

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

FORM 10-Q

(Mark one)

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

For the quarterly period ended September 30, 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

(State or other jurisdiction of
incorporation or organization)

58-2301143

(IRS Employer Identification Number)

210 Main Street West

Baudette, Minnesota

(Address of principal executive offices)

(218) 634-3500

(Registrant's telephone number including area code)

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES NO

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of 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
TABLE OF CONTENTS

	<u>Page</u>
<u>PART I—FINANCIAL INFORMATION</u>	
Item 1. Financial Statements (unaudited)	
<u>Condensed Consolidated Balance Sheets — As of September 30, 2018 and December 31, 2017</u>	<u>4</u>
<u>Condensed Consolidated Statements of Operations — For the Three and Nine Months Ended September 30, 2018 and 2017</u>	<u>5</u>
<u>Condensed Consolidated Statements of Comprehensive Income — For the Three and Nine Months Ended September 30, 2018 and 2017</u>	<u>6</u>
<u>Condensed Consolidated Statements of Cash Flows — For the Nine Months Ended September 30, 2018 and 2017</u>	<u>7</u>
<u>Notes to Condensed Consolidated Financial Statements</u>	<u>8</u>
Item 2. <u>Management’s Discussion and Analysis of Financial Condition and Results of Operations</u>	<u>38</u>
Item 3. <u>Quantitative and Qualitative Disclosures About Market Risk</u>	<u>54</u>
Item 4. <u>Controls and Procedures</u>	<u>55</u>
<u>PART II—OTHER INFORMATION</u>	
Item 1. <u>Legal Proceedings</u>	<u>57</u>
Item 1A. <u>Risk Factors</u>	<u>57</u>
Item 2. <u>Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities</u>	<u>58</u>
Item 3. <u>Defaults upon Senior Securities</u>	<u>58</u>
Item 4. <u>Mine Safety Disclosures</u>	<u>58</u>
Item 5. <u>Other Information</u>	<u>58</u>
Item 6. <u>Exhibits</u>	<u>58</u>
<u>Signatures</u>	<u>60</u>

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)

	<u>September 30,</u> <u>2018</u>	<u>December 31,</u> <u>2017</u>
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	<u>156,793</u>	<u>131,605</u>
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	<u>\$ 439,443</u>	<u>\$ 412,138</u>
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	<u>46,902</u>	<u>39,228</u>
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	<u>\$ 246,978</u>	<u>\$ 237,382</u>
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	<u>192,465</u>	<u>174,756</u>
Total Liabilities and Stockholders' Equity	<u>\$ 439,443</u>	<u>\$ 412,138</u>

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)

	<i>Three Months Ended September 30,</i>		<i>Nine Months Ended September 30,</i>	
	<i>2018</i>	<i>2017</i>	<i>2018</i>	<i>2017</i>
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)

	<i>Three Months Ended September 30,</i>		<i>Nine Months Ended September 30,</i>	
	<i>2018</i>	<i>2017</i>	<i>2018</i>	<i>2017</i>
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	<u>\$ 5,354</u>	<u>\$ 4,720</u>	<u>\$ 10,597</u>	<u>\$ 8,553</u>

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)

	<i>Nine Months Ended September 30,</i>	
	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 focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, 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	
	September 30, 2018	September 30, 2017	September 30, 2018	September 30, 2017
Location of Operations				
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.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
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		Nine Months Ended	
	September 30, 2018	September 30, 2017	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		Nine Months Ended	
	September 30, 2018	September 30, 2017	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.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
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		Administrative	Prompt
		Rebates	Returns	Fees and Other	Payment
	Rebates	Rebates	Rebates	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	<u>\$ 17,287</u>
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	<u>20,366</u>
Accounts payable and other current liabilities	2,413
Deferred revenue	666
Total liabilities assumed	<u>3,079</u>
Net assets acquired	<u>\$ 17,287</u>

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.

(in thousands)	Three Months Ended		Nine Months Ended	
	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.

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

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	<u>\$ 134,122</u>	<u>\$ 128,208</u>

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.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
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	<u>\$ 5,692</u>	<u>\$ 3,353</u>
(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	<u>\$ 65,954</u>	<u>\$ 69,946</u>

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

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:

(in thousands)	Three Months Ended		Nine Months Ended	
	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.

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
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.

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

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		Diluted		Basic		Diluted	
	Three Months Ended September 30,		Three Months Ended September 30,		Nine Months Ended September 30,		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	<u>\$ 4,986</u>	<u>\$ 4,685</u>	<u>\$ 4,986</u>	<u>\$ 4,685</u>	<u>\$ 9,963</u>	<u>\$ 8,489</u>	<u>\$ 9,963</u>	<u>\$ 8,489</u>
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	<u>\$ 40,006</u>	<u>\$ 37,727</u>

(1) Includes inventory acquired in acquisition of WellSpring (Note 3).

(2) Includes finished goods acquired in asset purchases (Note 13).

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

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
	<u>45,065</u>	<u>26,992</u>
Less: accumulated depreciation	(7,647)	(6,589)
Property, Plant, and Equipment, net	<u>\$ 37,418</u>	<u>\$ 20,403</u>

(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.

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

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.

