comprehensive income. Differences between the hedged LIBOR rate and the fixed rate recorded as interest expense in the same period that the related interest is recorded for the Term Loan based on the LIBOR rate. In three and nine months ended September 30, 2018, $0.1 million and $0.2 million of interest expense was recognized in relation to the interest rate swap, respectively.

**6. EARNINGS PER SHARE**

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

For periods of net income, and when the effects are not anti-dilutive, we calculate diluted earnings per share by dividing net income available to common shareholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options, shares to be purchased under our Employee Stock Purchase Plan (“ESPP”), unvested restricted stock awards, stock purchase warrants, and any conversion gain on our Notes (Note 4), using the treasury stock method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share.

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

For purposes of determining diluted earnings per share, we have elected a policy to assume that the principal portion of the Notes (Note 4) is settled in cash. As such, the principal portion of the Notes has no effect on either the numerator or denominator when determining diluted earnings per share. Any conversion gain is assumed to be settled in shares and is incorporated in diluted earnings per share using the treasury method. The warrants issued in conjunction with the issuance of the Notes (Note 4) are considered to be dilutive when they are in-the-money relative to our average stock price during the period; the bond hedge purchased in conjunction with the issuance of the Notes is always considered to be anti-dilutive.

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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**6. EARNINGS PER SHARE – continued**

Earnings per share for the three and nine months ended September 30, 2018 and 2017 are calculated for basic and diluted earnings per share as follows:

| **(in thousands, except per share amounts)** | **Basic Three Months Ended September 30,** | | **Diluted Three Months Ended September 30,** | | **Basic Nine Months Ended September30,** | | **Diluted Nine Months Ended September 30,** | |
|---|---|---|---|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** | **2018** | **2017** | **2018** | **2017** |
| Net income | $5,037 | $4,720 | $5,037 | $4,720 | $10,064 | $8,553 | $10,064 | $8,553 |
| Net income allocated to restricted stock | (51) | (35) | (51) | (35) | (101) | (64) | (101) | (64 |
| Net income allocated to common shares | $4,986 | $4,685 | $4,986 | $4,685 | $9,963 | $8,489 | $9,963 | $8,489 |
| Basic Weighted-Average Shares Outstanding | 11,706 | 11,553 | 11,706 | 11,553 | 11,659 | 11,542 | 11,659 | 11,542 |
| Dilutive effect of stock options and ESPP | | | 98 | 124 | | | 108 | 124 |
| Diluted Weighted-Average Shares Outstanding | | | 11,804 | 11,677 | | | 11,767 | 11,666 |
| Earnings Per Share | $0.43 | $0.41 | $0.42 | $0.40 | $0.85 | $0.74 | $0.85 | $0.73 |

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, including the shares underlying the Notes, was 4.8 million for both the three months ended September 30, 2018 and 2017 and was 4.7 million for both the nine months ended September 30, 2018 and 2017. Anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the treasury stock method, underlying shares related to out-of-the-money bonds issued as convertible debt, and out-of-the-money warrants exercisable for common stock.

**7. INVENTORIES**

Inventories consist of the following as of:

| (in thousands) | September 30, 2018[1] | December 31, 2017 | |
|---|---|---|---|
| Raw materials | $ 26,653 | $ 22,139 | |
| Packaging materials | 2,283 | 1,527 | |
| Work-in-progress | 1,282 | 510 | |
| Finished goods | 10,317 | 13,901 | [2] |
| | 40,535 | 38,077 | |
| Reserve for excess/obsolete inventories | (529) | (350) | |
| Inventories, net | $ 40,006 | $ 37,727 | |

[1] Includes inventory acquired in acquisition of WellSpring (Note 3).
[2] Includes finished goods acquired in asset purchases (Note 13).

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**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

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**7. INVENTORIES – continued**

**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 September 30, 2018, we purchased approximately 36% of our inventory (exclusive of inventory acquired in the acquisition of WellSpring (Note 3)) from one supplier. As of September 30, 2018, the amounts payable to this supplier was immaterial. During the nine months ended September 30, 2018, we purchased approximately 25% of our inventory (exclusive of inventory acquired in the acquisition of WellSpring (Note 3)) from two suppliers. As of September 30, 2018, the amounts payable to these suppliers was immaterial. During the three months ended September 30, 2017, we purchased approximately 40% of our inventory (exclusive of inventory acquired in asset purchases (Note 13)) from two suppliers. During the nine months ended September 30, 2017, we purchased approximately 24% of our inventory (exclusive of inventory acquired in asset purchases (Note 13)) from two suppliers.

**8. PROPERTY, PLANT, AND EQUIPMENT**

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

| **(in thousands)** | **September 30, 2018[1]** | **December 31, 2017** |
|---|---|---|
| Land | $ 4,558 | $ 160 |
| Buildings | 6,725 | 3,835 |
| Machinery, furniture, and equipment | 23,038 | 12,334 |
| Construction in progress | 10,744 | 10,663 |
| | 45,065 | 26,992 |
| Less: accumulated depreciation | (7,647) | (6,589) |
| Property, Plant, and Equipment, net | $ 37,418 | $ 20,403 |

(1) Includes property, plant, and equipment acquired in acquisition of WellSpring (Note 3).

Depreciation expense was $0.6 million and $0.3 million for the three months ended September 30, 2018 and 2017, respectively. Depreciation expense was $1.3 million and $0.9 million for the nine months ended September 30, 2018 and 2017, respectively. During the three months ended September 30, 2018 and 2017, there was $0.2 million and $0.1 million of interest capitalized into construction in progress, respectively. During the nine months ended September 30, 2018 and 2017, there was $0.6 million and $0.4 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.

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## 9. 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 $2.3 million in August 2018. We assess the recoverability of the carrying value of goodwill as of October 31st of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value during the nine months ended September 30, 2018. No impairment losses were recognized during the three or nine months ended September 30, 2018 or 2017.

### Definite-lived Intangible Assets

***Acquisition of Abbreviated New Drug Applications***

In April 2018, we entered into an agreement with Impax Laboratories, Inc. (now Amneal Pharmaceuticals, Inc., or "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 up front. The transaction closed in May 2018 and we made the $2.3 million payment using cash on hand. We also capitalized $0.1 million of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $1.0 million acquired ANDA intangible assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 13 for further details regarding the transaction.

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. The transaction closed in April 2018 and we made the $2.7 million payment using cash on hand. We also capitalized $18 thousand of costs directly related to the transaction. We accounted for this transaction as an asset purchase. The $2.5 million acquired ANDA intangible assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 13 for further details regarding the transaction.

***Acquisition of New Drug Applications and Product Rights***

In December 2017, we entered into an agreement with AstraZeneca AB and AstraZeneca UK Limited to purchase the right, title, and interest in the NDAs and the U.S. rights to market Atacand, Atacand HCT, Arimidex, and Casodex, for $46.5 million in cash. We also entered into a license agreement for use of these trademarks in the U.S. We made the $46.5 million cash payment with funds from our Term Loan (Note 3). We also capitalized $0.2 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $46.7 million product rights assets are being amortized in full over their estimated useful lives of 10 years. Please see Note 13 for further details regarding the transaction.

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark, and certain finished goods inventory for Inderal XL for $20.2 million in cash. We made the $20.2 million cash payment using cash on hand. We accounted for this transaction as an asset purchase. We also capitalized $40 thousand of costs directly related to the transaction. The $15.1 million product rights intangible asset acquired in the asset purchase is being amortized in full over its estimated useful life of 10 years. Please see Note 13 for further details regarding the transaction.

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**9. GOODWILL AND INTANGIBLE ASSETS – continued**

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for $30.6 million in cash. We made the $30.6 million cash payment using $30.0 million of funds from our former Line of Credit and $0.6 million of cash on hand. We accounted for this transaction as an asset purchase. We also capitalized $0.1 million of costs directly related to the transaction. The $19.0 million product rights intangible asset acquired in the asset purchase is being amortized in full over its estimated useful life of 10 years. Please see Note 13 for further details regarding the transaction.

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

| (in thousands) | September 30, 2018 | | December 31, 2017 | | Weighted Average Amortization Period |
|---|---|---|---|---|---|
| | Gross Carrying Amount | Accumulated Amortization | Gross Carrying Amount | Accumulated Amortization | |
| Acquired ANDA intangible assets | $46,194 | $ (15,940) | $42,076 | $ (12,592) | 10.0 years |
| NDAs and product rights | 230,974 | (55,939) | 230,974 | (37,091) | 10.0 years |
| Marketing and distribution rights | 10,423 | (6,569) | 11,042 | (5,087) | 4.7 years |
| Non-compete agreement | 624 | (223) | 624 | (156) | 7.0 years |
| | $288,215 | $ (78,671) | $284,716 | $ (54,926) | |

Definite-lived intangible assets are stated at cost, net of amortization, generally using the straight-line method over the expected useful lives of the intangible assets. In the case of the Inderal XL and InnoPran XL asset purchases, because we anticipate that the acquired assets will provide a greater economic benefit in the earlier years, we are amortizing 80% of the value of the intangible assets over the first five years of useful lives of the assets and amortizing the remaining 20% of the value of the intangible assets over the second five years of useful lives of the assets. Amortization expense was $7.9 million and $6.8 million for the three months ended September 30, 2018 and 2017, respectively. Amortization expense was $23.7 million and $20.0 million for the nine months ended September 30, 2018 and 2017, respectively.

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. No such triggering events were identified during the three and nine months ended September 30, 2018 and 2017 and therefore no impairment loss was recognized in the three and nine months ended September 30, 2018 or 2017.

Expected future amortization expense is as follows:

| **(in thousands)** | |
|---|---|
| 2018 (remainder of the year) | $7,940 |
| 2019 | 31,761 |
| 2020 | 31,279 |
| 2021 | 29,833 |
| 2022 | 26,428 |
| 2023 and thereafter | 82,303 |
| Total | $209,544 |

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**10.STOCK-BASED COMPENSATION**

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of September 30, 2018, we have 0.2 million shares of common stock available under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount. In the three and nine months ended September 30, 2018, we recognized $2 thousand and $6 thousand of stock-based compensation expense related to the ESPP in cost of sales, $5 thousand, and $8 thousand of stock-based compensation expense related to the ESPP in research and development, and $15 thousand and $43 thousand of stock-based compensation expense related to the ESPP in sales, general, and administrative expense in our accompanying unaudited interim condensed consolidated statements of operations, respectively. In the three and nine months ended September 30, 2017, we recognized $1 thousand and $5 thousand of stock-based compensation expense related to the ESPP in cost of sales and $11 thousand and $50 thousand of stock-based compensation expense related to the ESPP in sales, general, and administrative expense in our accompanying unaudited interim condensed consolidated statements of operations, respectively.

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the “2008 Plan”). As of September 30, 2018, 0.6 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 September 30,** | | **Nine Months Ended September 30,** | |
|---|---|---|---|---|
| | **2018** | **2017** | **2018** | **2017** |
| Cost of sales | $ 24 | $ 19 | $ 66 | $ 68 |
| Research and development | 184 | 173 | 564 | 485 |
| Selling, general, and adminstrative | 1,564 | 1,270 | 4,266 | 4,059 |
| | $ 1,772 | $ 1,462 | $ 4,896 | $ 4,612 |

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

A summary of stock option and restricted stock activity under the 2008 Plan during the nine months ended September 30, 2018 and 2017 is presented below:

| **(in thousands)** | **Options** | **RSAs** |
|---|---|---|
| Outstanding December 31, 2016 | 578 | 63 |
| Granted | 192 | 50 |
| Options Exercised/RSAs Vested | (7) | (27)[1] |
| Forfeited | (3) | - |
| Outstanding September 30, 2017 | 760 | 86 |
| | | |
| Outstanding December 31, 2017 | 767 | 86 |
| Granted | 156 | 65 |
| Options Exercised/RSAs Vested | (140) | (33)[2] |
| Forfeited | (22) | - |
| Outstanding September 30, 2018 | 761 | 118 |

[1] Includes five 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 $259 thousand total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

[2] Includes 11 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 $659 thousand total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

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**11. INCOME TAXES**

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. The utilization of our NOL carryforwards will be limited in future years as prescribed by Section 382 of the U.S. Internal Revenue Code. As of both September 30, 2018 and December 31, 2017, we had provided a valuation allowance against certain state net operating loss (“NOL”) carryforwards of $0.3 million.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any such amounts accrued as of September 30, 2018 and December 31, 2017. We are subject to taxation in various jurisdictions and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate, 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. 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 recently acquired 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.

The estimated consolidated effective tax rate for the three months ended September 30, 2018, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit can be recognized, was 20.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in the third quarter. Our effective tax rate for the three months ended September 30, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

The effective tax rate for the three months ended September 30, 2017 was 25.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017. Our effective tax rate for the three months ended September 30, 2017 was impacted primarily by the Domestic Production Activities Deduction, as well as the 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.

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**11. INCOME TAXES – continued**

The estimated consolidated effective tax rate for the nine months ended September 30, 2018, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit can be recognized, was 20.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in 2018. Our effective tax rate for the nine months ended September 30, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

The effective tax rate for the nine months ended September 30, 2017 was 28.7% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017. Our effective tax rate for the nine months ended September 30, 2017 was impacted primarily by the Domestic Production Activities Deduction, as well as the 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.

**12. COMMITMENTS AND CONTINGENCIES**

**Government Regulation**

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

**Unapproved Products**

Two of our products, Esterified Estrogen with Methyltestosterone (“EEMT”) and Opium Tincture, are marketed without approved NDAs or Abbreviated New Drug Applications (“ANDAs”). During the three months ended September 30, 2018 and 2017, net revenues for these products totaled $6.2 million and $7.9 million, respectively. During the nine months ended September 30, 2018 and 2017, net revenues for these products totaled $18.3 million and $20.9 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.

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**12. COMMITMENTS AND CONTINGENCIES – continued**

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for these unapproved products for both the three months ended September 30, 2018 and 2017 were $0.6 million. Our contract manufacturing revenues for these unapproved products for the nine months ended September 30, 2018 and 2017 were $1.6 million and $1.5 million, respectively.

We receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the contract customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products for the three and nine months ended September 30, 2018 and 2017 were less than 1% of total revenues.

**Louisiana Medicaid Lawsuit**

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

**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. The action is currently in the discovery phase. We intend to defend this action vigorously.