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

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
NDA's 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
	<u>\$ 288,215</u>	<u>\$ (78,671)</u>	<u>\$ 284,716</u>	<u>\$ (54,926)</u>	

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	<u>\$ 209,544</u>

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

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 administrative	1,564	1,270	4,266	4,059
	\$ 1,772	\$ 1,462	\$ 4,896	\$ 4,612

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

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	<u>760</u>	<u>86</u>
Outstanding December 31, 2017	767	86
Granted	156	65
Options Exercised/RSAs Vested	(140)	(33) ⁽²⁾
Forfeited	(22)	-
Outstanding September 30, 2018	<u>761</u>	<u>118</u>

⁽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.

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

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.

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

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.

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

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.

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

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 27th, 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.

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

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 focused on delivering value to our customers by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals. We focus on niche and high barrier to entry opportunities including controlled substances, anti-cancer (oncolytics), hormones and steroids, and complex formulations. We have 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

Cholestyramine
Desipramine Hydrochloride
Diphenoxylate Hydrochloride and Atropine Sulfate
Erythromycin Ethylsuccinate
Esterified Estrogen with Methyltestosterone
Etodolac
Ezetimibe-Simvastatin
Felbamate
Fenofibrate
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

Branded Products

Arimidex
Casodex
Cortenema
Inderal LA
Inderal XL
InnoPran XL
Lithobid
Reglan
Vancocin

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

- **Formulation Complexity.** Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that we intend to leverage in selecting products to develop or manufacture.
- **Patent Status.** We seek to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.
- **Market Size.** When determining whether to develop or acquire an individual product, we review the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. We endeavor to manufacture products with sufficient market size to enable us to enter the market with a strong likelihood of being able to price our products both competitively and at a profit.
- **Profit Potential.** We research the availability and cost of active pharmaceutical ingredients 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,		Change	% Change
	2018	2017		
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	<u>\$ 50,703</u>	<u>\$ 48,164</u>	<u>\$ 2,539</u>	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,		Change	% Change
	2018	2017		
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,		Change	% Change
	2018	2017		
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,		Change	% Change
	2018	2017		
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,		Change	% Change
	2018	2017		
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.

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,		Change	% Change
	2018	2017		
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	<u>\$ 144,454</u>	<u>\$ 129,556</u>	<u>\$ 14,898</u>	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,		Change	% Change
	2018	2017		
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,		Change	% Change
	2018	2017		
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,		Change	% Change
	2018	2017		
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,		Change	% Change
	2018	2017		
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	<u>\$ 156,793</u>	<u>\$ 131,605</u>
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	<u>\$ 46,902</u>	<u>\$ 39,228</u>

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.

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 on 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 on 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
<u>10.1</u>	<u>Stock Purchase Agreement by and among WellSpring Pharma Services Inc., WSP Pharma Holdings, LLC, ANI Pharmaceuticals Canada Inc., and ANI Pharmaceuticals, Inc.</u>
<u>31.1</u>	<u>Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>31.2</u>	<u>Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
<u>32.1</u>	<u>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.</u>
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)

STOCK PURCHASE AGREEMENT
DATED AS OF
AUGUST 6, 2018
BY AND AMONG

WellSpring Pharma Services Inc.,

as the Company,
WSP Pharma Holdings, LLC,

as Seller,

ANI Pharmaceuticals Canada Inc. ,

as Purchaser,

AND

ANI Pharmaceuticals, Inc. ,

as Parent (solely for purposes of Section 8.18)

TABLE OF CONTENTS

	Page
ARTICLE I—CERTAIN DEFINITIONS	1
Section 1.1 Certain Definitions	1
Section 1.2 Interpretive Provisions	12
ARTICLE II—PURCHASE AND SALE	13
Section 2.1 Purchase and Sale of the Shares	13
Section 2.2 Purchase Price	13
Section 2.3 Adjustment to Purchase Price and Closing Deliverables.	13
Section 2.4 Closing	18
Section 2.5 Section 116 of the Tax Act	18
ARTICLE III—REPRESENTATIONS AND WARRANTIES OF THE COMPANY	19
Section 3.1 Organization; Good Standing; Qualification and Power	19
Section 3.2 Authority; Execution and Delivery; Enforceability	19
Section 3.3 Non-contravention	20
Section 3.4 Consents	20
Section 3.5 Capitalization	20
Section 3.6 Financial Statements	20
Section 3.7 Absence of Undisclosed Liabilities	22
Section 3.8 Absence of Certain Developments	22
Section 3.9 Compliance with Laws.	24
Section 3.10 Litigation	25
Section 3.11 Taxes	25
Section 3.12 Environmental Matters	27
Section 3.13 Employee Matters	28
Section 3.14 Employee Benefit Plans	29
Section 3.15 Intellectual Property Rights	30
Section 3.16 Contracts	31
Section 3.17 Insurance	32
Section 3.18 Real Property	33
Section 3.19 Transaction with Affiliates	34
Section 3.20 Title and Condition of Assets; Sufficiency of Assets	34
Section 3.21 Customers	34
Section 3.22 Anti-Bribery	34
Section 3.23 International Trade Matters; Export Control and Import Laws	35
Section 3.24 Indebtedness	36
Section 3.25 Privacy and Data Security	36
Section 3.26 Information Technology	37
Section 3.27 Regulatory Matters	37
Section 3.28 Government Contracts	38
Section 3.29 Inventory	38
Section 3.30 Brokers	38

Section 3.31	Books and Records	38
Section 3.32	NO ADDITIONAL REPRESENTATIONS	39
ARTICLE IV —REPRESENTATIONS AND WARRANTIES OF SELLER		39
Section 4.1	Shares	39
Section 4.2	Authority	39
Section 4.3	Non-Contravention	40
Section 4.4	Seller Consents	40
Section 4.5	NO ADDITIONAL REPRESENTATIONS	40
ARTICLE V —REPRESENTATIONS AND WARRANTIES OF PURCHASER		41
Section 5.1	Organization	41
Section 5.2	Authorization	41
Section 5.3	Non-contravention	41
Section 5.4	Consents	41
Section 5.5	Litigation	42
Section 5.6	Brokers	42
Section 5.7	R&W Insurance Policy	42
Section 5.8	Acknowledgement by Purchaser	42
ARTICLE VI —COVENANTS AND AGREEMENTS		43
Section 6.1	Confidentiality; Reservation of Documents	43
Section 6.2	Personal Information	44
Section 6.3	No Modification of R&W Insurance Policy	44
Section 6.4	Reasonable Efforts; Further Assurances	44
Section 6.5	Public Announcements	45
Section 6.6	Indemnification of Directors and Officers	46
Section 6.7	Transfer Taxes	46
Section 6.8	Tax Matters	46
Section 6.9	Seller Release	47
Section 6.10	Use of Name	47
ARTICLE VII —SURVIVAL OF REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION		48
Section 7.1	Survival of Representations and Warranties	48
Section 7.2	General Indemnification	48
Section 7.3	Third Party Claims.	49
Section 7.4	Limitations on Indemnification Obligations	50
Section 7.5	Release of Indemnity Escrow Funds.	52
Section 7.6	Exclusive Remedy	52
ARTICLE VIII —MISCELLANEOUS		53
Section 8.1	Notices	53
Section 8.2	Exhibits and Schedules	54
Section 8.3	Time of the Essence; Computation of Time	54
Section 8.4	Expenses	54
Section 8.5	Governing Law	54

Section 8.6	Jurisdiction and Venue	55
Section 8.7	Assignment; Successors and Assigns; No Third Party Rights	55
Section 8.8	Counterparts	55
Section 8.9	Titles and Headings	55
Section 8.10	Entire Agreement	56
Section 8.11	Severability	56
Section 8.12	No Strict Construction	56
Section 8.13	Specific Performance	56
Section 8.14	Waiver Of Jury Trial	56
Section 8.15	Failure or Indulgence not Waiver	56
Section 8.16	Amendments	57
Section 8.17	Conflicts; Privileges	57
Section 8.18	Parent Guarantee	57

Exhibits & Schedules

Exhibit A	<i>Non-Solicitation, No-Hire and Non-Disparagement Agreement</i>
Exhibit B	<i>Escrow Agreement</i>
Exhibit C	<i>Section 116 Escrow Agreement</i>
Schedule 1.1	<i>Funded Indebtedness</i>
Schedule 1.2	<i>Permitted Liens</i>
Schedule 1.3	<i>Sponsors</i>
Schedule 1.4	<i>Affiliates</i>
Schedule 2.3.1	<i>Estimated Purchase Price</i>
Schedule 2.3.1.2	<i>Wire Instructions</i>
Schedule 3.3	<i>Non-contravention</i>
Schedule 3.4	<i>Consents</i>
Schedule 3.5	<i>Capitalization</i>
Schedule 3.6.2	<i>GAAP Exceptions</i>
Schedule 3.7	<i>Absence of Undisclosed Liabilities</i>
Schedule 3.8	<i>Absence of Certain Developments</i>
Schedule 3.9	<i>Compliance with Laws</i>
Schedule 3.10	<i>Litigation</i>
Schedule 3.11	<i>Taxes</i>
Schedule 3.12	<i>Environmental Matters</i>
Schedule 3.16	<i>Contracts</i>
Schedule 3.17	<i>Insurance</i>
Schedule 3.21	<i>Customers</i>
Schedule 4.4	<i>Seller Consents</i>
Schedule 5.4	<i>Consents</i>

STOCK PURCHASE AGREEMENT

This STOCK PURCHASE AGREEMENT (this “Agreement”), dated as of August 6, 2018, is by and among (i) WellSpring Pharma Services Inc., a Nova Scotia company limited by shares (the “Company”), (ii) WSP Pharma Holdings, LLC, a Delaware limited liability company (“Seller”), (iii) ANI Pharmaceuticals Canada Inc., a Nova Scotia company limited by shares (“Purchaser”), and (iv) ANI Pharmaceuticals, Inc., a Delaware corporation (“Parent”) (solely for purposes of Section 8.18).