**Other Commitments and Contingencies**

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, have faced allegations from plaintiffs in various states, including California, New Jersey, and Pennsylvania, claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA's February 2009 Black Box warning requirement. In August 2012, we were dismissed with prejudice from all New Jersey complaints. In August 2016, we settled the outstanding California short form complaints and in February 2018, we settled the remaining four complaints that were not captured in the 2016 settlement. We consider our exposure to this litigation to be limited due to several factors: (1) the only generic metoclopramide that we manufactured prior to the implementation of the FDA's warning requirement was an oral solution introduced after May 28, 2008; (2) our market share for the oral solution was a very small portion of the overall metoclopramide market; and (3) once we received a request for change of labeling from the FDA, we submitted our proposed changes within 30 days, and such changes were subsequently approved by the FDA.

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**12. COMMITMENTS AND CONTINGENCIES – continued**

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

Our ANDA for Erythromycin Ethylsuccinate ("EES") was originally approved by the FDA on November 27, 1978. We purchased the EES ANDA from Teva on July 10, 2015, and subsequently launched EES on September 27, 2016. In August 2016, we filed with the FDA to reintroduce this product under a Changes Being Effected in 30 Days submission (a "CBE-30 submission"). Under a CBE-30 submission, certain defined changes to an ANDA can be made if the FDA does not object in writing within 30 days. The FDA's regulations, guidance documents, and historic actions support the filing of a CBE-30 for the types of changes that we proposed for our EES ANDA. We received no formal written letter from the FDA within 30 days of the CBE-30 submission date, and as such, launched the product in accordance with FDA regulations. On December 16, 2016, and nearly four months after our CBE-30 submission, the FDA sent us a formal written notice that a Prior Approval Supplement ("PAS") was required for this ANDA. Under a PAS, proposed changes to an ANDA cannot be implemented without prior review and approval by the FDA. Because we did not receive this notice in the timeframe prescribed by the FDA's regulations, we believe that our supplemental ANDA is valid, and as such continued to market the product. In addition, we filed a PAS which was approved by the FDA on November 2, 2018.

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.

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## 13. FAIR VALUE DISCLOSURES

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, borrowings under line of credit, and other current liabilities) approximate their carrying values because of their short-term nature. While our Notes are recorded on our accompanying unaudited interim condensed consolidated balance sheets at their net carrying value of $134.1 million as of September 30, 2018, the Notes are being traded on the bond market and their fair value is $146.8 million, based on their closing price on September 30, 2018, a Level 1 input.

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

Our contingent value rights (“CVRs”), which were granted coincident with our merger with BioSante and expire in June 2023, are considered contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of our projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs was immaterial as of September 30, 2018 and December 31, 2017. We also determined that the changes in such fair value were immaterial in the three and nine months ended September 30, 2018 and 2017.

In April 2018, we entered into an interest rate swap (Note 5) to manage our exposure to the variable interest rate on our Term Loan (Note 4). The notional amount of our interest rate swap is set to match the balance of our Term Loan. Both the notional amount of the interest rate swap and the balance of our Term Loan were $72.2 million as of

September 30, 2018. 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 5, the fair value of the interest rate swap was a $0.7 million asset at September 30, 2018.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

**13. FAIR VALUE DISCLOSURES – continued**

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of September 30, 2018 and December 31, 2017, by level within the fair value hierarchy:

**(in thousands)**

| **Description** | **Fair Value at September 30, 2018** | **Level 1** | **Level 2** | **Level 3** |
|---|---|---|---|---|
| Assets | | | | |
| Interest rate swap | $ 699 | $ - | $ 699 | $ - |
| Liabilities | | | | |
| CVRs | $ - | $ - | $ - | $ - |

| **Description** | **Fair Value at December 31, 2017** | **Level 1** | **Level 2** | **Level 3** |
|---|---|---|---|---|
| Assets | | | | |
| Interest rate swap | $ - | $ - | $ - | $ - |
| Liabilities | | | | |
| CVRs | $ - | $ - | $ - | $ - |

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

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

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

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

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

We measure our long-lived assets, including property, plant, and equipment, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three and nine months ended September 30, 2018 and 2017. Please see Note 3 for discussion of assets and liabilities acquired in the acquisition of WellSpring.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

**13. FAIR VALUE DISCLOSURES – continued**

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

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 (Note 9). 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 do elect to purchase the finished goods from Amneal for this period, we may be required to pay a milestone payment of up to $10.0 million upon launch, depending on the number of competitors selling the product at the time of launch. This milestone payment was determined to be contingent consideration and will be recognized when the contingency is resolved. When one of the approved ANDAs that have not yet been commercialized is launched, we could be required to pay a milestone of $25.0 million to Teva Pharmaceuticals (“Teva”), depending on the number of competitors selling the product at the time of launch. In addition, depending on the number of competitors selling the product one year after the launch date, we could be required to pay a second milestone of $15.0 million to Teva. These milestones are determined to be contingent liabilities and will be recognized if and when they are both estimable and probable. Because we believe that neither milestone is both estimable and probable, we did not record a contingent liability for the milestones. 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 September 30, 2018 and therefore no impairment loss was recognized for the nine months ended September 30, 2018. 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.

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 (Note 9). 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 September 30, 2018 and therefore no impairment loss was recognized for the nine months ended September 30, 2018. 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.

**ANI PHARMACEUTICALS, INC. and subsidiarIES**

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**

***(unaudited)***

**13. FAIR VALUE DISCLOSURES – continued**

In December 2017, we entered into an agreement with AstraZeneca AB and AstraZeneca UK Limited to purchase the right, title, and interest in the NDAs and the U.S. right to market Atacand, Atacand HCT, Arimidex, and Casodex, for $46.5 million in cash (Note 9). We also licensed these trademarks for use in the U.S. We made the $46.5 million cash payment with funds from our Term Loan (Note 3) and capitalized $0.2 million of costs directly related to the asset purchase. The agreement included a $3.0 million contingent payment due in early 2023 if the annual net sales of the Atacand and Atacand HCT products equals or exceeds certain threshold amounts in 2020, 2021, and 2022. Because we believe that the likelihood of meeting or exceeding the threshold amounts is not probable, we did not record a contingent liability in relation to the agreement. We accounted for this transaction as an asset purchase. The $46.7 million product rights intangible assets were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible assets, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over their 10-year useful lives, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to September 30, 2018 and therefore no impairment loss was recognized for the nine months ended September 30, 2018.

In February 2017, we entered into an agreement with Cranford Pharmaceuticals, LLC to purchase a distribution license, trademark, and certain finished goods inventory for Inderal XL for $20.2 million in cash (Note 9). We made the $20.2 million cash payment using cash on hand and capitalized $40 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $15.1 million product rights intangible asset was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible asset, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over its 10-year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to September 30, 2018 and therefore no impairment loss was recognized for the nine months ended September 30, 2018. We also recorded $5.0 million of finished goods inventory. The fair value of the finished goods inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin.

In February 2017, we entered into an agreement with Holmdel Pharmaceuticals, LP to purchase the NDA, trademark, and certain finished goods inventory for InnoPran XL, including a license to an Orange Book listed patent, for $30.6

million in cash (Note 9). We made the $30.6 million cash payment using $30.0 million of funds from our former Line of Credit and $0.6 million of cash on hand. We also capitalized $0.1 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The $19.0 million product rights intangible asset was recorded at its relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible asset, we used the present value of the estimated cash flows related to the product rights, using a discount rate of 10%. The product rights will be amortized in full over its 10-year useful life, and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to September 30, 2018 and therefore no impairment loss was recognized for the nine months ended September 30, 2018. We also recorded $11.6 million of finished goods inventory. The fair value of the finished goods inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin.