RECITALS

WHEREAS, the Company is engaged in the business of providing outsourced contract pharmaceutical product development and manufacturing services for third party customers based in the United States, Canada and Australia (the “Business”);

WHEREAS, Seller owns beneficially and of record all of the issued and outstanding common shares in the capital of the Company, consisting of 24,966,694 common shares without nominal or par value (the “Shares,” and each individually, a “Share”);

WHEREAS, Seller desires to sell to Purchaser, and Purchaser desires to purchase from Seller, all of the Shares upon the terms and conditions hereinafter set forth; and

NOW, THEREFORE, in consideration of the mutual covenants contained herein and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, and intending to be legally bound, the parties hereto agree as follows:

ARTICLE I—CERTAIN DEFINITIONS

Section 1.1 *Certain Definitions* . As used in this Agreement, the following terms have the respective meanings set forth below.

“2017 Audited Financial Statements” has the meaning set forth in Section 3.6.1.1.

“Accounting Firm” has the meaning set forth in Section 2.3.3.3.

“Accounting Principles” means GAAP applied on a basis consistent with the methodologies, practices, classifications, judgments, estimation techniques, assumptions, and principles used by the Company in the preparation of the Latest Balance Sheet, except (i) to the extent that the methodologies, practices, classifications, judgments, estimation techniques, assumptions, and principles used in the preparation of the Latest Balance Sheet are not in accordance with GAAP, or (ii) if any item included in an Adjustment Statement is not reflected in the Latest Balance Sheet, then in case of each of the foregoing clauses (i) and (ii), the methodologies, practices, classifications, judgments, estimation techniques, assumptions, and principles to be used with respect to the applicable item in such Adjustment Statement, as applicable, shall be as determined in accordance with GAAP. For further clarification, if alternative methodologies exist for calculating current asset and current liability balances under GAAP, the methodology utilized by the Company in the Latest Balance Sheet shall govern.

“Actual Adjustment” means the amount, which may be a positive or negative number, equal to (x) the Purchase Price as set forth on the Final Statement of Purchase Price minus (y) the Estimated Purchase Price.

“Additional Section 116 Escrow Amount” has the meaning set forth in the Section 116 Escrow Agreement.

“Adjustment Escrow Account” has the meaning set forth in the Escrow Agreement.

“Adjustment Escrow Amount” means an amount equal to \$600,000.

“Adjustment Escrow Funds” has the meaning set forth in the Escrow Agreement.

“Adjustment Statement” means any of the following deliverables under this Agreement: (i) Schedule 2.3.1 (Estimated Purchase Price), (ii) the Proposed Closing Date Calculations, (iii) a Purchase Price Dispute Notice, or (iv) any disputed items submitted to the Accounting Firm under Section 2.3.3.3.

“Affiliate” means, with respect to any Person, any other Person who directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term “control” means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract or otherwise, and the terms “controlled” and “controlling” have meanings correlative thereto. For the avoidance of doubt, the individual set forth on Schedule 1.4 shall not be deemed an Affiliate of the Company or the Seller.

“Agreement” has the meaning set forth in the preamble to this Agreement.

“Business” has the meaning set forth in the recitals to this Agreement.

“Business Day” means a day, other than a Saturday or Sunday, on which commercial banks in New York, New York, Baudette, Minnesota, and Toronto, Canada are open for the general transaction of business.

“Cash and Cash Equivalents” means, without duplication, the sum of the fair market value of (a) all cash plus (b) cash equivalents (including marketable securities and short term investments) plus (c) \$50,000; *provided* that “Cash and Cash Equivalents” (i) in each of the foregoing clauses (a) and (b), shall be Cash and Cash Equivalents of the Company determined in accordance with the Accounting Principles as of immediately prior to the Closing, (ii) shall not include any cash which is restricted cash (it being understood and agreed that the C\$10,000 required to be held in connection with the termination of the Credit Facility shall not be restricted cash), and (iii) shall be calculated net of issued but uncleared checks and bank drafts to the extent such checks and bank drafts are not counted as a current liability in the calculation of Net Working Capital.

“Claim” means any action, suit, case, litigation, proceeding, claim, arbitration, charge, criminal prosecution, investigation, demand letter, warning letter, finding of deficiency or non-compliance, adverse inspection report, notice of violation, notice of alleged liability, penalty, fine, sanction, subpoena, request for recall or remedial action.

“Closing” has the meaning set forth in Section 2.4.

“Closing Date” has the meaning set forth in Section 2.4.

“Closing Date Funded Indebtedness” means the Funded Indebtedness as of immediately prior to the Closing.

“Closing Liabilities” means, without duplication and to the extent not included in Funded Indebtedness, Net Working Capital or Seller Expenses, and to the extent not paid in full prior to or at the Closing, (i) any payments owing by the Company under stock appreciation rights, phantom equity or similar plans, in each case attributable to periods prior to the Closing, plus the Company’s share of any payroll Taxes due in connection with any such payments, (ii) deferred compensation, severance, bonus and profit sharing payments of the Company to employees attributable to pre-Closing periods, plus the Company’s share of any payroll Taxes due in connection with any such payments, (iii) any sale bonuses, profit sharing payments, change in control bonuses or retention bonuses that become payable by the Company upon, and solely by reason of, the consummation of the transactions contemplated hereby and that were incurred by the Company prior to the Closing, plus the Company’s share of any payroll Taxes due in connection with any such payments, and (iv) all Taxes of the Company (a) with respect to a taxable period ending on or prior to the Closing Date, the Tax Returns for which have not been filed on or before the Closing Date, and (b) for the portion of fiscal year 2018 ending on the Closing Date (determined in accordance with Section 6.8.1). The determination of clause (iv) in the preceding sentence shall, to the extent permitted by applicable Tax law, treat any deductions for Seller Expenses or Closing Liabilities available to the Company as deductions in such pre-Closing period.