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

*The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this Form 10-Q quarterly report. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2017.*

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries, ANIP Acquisition Company and ANI Pharmaceuticals Canada Inc. (together, "ANI," the "Company," "we," "us," or "our") is an integrated specialty pharmaceutical company focuse on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations. We have three pharmaceutical manufacturing facilities, two located in Baudette, Minnesota and one located in Oakville, Canada, which are capable of producing oral solid dose products, as well as liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment.

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

As of September 30, 2018, our products include both branded and generic pharmaceuticals, specifically:

| **Generic Products** | **Branded Products** |
|---|---|
| Cholestyramine | Arimidex |
| Desipramine Hydrochloride | Casodex |
| Diphenoxylate Hydrochloride and Atropine Sulfate | Cortenema |
| Erythromycin Ethylsuccinate | Inderal LA |
| Esterified Estrogen with Methyltestosterone | Inderal XL |
| Etodolac | InnoPran XL |
| Ezetimibe-Simvastatin | Lithobid |
| Felbamate | Reglan |
| Fenofibrate | Vancocin |
| Flecainide | |
| Fluvoxamine | |
| Hydrocortisone Enema | |
| Hydrocortisone Rectal Cream (1% and 2.5%) | |
| Indapamide | |
| Lithium Carbonate ER | |
| Mesalamine Enema | |
| Methazolamide | |
| Metoclopramide Syrup | |
| Morphine Sulfate Oral Solution | |
| Nilutamide | |
| Nimodipine | |

Opium Tincture

Oxycodone Capsules

Oxycodone Hydrochloride Oral Solution (5 mg/5 mL)

Oxycodone Hydrochloride Oral Solution (100 mg/5 mL)

Pindolol

Propafenone

Propranolol ER

Vancomycin

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

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

**Recent Developments**

***Acquisition of WellSpring Pharma Services Inc.***

On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. (“ANI Canada”), acquired all the issued and outstanding equity interests of WellSpring, a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Subject to further adjustments, the estimated consideration was $17.3 million. The consideration was paid entirely from cash on hand. In conjunction with the transaction, we acquired WellSpring’s pharmaceutical manufacturing facility, laboratory, and offices, its current book of commercial business, as well as an organized workforce. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity’s name being ANI Pharmaceuticals Canada Inc.

We acquired WellSpring to provide an additional tech transfer site in order to accelerate the re-commercialization of the previously-approved ANDAs in our pipeline, to expand our contract manufacturing revenue base, and to broaden our manufacturing capabilities to three manufacturing facilities.

***Launch of Authorized Generic of Atacand HCT Tablets***

In October 2018, we launched Candesartan Hydrochlorothiazide Tablets, 16mg/12.5mg, 32mg/12.5mg, and 32mg/25mg, an authorized generic of Atacand HCT, for the treatment of hypertension.

***Launch of Authorized Generic of Brethine***

In October 2018, we launched Terbutaline Sulfate Tablets USP, 2.5mg and 5mg, an authorized generic of Brethine. Terbutaline sulfate is indicated for the prevention and reversal of bronchospasm in patients 12 years of age and older with asthma and reversible bronchospasm associated with bronchitis and emphysema.

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

In the third quarter of 2018, we continued commercial scale manufacturing of Corticotropin API. Thus far, commercial scale Corticotropin API appears to be consistent with the pilot scale batches previously manufactured, and moreover, consistent with legacy API batches that had been manufactured previously. We are on track to initiate API process validation, viral clearance validation and API registration batch manufacturing in the first quarter of 2019.

We have finalized development of all API and drug product analytical methods to be used to support the API characterization package. Analytical methods to be used for batch release and stability have also been developed and will be validated prior to initiation of process validation and registration batch manufacturing, specifically by the first quarter of 2019 for API and by the second quarter of 2019 for drug product.

We continued to manufacture Cortrophin Gel finished dose drug product, which has been placed on stability. Commercial scale drug product manufacturing activities are scheduled to begin in the fourth quarter of 2018, utilizing API that was also manufactured at commercial scale. We are on track to initiate media fill simulations in the first quarter of 2019 and drug product process validation and registration batch manufacturing in the second quarter of 2019.

***Vancocin Oral Solution Update***

We are currently advancing a commercialization effort for Vancocin oral solution. We filed a prior approval supplement (“PAS”) for the product in September 2018. This product will be manufactured at our site in Baudette, Minnesota.

GENERAL

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

| (in thousands) | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net revenues | $ 50,703 | $ 48,164 | $ 144,454 | $ 129,556 |
| Operating expenses | | | | |
| Cost of sales (exclusive of depreciation and amortization) | 15,605 | 21,078 | 52,891 | 58,586 |
| Research and development | 4,667 | 2,634 | 11,906 | 6,419 |
| Selling, general, and administrative | 11,769 | 8,022 | 30,687 | 22,695 |
| Depreciation and amortization | 8,548 | 7,099 | 25,056 | 20,906 |
| Operating income | 10,114 | 9,331 | 23,914 | 20,950 |
| Interest expense, net | (3,768) | (3,052) | (11,132) | (9,009) |
| Other income/(expense), net | 20 | 95 | (71) | 58 |
| Income before provision for income taxes | 6,366 | 6,374 | 12,711 | 11,999 |
| Provision for income taxes | (1,329) | (1,654) | (2,647) | (3,446) |
| Net income | $ 5,037 | $ 4,720 | $ 10,064 | $ 8,553 |

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 September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | 2018 | 2017 | 2018 | 2017 |
| Net revenues | 100.0 % | 100.0 % | 100.0 % | 100.0 % |
| Operating expenses | | | | |
| Cost of sales (exclusive of depreciation and amortization) | 30.8 % | 43.8 % | 36.6 % | 45.2 % |
| Research and development | 9.2 % | 5.5 % | 8.2 % | 5.0 % |
| Selling, general, and administrative | 23.2 % | 16.7 % | 21.3 % | 17.5 % |
| Depreciation and amortization | 16.9 % | 14.7 % | 17.3 % | 16.1 % |
| Operating income | 19.9 % | 19.3 % | 16.6 % | 16.2 % |
| Interest expense, net | (7.4)% | (6.3)% | (7.8)% | (7.0)% |
| Other income/(expense), net | - % | 0.2 % | - % | - % |
| Income before provision for income taxes | 12.5 % | 13.2 % | 8.8 % | 9.2 % |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Provision for income taxes | (2.6 | )% | (3.4 | )% | (1.8 | )% | (2.7 | )% |
| Net income | 9.9 | % | 9.8 | % | 7.0 | % | 6.5 | % |

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

**Net Revenues**

| **(in thousands)** | **Three Months Ended September 30,** | | | |
|---|---|---|---|---|
| | **2018** | **2017** | **Change** | **% Change** |
| Generic pharmaceutical products | $ 30,287 | $ 30,546 | $ (259) | (0.8)% |
| Branded pharmaceutical products | 14,589 | 15,688 | (1,099) | (7.0)% |
| Contract manufacturing | 2,826 | 1,829 | 997 | 54.5 % |
| Royalty and other income | 3,001 | 101 | 2,900 | NM (1) |
| Total net revenues | $ 50,703 | $ 48,164 | $ 2,539 | 5.3 % |

(1) Not Meaningful

We derive substantially all of our revenues from sales of generic and branded pharmaceutical products, contract manufacturing, and royalty and other income, which includes royalties on net sales of certain products, as well as product development services and laboratory services. We adopted the Financial Accounting Standards Boards ("FASB's") guidance for revenue recognition for contracts on January 1, 2018, using the modified retrospective method. The adoption of this guidance did not have a material impact on our net revenues.

Net revenues for the three months ended September 30, 2018 were $50.7 million compared to $48.2 million for the same period in 2017, an increase of $2.5 million, or 5.3%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $30.3 million during the three months ended September 30, 2018, a decrease of 0.8% compared to $30.5 million for the same period in 2017. The primary reason for the decrease was volume decreases for Fenofibrate, Esterified Estrogen with Methyltestosterone ("EEMT"), and Nilutamide, tempered by the second quarter 2018 launch of Ezetimibe-Simvastatin.

As described in Note 12, *Commitments and Contingencies,* in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market EEMT and Opium Tincture without FDA approved NDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs. Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we

comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the three months ended September 30, 2018 and 2017 were $6.2 million and $7.9 million, respectively.

- Net revenues for branded pharmaceutical products were $14.6 million during the three months ended September 30, 2018, a decrease of 7.0% compared to $15.7 million for the same period in 2017. The primary reason for this decrease was lower revenue from Inderal LA due to decreased unit sales and price decreases and lower revenue from Vancocin due decreased unit sales, tempered by sales of Casodex and Arimidex, which were launched in July 2018 and sales of Inderal XL and InnoPran XL, both of which were re-launched under our label in the first quarter of 2018.

- Contract manufacturing revenues were $2.8 million during the three months ended September 30, 2018, an increase of 54.5% compared to $1.8 million for the same period in 2017, due primarily to contract manufacturing revenue in our ANI Canada subsidiary, partially offset by timing of orders from contract manufacturing customers in the period. We acquired WellSpring in August 2018. As described in Note 12, *Commitments and Contingencies,* in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for both the three months ended September 30, 2018 and 2017 were $0.6 million.

- Royalty and other income were $3.0 million during the three months ended September 30, 2018, an increase of $2.9 million from $0.1 million for the same period in 2017, due primarily to royalties on sales of Atacand and Atacand HCT. We acquired the right, title, and interest in the NDAs and the U.S. right to market these products in December 2017. During the three months ended September 30, 2018, we also recognized $0.5 million of royalties from a license for patent rights initially owned by Cell Genesys, which merged with BioSante in 2009. The royalties stem from sales and milestones related to the Yescarta® product. Royalty and other income also includes the impact of product development and laboratory services revenue from our ANI Canada subsidiary.

As described in Note 12, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products were less than 1% of total revenues for the three months ended September 30, 2018 and 2017.

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

| **(in thousands)** | **Three Months Ended September 30,** | | | |
|---|---|---|---|---|
| | **2018** | **2017** | **Change** | **% Change** |
| Cost of sales (excl. depreciation and amortization) | $ 15,605 | $ 21,078 | $(5,473) | (26.0)% |

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 September 30, 2018, cost of sales decreased to $15.6 million from $21.1 million for the same period in 2017, a decrease of $5.5 million or 26.0%, primarily due to lower sales of products subject to profit-sharing arrangements, as well as the lack of $2.8 million of costs of sales related to the excess of fair value over cost on Inderal XL and InnoPran XL inventory, which impacted 2017. Cost of sales as a percentage of net revenues decreased to 30.8% during the three months ended September 30, 2018, from 43.8% during same period in 2017, primarily as a result of increased royalty income and lower sales of products subject to profit-sharing arrangements. Cost of sales in the three months ended September 30, 2017 also included $2.8 million net impact on costs of sales (5.7% as a percent of net revenues) of the excess of fair value over cost for Inderal XL and InnoPran XL inventory sold during the period.

We source the raw materials for our products, including APIs from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. Changes in API suppliers usually must be approved by the FDA, which can take 18 months or longer. As a result, we are dependent upon our current vendors to reliably supply the API required for on-going product manufacturing. In addition, certain of our API for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported APIs due to FDA inspections.

During the three months ended September 30, 2018, we purchased 36% of our inventory (exclusive of inventory acquired in the acquisition of WellSpring as described in Note 3, *Business Combinations*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report) from one supplier. As of September 30, 2018, the amounts payable to this supplier was immaterial. In the three months ended September 30, 2017, we purchased approximately 40% of our inventory (exclusive of inventory acquired in asset purchases as described in Note 13, *Fair Value Disclosures*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report) from two suppliers.

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

**Other Operating Expenses**

| **(in thousands)** | **Three Months Ended September 30,** | | | | |
|---|---|---|---|---|---|
| | **2018** | **2017** | **Change** | **% Change** | |
| Research and development | $ 4,667 | $ 2,634 | $ 2,033 | 77.2 | % |
| Selling, general, and administrative | 11,769 | 8,022 | 3,747 | 46.7 | % |
| Depreciation and amortization | 8,548 | 7,099 | 1,449 | 20.4 | % |
| Total other operating expenses | $ 24,984 | $ 17,755 | $ 7,229 | 40.7 | % |

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

For the three months ended September 30, 2018, other operating expenses increased to $25.0 million from $17.8 million for the same period in 2017, an increase of $7.2 million, or 40.7%, primarily as a result of the following factors:

- Research and development expenses increased from $2.6 million to $4.7 million, an increase of 77.2%, due to timing of work on development projects, primarily the Cortrophin gel re-commercialization project and work on the ANDAs acquired in the asset purchase agreement with Impax Laboratories, Inc. (now Amneal). We anticipate that research and development costs will continue to be greater in 2018 than in 2017, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Cortrophin product.

- Selling, general, and administrative expenses increased from $8.0 million to $11.8 million, an increase of 46.7%, primarily due to increases in personnel and related costs and costs associated with the WellSpring acquisition. We anticipate that selling, general, and administrative expenses will continue to be greater in 2018 than in 2017 as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $7.1 million to $8.5 million, an increase of 20.4%, primarily due to the amortization of the rights, title, and interest in the NDAs for Atacand, Atacand HCT, Arimidex, and Casodex, which were acquired in December 2017. We anticipate that depreciation and amortization expense will continue to be greater in 2018 than in 2017 as a result of our amortization of the NDAs for Atacand, Atacand HCT, Arimidex, and Casodex, which were acquired in late December 2017 and the amortization of the ANDAs acquired in April and May 2018.

**Other Expense, net**

| (in thousands) | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2018 | 2017 | Change | % Change |
| Interest expense, net | $ (3,768) | $ (3,052) | $ (716) | 23.5 % |
| Other (expense)/income, net | 20 | 95 | (75) | (78.9)% |
| Total other expense, net | $ (3,748) | $ (2,957) | $ (791) | 26.8 % |

For the three months ended September 30, 2018, we recognized other expense of $3.7 million versus other expense of $3.0 million for the same period in 2017, an increase of $0.8 million. Interest expense, net for 2018 consists primarily of interest expense on our convertible debt and interest expense on borrowings under our term loan. Interest expense, net for 2017 consisted primarily of interest expense on our convertible debt and interest expense on borrowings under our former line of credit. For the three months ended September 30, 2018 and 2017, there was $0.2 million and $0.1 million of interest capitalized into construction in progress, respectively.