“Company” has the meaning set forth in the preamble to this Agreement.

“Company Intellectual Property Rights” has the meaning set forth in Section 3.15.

“Confidentiality Agreement” means the Non-Disclosure Agreement, dated January 26, 2018, by and between Fairmount Partners (on behalf of the Company) and Parent.

“Contracts” has the meaning set forth in Section 3.16.

“Controlled Substance” means any substance set forth in 21 U.S.C. § 812, and/or attendant federal or state regulations, including but not limited to, 21 C.F.R. Part 1308.

“Covington” has the meaning set forth in Section 8.17.

“CRA” means the Canada Revenue Agency.

“Credit Facility” means the revolving demand facility in the principal amount of up to C\$3,000,000 pursuant to a demand operating facility agreement accepted on December 21, 2017 between The Toronto-Dominion Bank, as lender, and the Company, as borrower.

“Current Good Manufacturing Practices” means the current good manufacturing practices for drugs and finished pharmaceutical products contained in 21 C.F.R. Part 210 and 211 as in effect at the time of manufacture and, in the case of active pharmaceutical ingredients, means the ICH Q7A Guidance, Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients.

“Data Security Requirements” means all of the following, to the extent relating to privacy or data security and applicable to the Company: (a) all applicable laws; (b) Payment Card Industry Data Security Standard (PCI DSS) and (c) the Company’s written security policies.

“Deductible” has the meaning set forth in Section 7.4.3.

“Discussions Period” has the meaning set forth in Section 2.3.3.3.

“Documents” means this Agreement, the Escrow Agreement, and the Non-Solicitation, No-Hire and Non-Disparagement Agreements and the other agreements, instruments, and documents contemplated by any of the foregoing agreements to be entered into at or prior to the Closing, including each exhibit hereto and thereto.

“Employee Benefit Plan” means all written and unwritten, registered or unregistered, funded or unfunded compensation or severance plans, pension plans, supplemental pension plans, retirement savings plans or arrangements, savings bonds plans and group insurance plans for life insurance, accidental death and dismemberment, disability, health care, dental care and medical travel insurance benefits, termination, supplemental unemployment benefits, bonus, incentive, profit sharing, change of control, retention, retirement, stock option, stock purchase, stock appreciation, employee assistance, welfare and fringe benefits and similar plans, programs or arrangements (i) that are administered, sponsored, maintained, contributed to, required to be contributed to or offered to current or former employees of Company as of the date of this Agreement, or (ii) with respect to which the Company has or may have any liability or obligation, including in the case of (i) or (ii) any such plan, program or arrangement offered or provided pursuant to an employment agreement, offer letter or labor agreement, except for any statutory plans to which Company is obliged to contribute or comply with, including the Canada Pension Plan and plans administered pursuant to applicable federal or provincial health, workers’ compensation or employment insurance legislation.

“Enterprise Value” means \$18,000,000.

“Environmental Laws” means all applicable federal, state, provincial, municipal, local and foreign statutes, regulations, ordinances and common law concerning pollution or protection of the natural environment and human health (including all those relating to the generation, handling, transportation, treatment, storage, disposal, distribution, labeling, discharge, release, control, or cleanup of any toxic or hazardous materials, substances or wastes), as such of the foregoing are in effect on or prior to the Closing Date, including requirements under Canada’s Workplace Hazardous Materials Information System.

“Escrow Agent” has the meaning set forth in Section 2.3.1.1.

“Escrow Agreement” has the meaning set forth in Section 2.3.1.1.

“Escrow Amount” means the Adjustment Escrow Amount plus the Indemnity Escrow Amount.

“Estimated Purchase Price” means a good faith estimate of the Purchase Price, as prepared in accordance with the Accounting Principles by the Company, with each component of the Purchase Price (including each line item category of Net Working Capital) as set forth on Schedule 2.3.1.

“Export Controls” has the meaning set forth in Section 3.23.1.

“FCPA” has the meaning set forth in Section 3.22.1.

“FDA” means the U.S. Food and Drug Administration.

“FDC Act” means the Federal Food, Drug, and Cosmetic Act, as amended.

“Final Statement of Purchase Price” has the meaning set forth in Section 2.3.3.3.

“Financial Advisor” means Fairmount Partners, L.P.

“Financial Statements” has the meaning set forth in Section 3.6.1.

“fraud” means that all of the following elements have been satisfied: (a) the representations and warranties contained in Article III, Article IV or Article V (as modified by the Schedules) contain a false statement of a material fact, (b) the party making such false statement of material fact (i) has actual knowledge of the falsity of such statement, (ii) makes such false statement with the intent to deceive the party to whom such false statement of material fact is made and (iii) makes such false statement with the intent to induce reliance in the party to whom such false statement of material fact is made, and (c) the party to whom such false statement of material fact is made (i) justifiably relies on such false statement of fact and (ii) suffers actual Loss as a result of such reliance. In no event shall any Person be liable for the fraud of any other Person.

“Funded Indebtedness” means, as of any date, without duplication, the sum of the outstanding principal amount of, accrued and unpaid interest on and other payment obligations (including any prepayment penalties, premiums, breakage costs, fees and other costs and expenses associated with repayment) arising under any obligations of the Company consisting of (i) indebtedness for borrowed money owed to any third party or indebtedness issued in substitution or exchange for borrowed money or for the deferred purchase price of property or services (other than trade payables and accrued expenses arising in the ordinary course of business substantially consistent with past practices), (ii) indebtedness evidenced by any note, bond, debenture or other debt security, (iii) any obligations of the Company as lessee under the leases that have been recorded as capital leases in accordance with GAAP, (iv) obligations under acceptance credit, letters of credit, performance bonds, surety bonds or similar facilities, in each case, to the extent drawn, (v) obligations under direct financing leases and purchase money or vendor financing (in each case, other than with respect to trade payables, accrued expenses, current accounts and similar obligations to the extent included within Net Working Capital), (vi) the full amount of any direct or indirect obligations in respect of any earnout, assets or services, with respect to which the Company is liable, contingent or otherwise, as obligor or otherwise, (vii) Indebtedness secured by any Lien, (viii) deferred rent, (ix) Indebtedness guaranteed by the Company, (x) any drawn obligations under surety or performance bonds and similar instruments, banker’s acceptance or any bank overdrafts and similar charges, (xi) accrued and unpaid dividends, distributions, management fees, or other similar payments to direct or indirect equityholders, (xii) items set forth on Schedule 1.1 or (xiii) intercompany liabilities (to the extent not eliminated or settled prior to the Closing Date). Notwithstanding the foregoing, “Funded Indebtedness” shall not include (a) any obligations under operating leases, (b) any undrawn letter of credit and (c) any amounts taken into account in calculating Net Working Capital or Seller Expenses.

“GAAP” means generally accepted accounting principles as in effect from time to time in the United States, applied on a consistent basis.

“GAAP Financial Statements” has the meaning set forth in Section 3.6.1.2.

“Governing Documents” means the legal document(s) by which any Person (other than an individual) establishes its legal existence or which govern its internal affairs. For example, the “Governing Documents” of the Company are its certificate of incorporation, memorandum of association and articles of association, the “Governing Documents” of a corporation are its certificate or articles of incorporation and by-laws, the “Governing Documents” of a limited partnership are its certificate of formation and its limited partnership agreement and the “Governing Documents” of a limited liability company are its certificate of formation and its operating agreement or limited liability company agreement.

“Governmental Authority” means the government of any nation, state, province, commonwealth, territory, possession, county, or municipality thereof, or the government of any political subdivision of any of the foregoing, or any entity, authority, agency, ministry or other similar body exercising executive, legislative, judicial, regulatory or administrative authority or functions of or pertaining to government, including any authority or other quasi-governmental entity established to perform any of such functions, in each case, where such Person acts with executive branch power.

“Health Canada” means the Department of Health of the federal government of Canada.

“Improper Payment Laws” has the meaning set forth in Section 3.22.1.

“Indemnified Party” has the meaning set forth in Section 7.3.1.

“Indemnity Escrow Account” has the meaning set forth in the Escrow Agreement.

“Indemnity Escrow Amount” means an amount equal to \$90,000.

“Indemnity Escrow Funds” has the meaning set forth in the Escrow Agreement.

“Intellectual Property Rights” means all issued patents and patent applications, all trademarks, tradenames, business names, and service marks and applications, registrations and renewals with respect thereto and goodwill associated therewith, all domain names and URLs, all copyrights and applications, registrations, and renewals with respect thereto, and all trade secrets, in each case, to the extent protectable under applicable law.

“IT Assets” has the meaning set forth in Section 3.26.

“ITAR” has the meaning set forth in Section 3.23.1.

“Knowledge” means, with respect to any Person, actual knowledge without independent investigation (and except as expressly set forth herein shall in no event encompass constructive, imputed or similar concepts of knowledge); *provided* that in the case of the Company, such actual knowledge shall (i) be limited to the Knowledge of Sam Richezza, Wendy Shusko and David Watt, and (ii) include any Knowledge which such person would have obtained as a result of reasonable inquiry of such person’s direct reports.

“Latest Balance Sheet” has the meaning set forth in Section 3.6.1.2.

“Legal Counsel” has the meaning set forth in Section 8.17.

“Lien” means any mortgage, pledge, security interest, encumbrance, lien, or charge of any kind. For avoidance of doubt, “Lien” shall not include any license or option of, or covenant or other right with respect to any, Intellectual Property Rights.

“Listed Chemical” means any List I Chemical, List II Chemical, and Schedule Listed Chemical Product as those terms are defined under the Controlled Substances Act or regulations implemented by the Drug Enforcement Administration.

“Loss” means any actual loss, liability, demand, claims, cause of action, cost, damage, obligation, debt, deficiency, Tax, assessment, penalty, fine, or expense (including interest, penalties, reasonable attorneys’ fees and expenses, and all amounts paid in investigation, defense or settlement of any of the foregoing and enforcement of its rights hereunder whether or not litigation has commenced); *provided* that “Losses” shall not include any and all punitive damages, except to the extent such damages are payable to a third party in a Third Party Claim.