**Provision for Income Taxes**

| (in thousands) | Three Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2018 | 2017 | Change | % Change |
| Provision for income taxes | $ (1,329) | $ (1,654) | $ 325 | (19.6)% |

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

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

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For the three months ended September 30, 2018, we recognized income tax expense of $1.3 million, versus $1.7 million for the same period in 2017, a decrease of $0.3 million. The estimated consolidated effective tax rate for the three months ended September 30, 2018, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit can be recognized, was 20.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in the third quarter. Our effective tax rate for the three months ended September 30, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

The effective tax rate for the three months ended September 30, 2017 was 25.9% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017. Our effective tax rate for the three months ended September 30, 2017 was impacted primarily by the Domestic Production Activities Deduction, as well as the 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.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2018 AND 2017

**Net Revenues**

| **(in thousands)** | **Nine Months Ended September 30,** | | | | |
|---|---|---|---|---|---|
| | **2018** | **2017** | **Change** | **% Change** | |
| Generic pharmaceutical products | $ 83,716 | $ 88,608 | $(4,892 ) | (5.5 | )% |
| Branded pharmaceutical products | 41,714 | 35,398 | 6,316 | 17.8 | % |
| Contract manufacturing | 5,450 | 5,151 | 299 | 5.8 | % |
| Royalty and other income | 13,574 | 399 | 13,175 | NM | (1) |
| Total net revenues | $ 144,454 | $ 129,556 | $14,898 | 11.5 | % |

(1) Not Meaningful

Net revenues for the nine months ended September 30, 2018 were $144.5 million compared to $129.6 million for the same period in 2017, an increase of $14.9 million, or 11.5%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $83.7 million during the nine months ended September 30, 2018, a decrease of 5.5% compared to $88.6 million for the same period in 2017. The primary reason for the decrease was volume decreases for Fenofibrate, EEMT, and Nilutamide, as well as sales decreases for Propranolol ER driven by price, tempered by the impact of the second quarter 2017 launch of Diphenoxylate Hydrochloride and Atropine Sulfate and the second quarter 2018 launch of Ezetimibe-Simvastatin.

As described in Note 12, *Commitments and Contingencies,* in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we market EEMT and Opium Tincture without FDA approved NDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled “Marketed New Drugs without Approved NDAs or Abbreviated New Drug Applications ANDAs.” Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. While we believe that, so long as we comply with applicable manufacturing standards, the FDA will not take action against us under the current enforcement policy, we can offer no assurances that the FDA will continue this policy or not take a contrary position with any individual product or group of products. Our combined net revenues for these products for the nine months ended September 30, 2018 and 2017 were $18.3 million and $20.9 million, respectively.

- Net revenues for branded pharmaceutical products were $41.7 million during the nine months ended September 30, 2018, an increase of 17.8% compared to $35.4 million for the same period in 2017. The primary reason for the increase was sales of Inderal XL and InnoPran XL, both of which were acquired in the first quarter of 2017, and which were re-launched under our label in the first quarter of 2018, as well as sales of Arimidex and Casodex, which were launched in July 2018. These increases were tempered by lower unit sales of Inderal LA and Vancocin.

- Contract manufacturing revenues were $5.5 million during the nine months ended September 30, 2018, an increase of 5.8% compared to $5.2 million for the same period in 2017, due primarily to contract manufacturing revenue in our ANI Canada subsidiary, partially offset by timing of orders from contract manufacturing customers in the period. We acquired WellSpring in August 2018. As described in Note 12, *Commitments and Contingencies,* in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we contract manufacture a group of products on behalf of a customer that are marketed by that customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the nine months ended September 30, 2018 and 2017 were $1.6 million and $1.5 million, respectively.

- Royalty and other income were $13.6 million during the nine months ended September 30, 2018, an increase of $13.2 million from $0.4 million for the same period in 2017, due primarily to royalties on sales of Atacand, Atacand HCT, Casodex, and Arimidex. We acquired the right, title, and interest in the NDAs and the U.S. right to market these products in December 2017. During the nine months ended September 30, 2018, we also recognized $1.4 million of royalties from a license for patent rights initially owned by Cell Genesys, Inc., which merged with BioSante in 2009. The royalties stem from sales and milestones related to the Yescarta® product. Royalty and other income also includes the impact of product development and laboratory services revenue from our ANI Canada subsidiary.

As described in Note 12, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we receive royalties on the net sales of a group of contract-manufactured products, which are marketed by the customer without an FDA-approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our royalties on the net sales of these unapproved products were less than 1% of total revenues for the nine months ended September 30, 2018 and 2017.

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

| **(in thousands)** | **Nine Months Ended September 30,** | | | |
|---|---|---|---|---|
| | **2018** | **2017** | **Change** | **% Change** |
| Cost of sales (excl. depreciation and amortization) | $ 52,891 | $ 58,586 | $(5,695) | (9.7)% |

For the nine months ended September 30, 2018, cost of sales decreased to $52.9 million from $58.6 million for the same period in 2017, a decrease of $5.7 million or 9.7%, primarily due to lower sales of products subject to profit-sharing arrangements, as well as the lack of $7.5 million of costs of sales related to the excess of fair value over cost on Inderal XL and InnoPran XL inventory, which impacted 2017. This decrease was tempered by $5.6 million of cost of sales related to the excess of fair value over costs on Inderal XL and InnoPran XL inventory and the write-off of remaining inventory acquired as part of the acquisition when we re-launched the products under our own label during the first quarter of 2018. Cost of sales as a percentage of net revenues decreased to 36.6% during the nine

months ended September 30, 2018, from 45.2% during same period in 2017, primarily as a change in product mix towards higher-margin brand products and lower sales of products subject to profit-sharing arrangements. Cost of sales in the nine months ended September 30, 2017 also included $7.5 million net impact on cost of sales (5.8% as a percent of net revenues) of the excess of fair value over the cost for Inderal XL and InnoPran XL inventory sold during the period.

During the nine months ended September 30, 2018, we purchased 25% of our inventory (exclusive of inventory acquired in the acquisition of WellSpring as described in Note 3, *Business Combinations*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report) from two suppliers. As of September 30, 2018, the amounts payable to these suppliers was immaterial. During the nine months ended September 30, 2017, we purchased 24% of our inventory (exclusive of inventory acquired in asset purchases as described in Note 13, *Fair Value Disclosures*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report) from two suppliers.

**Other Operating Expenses**

| (in thousands) | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2018 | 2017 | Change | % Change |
| Research and development | $ 11,906 | $ 6,419 | $5,487 | 85.5 % |
| Selling, general, and administrative | 30,687 | 22,695 | 7,992 | 35.2 % |
| Depreciation and amortization | 25,056 | 20,906 | 4,150 | 19.9 % |
| Total other operating expenses | $ 67,649 | $ 50,020 | $17,629 | 35.2 % |

For the nine months ended September 30, 2018, other operating expenses increased to $67.6 million from $50.0 million for the same period in 2017, an increase of $17.6 million, or 35.2%, primarily as a result of the following factors:

- Research and development expenses increased from $6.4 million to $11.9 million, an increase of 85.5%, due to timing of work on development projects, primarily the Cortrophin gel re-commercialization project and work on the ANDAs acquired in the asset purchase agreement with Impax Laboratories, Inc. (now Amneal), as well as $1.3 million of expense related to in-process research and development acquired from Amneal in an asset purchase in May. We anticipate that research and development costs will continue to be greater in 2018 than in 2017, in support of our strategy to expand our product portfolio and as we continue to focus on the development of our Cortrophin product.

- Selling, general, and administrative expenses increased from $22.7 million to $30.7 million, an increase of 35.2%, primarily due to increases in personnel and related costs and costs associated with the WellSpring acquisition. We anticipate that selling, general, and administrative expenses will continue to be greater in 2018 than in 2017 as we support anticipated additional revenue growth.

- Depreciation and amortization increased from $20.9 million to $25.1 million, an increase of 19.9%, primarily due to the amortization of the rights, title, and interest in the NDAs for Atacand, Atacand HCT, Arimidex, and Casodex, which were acquired in December 2017. We anticipate that depreciation and amortization expense will continue to be greater in 2018 than in 2017 as a result of our amortization of the NDAs for Atacand, Atacand HCT, Arimidex, and Casodex, which were acquired in late December 2017 and the amortization of the ANDAs acquired in April and May 2018.

**Other Expense, net**

| (in thousands) | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2018 | 2017 | Change | % Change |

| | | | | |
|---|---|---|---|---|
| Interest expense, net | $ (11,132) | $ (9,009) | $(2,123) | 23.6 % |
| Other (expense)/income, net | (71) | 58 | (129) | (222.4)% |
| Total other expense, net | $ (11,203) | $ (8,951) | $(2,252) | 25.2 % |

For the nine months ended September 30, 2018, we recognized other expense of $11.2 million versus other expense of $9.0 million for the same period in 2017, an increase of $2.3 million. Interest expense, net for 2018 consists primarily of interest expense on our convertible debt and interest expense on borrowings under our term loan. Interest expense, net for 2017 consisted primarily of interest expense on our convertible debt and interest expense on borrowings under our former line of credit. For the nine months ended September 30, 2018 and 2017, there was $0.6 million and $0.4 million of interest capitalized into construction in progress, respectively.

**Provision for Income Taxes**

| (in thousands) | Nine Months Ended September 30, | | | |
|---|---|---|---|---|
| | 2018 | 2017 | Change | % Change |
| Provision for income taxes | $ (2,647) | $ (3,446) | $ 799 | (23.2)% |

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

For the nine months ended September 30, 2018, we recognized income tax expense of $2.6 million, versus $3.4 million for the same period in 2017, a decrease of $0.8 million. The estimated consolidated effective tax rate for the nine months ended September 30, 2018, calculated after excluding the taxable losses projected in our Canadian operations for which no tax benefit can be recognized, was 20.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in 2018. Our effective tax rate for the nine months ended September 30, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options, all of which impact the consolidated effective rate in the period in which they occur.

The effective tax rate for the nine months ended September 30, 2017 was 28.7% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017. Our effective tax rate for the nine months ended September 30, 2017 was impacted primarily by the Domestic Production Activities Deduction, as well as the 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)** | **September 30, 2018** | **December 31, 2017** |
|---|---|---|
| Cash and cash equivalents | $ 44,136 | $ 31,144 |
| Accounts receivable, net | 67,647 | 58,788 |
| Inventories, net | 40,006 | 37,727 |
| Prepaid income taxes | - | 1,162 |
| Prepaid expenses and other current assets | 5,004 | 2,784 |
| Total current assets | $ 156,793 | $ 131,605 |
| | | |
| Current component of long-term borrowing, net of deferred financing costs | $ 5,692 | $ 3,353 |
| Accounts payable | 7,257 | 3,630 |
| Accrued expenses and other | 2,818 | 1,571 |
| Accrued royalties | 7,455 | 12,164 |
| Accrued compensation and related expenses | 2,773 | 2,306 |
| Current income taxes payable | 318 | - |
| Accrued government rebates | 9,014 | 7,930 |
| Returned goods reserve | 10,840 | 8,274 |
| Deferred revenue | 735 | - |
| Total current liabilities | $ 46,902 | $ 39,228 |

At September 30, 2018, we had $44.1 million in unrestricted cash and cash equivalents. At December 31, 2017, we had $31.1 million in unrestricted cash and cash equivalents. We generated $39.8 million of cash from operations in the nine months ended September 30, 2018. In December 2017, we entered into a Credit Agreement with Citizens Bank, N.A. that includes a $75.0 million five-year Term Loan, as well as a $50.0 million Revolving Credit Facility, which remains undrawn at September 30, 2018. In April 2018, we entered into an interest rate swap to manage our exposure to the variable interest rate on our Term Loan. The interest rate swap hedges the variable cash flows associated with the Term Loan borrowings under the Term Loan, effectively providing a fixed rate of interest throughout the life of the Term Loan. In April 2018, we purchased from IDT Australia, Limited 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 payment using cash on hand. In May 2018, we purchased from Impax Laboratories, Inc. (now Amneal) 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. We made the $2.3 million payment using cash on hand. In August 2018, we acquired WellSpring Pharma Services Inc. (“WellSpring”), a Canadian company that performs contract development and manufacturing of pharmaceutical products for a purchase price of $18.0 million, subject to certain customary adjustments. Subject to further adjustments, the estimated consideration was $17.3 million. The consideration was

paid entirely from cash on hand. As a result of the transaction, we acquired WellSpring's pharmaceutical manufacturing facility, laboratory, and offices, current book of commercial business, as well as an organized workforce.

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

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

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

| (in thousands) | Nine Months Ended September 30, | |
|---|---|---|
| | 2018 | 2017 |
| Operating Activities | $ 39,842 | $ 23,614 |
| Investing Activities | $ (26,972) | $ (57,878) |
| Financing Activities | $ 130 | $ 24,932 |

**Net Cash Provided by Operations**

Net cash provided by operating activities was $39.8 million for the nine months ended September 30, 2018, compared to $23.6 million during the same period in 2017, an increase of $16.2 million. This increase was principally due to changes in working capital, as well as increased sales volume and corresponding gross profit dollars.

**Net Cash Used in Investing Activities**

Net cash used in investing activities for the nine months ended September 30, 2018 was $27.0 million, principally due to the preliminary payment of $17.1 million of consideration, net of cash acquired, to acquire WellSpring, the April and May 2018 asset acquisitions of ANDAs for $5.2 million, and $4.7 million of capital expenditures during the period. Net cash used in investing activities for the nine months ended September 30, 2017 was $57.9 million, principally due to the February 2017 $20.3 million asset acquisition of the product rights for Inderal XL, the February 2017 $30.7 million asset acquisition of the product rights for InnoPran XL, and $6.9 million of capital expenditures during the period, primarily related to new equipment to expand our manufacturing capability as our product lines continue to grow.

**Net Cash Provided by Financing Activities**

Net cash provided by financing activities was $0.1 million for the nine months ended September 30, 2018, principally due to $2.8 million of proceeds from stock option exercises, partially offset by $1.9 million of payments on the Term Loan, $0.7 million treasury stock purchased in relation to restricted stock vestings, and $0.2 million of debt issuance fees paid in relation to the Term Loan. Net cash provided by financing activities was $24.9 million for the nine months ended September 30, 2017, principally due to the $25.0 million net draw-down on the line of credit.