“Material Adverse Effect” means an event, circumstance, occurrence, change, action or omission, or development that has, or would reasonably be expected to have, individually or in the aggregate, a material adverse effect on the financial condition, business or results of operations, of the Company; *provided*, that any change, event or effect arising from or related to: (i) conditions affecting the Business generally, the industries, markets or geographical areas in which the Company conducts activities generally, or the economy or political climate generally; (ii) acts of terrorism, sabotage, military action, armed hostilities, or war (whether or not declared), or the escalation or worsening thereof; (iii) financial, credit, banking or securities markets (including any disruption thereof, any decline in the price of any security or any market index and changes in interest rates or the availability of financing); (iv) changes in accounting requirements or principles (including GAAP); (v) changes in any laws, rules, regulations, orders, or other binding directives issued by any Governmental Authority or interpretations thereof; (vi) any failure by the Company to meet any internal or published projections, forecasts or revenue or earnings predictions for any period ending on or after the date of this Agreement (it being understood that the underlying causes of such failure may, if they are not otherwise excluded from the definition of Material Adverse Effect, be taken into account in determining whether a Material Adverse Effect has occurred); (vii) any changes in the price of products, supplies, and materials from third-party suppliers; or (viii) changes in weather, meteorological conditions or climate or natural disasters (including hurricanes, storms, tornados, flooding, earthquakes, volcanic eruptions, fires, tsunamis or similar occurrences) affecting the Business, shall not be taken into account in determining whether a “Material Adverse Effect” has occurred or would reasonably be expected to occur; *provided, that*, the exceptions contained in the foregoing (i), (ii), (iii), (iv), (v), (vii), and (viii) shall be disregarded in determining whether a Material Adverse Effect has occurred solely to the extent that such change has a disproportionate adverse effect on the Company compared to other participants in the industries or markets in which the Company operates.

“Material Customers” means the 10 largest customers of the Company as measured by the dollar amount of revenue received by the Company from such customers during the twelve (12) months ended on May 31, 2018.

“Material Permits” has the meaning set forth in Section 3.9.2.

“Net Working Capital” means (i) the net book value of the current assets of the Company as of 11:59 P.M. Eastern Time on the day immediately prior to the Closing Date that are included in the line item categories of current assets on Schedule 2.3.1, less (ii) the net book value of the current liabilities of the Company as of 11:59 P.M. Eastern Time on the day immediately prior to the Closing Date that are included in the line item categories of current liabilities on Schedule 2.3.1; provided, however, that in both clauses (i) and (ii), as applicable, Net Working Capital shall (x) exclude (a) the current portion of any Closing Date Funded Indebtedness and accrued interest taken into account in Funded Indebtedness, (b) the Seller Expenses and the Closing Liabilities, (c) all intercompany payables and receivables, (d) current and deferred Tax assets and current and deferred Tax liabilities, (e) Cash and Cash Equivalents and (f) the items set forth on Schedule 1.1, in each case, without duplication, and (y) determined in accordance with the Accounting Principles.

“Net Working Capital Adjustment” means (i) the amount by which Net Working Capital exceeds the Net Working Capital Target, or (ii) the amount by which Net Working Capital is less than the Net Working Capital Target, in each case, if applicable; *provided* that any amount which is calculated pursuant to clause (ii) above shall be deemed to be a negative number.

“Net Working Capital Target” means \$2,944,000.

“Non-Solicitation, No-Hire and Non-Disparagement Agreements” means each of the Non-Solicitation, No-Hire and Non-Disparagement Agreements entered into on the Closing Date between the Company and each Sponsor, each in the form attached hereto as Exhibit A.

“OFAC” has the meaning set forth in Section 3.23.1.

“Owned Real Property” has the meaning set forth in Section 3.18.1.

“Parent” has the meaning set forth in the preamble to this Agreement.

“Permitted Liens” means (a) mechanics, materialmen’s, construction, carrier’s, repairer’s and other Liens arising or incurred in the ordinary course of business substantially consistent with past practices relating to obligations shown in the financial records of the Company disclosed to the Purchaser and that are not yet delinquent or are being contested in good faith; (b) Liens for Taxes, assessments or other governmental charges not yet delinquent or which are being contested in good faith; (c) easements, restrictive covenants, restrictions, rights of way and similar encumbrances affecting title to real property that do not materially interfere with the present uses of such real property, including any right of expropriation and including Liens of any nature claimed by or held by Her Majesty the Queen in Right of Canada or Her Majesty the Queen in Right of any province of Canada in which the Owned Real Property is located; (d) Liens granted to any lender at the Closing in connection with any financing by Purchaser of the transactions contemplated hereby; (e) zoning, building codes and other land use laws regulating the use or occupancy of real property or the activities conducted thereon which are imposed by any Governmental Authority having jurisdiction over such real property which are not violated in any material respect by the current use or occupancy of such real property or the operation of the Business; (f) matters that would be disclosed by an accurate survey of real property; (g) purchase money Liens and Liens securing rental payments under lease arrangements relating to obligations shown in the financial records of the Company disclosed to the Purchaser prior to the date of this Agreement; (h) Liens arising under worker’s compensation, unemployment insurance, social security, retirement or other similar Liens incurred in the ordinary course of business relating to obligations shown in the financial records of the Company disclosed to the Purchaser prior to the date of this Agreement and that are not yet delinquent or that are being contested in good faith; and (i) Liens described on Schedule 1.2.