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CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

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

A summary of our significant accounting policies is included in Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2017. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Such policies are summarized in Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2017.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

CONTRACTUAL OBLIGATIONS AND OFF-BALANCE SHEET ARRANGEMENTS

As of September 30, 2018 and December 31, 2017, we did not have any off-balance sheet arrangements, as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated by the SEC.

**Item 3. Quantitative and Qualitative Disclosures About Market Risk**

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

As of September 30, 2018, our largest debt obligation was related to our Notes. In order to reduce the potential equity dilution that would result upon conversion of the Senior Convertible Notes issued in December 2014, we entered into note hedge transactions with a financial institution affiliated with one of the underwriters of the Senior Convertible Note offering. The note hedge transactions are expected generally, but not guaranteed, to reduce the potential dilution to our common stock and/or offset the cash payments we are required to make in excess of the principal amount upon any conversion of Senior Convertible Notes, in the event that the market price per share of our common stock, as measured under the terms of the Convertible Note Hedge Transactions, is greater than the conversion price of the Senior Convertible Notes, which is initially approximately $69.48. In addition, in order to partially offset the cost of the note hedge transactions, we issued warrants to the hedge counterparty to purchase approximately 2.1 million shares of our common stock at a strike price of $96.21. The warrants would separately have a dilutive effect to the extent that the market value per share of our common stock exceeds the strike price of the warrants. In addition, non-performance by the counterparties under the hedge transactions would potentially expose us to dilution of our common stock to the extent our stock price exceeds the conversion price.

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

On December 29, 2017, we entered into our five-year Credit Agreement with Citizens Bank, N.A. The Credit Agreement is comprised of a $75.0 million five-year Term Loan and a $50.0 million Revolving Credit Facility. Amounts drawn bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.25% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.25%, depending our total leverage ratio. We will incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.35%, depending on our leverage ratio. In April 2018, we entered into an interest rate swap to manage our exposure to the variable interest rate on our Term Loan. The interest rate swap hedges the variable cash flows associated with the Term Loan borrowings under the Term Loan, effectively providing a fixed rate of interest throughout the life of the Term Loan. 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 three and nine months ended September 30, 2018 by approximately $5 thousand and $10 thousand, respectively.

We are exposed to risks associated with foreign currency exchange rate risks as we translate 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. As of, and for period ended September 30, 2018, currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity.

**Item 4. Controls and Procedures**

***Evaluation of Disclosure Controls and Procedures***

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), is recorded, processed, summarized, and reported within the time periods specified in the Securities

and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of September 30, 2018. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the quarter ended September 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except as noted below.

On August 6, 2018, our subsidiary, ANI Pharmaceuticals Canada Inc. (“ANI Canada”), acquired all the issued and outstanding equity interests of WellSpring Pharma Services Inc. (“WellSpring”) in an all cash transaction. Following the consummation of the transaction, WellSpring was merged into ANI Canada with the resulting entity’s name being ANI Pharmaceuticals Canada Inc. In conjunction with the transaction, we are currently in the process of integrating ANI Canada’s policies, processes, people, technology, and operations into the consolidated company, and integrating ANI Canada’s operations into our system of internal control over financial reporting. As permitted by the Securities and Exchange Commission, we expect to exclude ANI Canada from the assessment of internal control over financial reporting the year ending December 31, 2018.

**Part II — OTHER INFORMATION**

**Item 1. Legal Proceedings**

Please refer to Note 12, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, which is incorporated into this item by reference.

**Item 1A. Risk Factors**

In addition to the other information set forth in this report, please carefully consider the factors described in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2017 under the heading "Part I — Item 1A. Risk Factors." The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition, and/or operating results. Other than the risk factors discussed below, there have been no material changes to those risk factors since their disclosure in our most recent Annual Report on Form 10-K.

***We may not achieve the anticipated benefits from our acquisition and we may face integration difficulties, which could have a material adverse effect on our business, financial position, and operating results.***

Our acquisition of WellSpring Pharma Services Inc. ("WellSpring"), now ANI Pharmaceuticals Canada Inc. ("ANI Canada") involved the combination of two companies that operated as independent companies prior to the closing of the business combination. The integration of the business may be more time consuming and require more resources than initially estimated and we may fail to realize some or all of the anticipated benefits of the acquisition if the integration process takes longer than expected or is more costly than expected. The integration process could also result in the diversion of management's attention, the disruption or interruption of, or the loss of momentum in, the businesses of ANI and ANI Canada or inconsistencies in standards, controls, procedures, and policies, any of which could adversely affect our ability to maintain relationships with customers, partners, and employees or our ability to achieve the anticipated benefits of the acquisition. Any of these could reduce our earnings or otherwise have a material adverse effect our business, financial position, and operating results.

***Our operations in an international market subjects us to additional regulatory oversight both in the international market and in the U.S., as well as economic, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results.***

We are subject to certain risks associated with having assets and operations located in a foreign jurisdiction, including our operations in Canada. Our Canadian operations are subject to regulation by Health Canada and other federal, provincial, and local regulatory authorities. Health Canada regulates the testing, manufacture, labeling, marketing, and sale of pharmaceutical products manufactured and distributed in Canada. Our operations in this jurisdiction may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results.

***We have increased exposure to tax liabilities, including foreign tax liabilities.***

As a company based in the U.S. with a subsidiary in Canada, we are subject to, or potentially subject to, income taxes as well as non-income based taxes in this jurisdiction as well as the U.S. Significant judgment is required in determining our international provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. In addition, we have potential tax exposures resulting from the varying application of statutes, regulations, and interpretations, which include exposures on intercompany terms of cross-border arrangements between our U.S. operations and our Canadian subsidiary in relation to various aspects of our business, including tech transfers and contract manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions; such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and which could have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations.

***Currency fluctuations and changes in exchange rates could have a material adverse effect on our business, financial position, and operating results.***

A portion of our transactions are denominated in a foreign currency, the Canadian dollar. Because we engage in certain transactions in a foreign currency, we are subject to the effects of exchange rate fluctuations. If the U.S. dollar depreciates against the Canadian dollar, the expenses we recognize from Canadian-denominated transactions made by our Canadian subsidiary could be translated at an unfavorable rate, leading to foreign exchange losses. Foreign exchange gains or losses as a result of exchange rate fluctuations in any given period could harm our operating results and negatively impact our financial position and results of operations.

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

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

None.

**Item 5. Other Information**

None.

**Item 6. Exhibits**

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

**INDEX TO EXHIBITS**

| Exhibit No. | Description |
|---|---|
| 10.1 | Stock Purchase Agreement by and among WellSpring Pharma Services Inc., WSP Pharma Holdings, LLC, ANI Pharmaceuticals Canada Inc., and ANI Pharmaceuticals, Inc. |
| 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: November 6, 2018 By: /s/ Arthur S. Przybyl
Arthur S. Przybyl
President and
Chief Executive Officer
(principal executive officer)

Date: November 6, 2018 By: /s/ Stephen P. Carey
Stephen P. Carey
Vice President, Finance and
Chief Financial Officer
(principal financial officer)