“Person” means an individual, partnership, corporation, limited liability company, joint stock company, unincorporated organization or association, trust, joint venture, association or other organization, whether or not a legal entity or a Governmental Authority.

“Personal Information” means information about an individual who can be identified by the Person who holds that information.

“Personal Property” has the meaning set forth in Section 3.20.1.

“Privacy Laws” means any laws that regulate the collection, use or disclosure of Personal Information.

“Proceedings” has the meaning set forth in Section 3.10.

“Product” means any product tested, manufactured, produced, supplied, packaged, labelled, stored, or prepared for shipment by or on behalf of the Company prior to the Closing Date, including all such products that are currently subject to any of the Company’s existing Contracts.

“Prohibited Fund” has the meaning set forth in Section 3.22.3.

“Prohibited Payment” has the meaning set forth in Section 3.22.2.

“Prohibited Person” has the meaning set forth in Section 3.23.2.

“Proposed Cash and Cash Equivalents” has the meaning set forth in Section 2.3.3.1.

“Proposed Closing Date Calculations” has the meaning set forth in Section 2.3.3.1.

“Proposed Closing Date Funded Indebtedness” has the meaning set forth in Section 2.3.3.1.

“Proposed Closing Date Statement of Net Working Capital” has the meaning set forth in Section 2.3.3.1.

“Proposed Closing Liabilities” has the meaning set forth in Section 2.3.3.1.

“Proposed Purchase Price Calculation” has the meaning set forth in Section 2.3.3.1.

“Proposed Seller Expenses” has the meaning set forth in Section 2.3.3.1.

“Purchase Price” means (i) the Enterprise Value, plus (ii) the Net Working Capital Adjustment (which may be a negative number), plus (iii) the amount of Cash and Cash Equivalents, minus (iv) the amount of Closing Date Funded Indebtedness, minus (v) the amount of Seller Expenses, minus (v) the amount of Closing Liabilities.

“Purchase Price Dispute Notice” has the meaning set forth in Section 2.3.3.3.

“Purchaser” has the meaning set forth in the preamble to this Agreement.

“Purchaser Indemnitee” has the meaning set forth in Section 7.2.1.

“Regulatory Licenses” has the meaning set forth in Section 3.27.2.

“Responsible Party” has the meaning set forth in Section 7.3.1.

“R&W Insurance Policy” means that certain buy-side representations and warranty insurance policy number 18126469 issued by the R&W Policy Provider for the benefit of the Purchaser Indemnitees.

“R&W Policy Provider” means AIG Specialty Insurance Company.

“Schedules” has the meaning set forth in the introductory paragraph to Article III.

“Section 116 Certificate” has the meaning set forth in Section 2.5.1.

“Section 116 Escrow Account” has the meaning set forth in Section 2.5.2.

“Section 116 Escrow Amount” has the meaning set forth in Section 2.5.2.

“Section 116 Escrow Agreement” has the meaning set forth in Section 2.3.1.2.

“Securities Act” means the Securities Act of 1933, as amended (together with the rules and regulations promulgated thereunder).

“Seller” has the meaning set forth in the preamble to this Agreement.

“Seller’s Equityholder” has the meaning set forth in Section 8.17.

“Seller Expenses” means, without duplication, the collective amount of all out-of-pocket costs and expenses incurred by the Company or for which the Company is obligated to reimburse another Person whether accrued for or not, in connection with the sale of the Company (including any contemplated sale of the Company alternative to the transaction contemplated hereby), payable by the Company to outside legal counsel, accountants, advisors, brokers and other third parties and unpaid as of the Closing (*provided* that any item taken into account in Net Working Capital shall be excluded from “Seller Expenses”). “Seller Expenses” shall include (a) any costs or expenses incurred by Seller or the Company in obtaining the Tail Policy in accordance with Section 6.6, (b) an amount equal to the lesser of (i) fifty percent (50%) of all out-of-pocket costs and expenses incurred by Purchaser in connection with the acquisition of the R&W Insurance Policy (including any premiums, commissions and due diligence fees due to the R&W Policy Provider) and (ii) \$100,000, and (c) Taxes payable by Seller in accordance with Section 6.7.

“Seller Indemnitee” has the meaning set forth in Section 7.2.2.

“Shares” has the meaning set forth in the recitals to this Agreement.

“Sponsors” means the Persons set forth on Schedule 1.3.

“Straddle Period” means any taxable period beginning before and ending after the Closing Date.

“Subsidiary” means, with respect to any Person, any corporation, partnership, limited liability company, association or other business entity of which (i) if a corporation, a majority of the total voting power of shares of stock entitled (without regard to the occurrence of any contingency) to vote in the election of directors, managers or trustees thereof is at the time owned or controlled, directly or indirectly, by that Person or one or more of the other Subsidiaries of that Person or a combination thereof, or (ii) if a partnership, limited liability company, association or other business entity, a majority of the partnership or other similar ownership interests thereof is at the time owned or controlled, directly or indirectly, by any Person or one or more Subsidiaries of that Person or a combination thereof. For purposes hereof, a Person or Persons shall be deemed to have a majority ownership interest in a partnership, limited liability company, association or other business entity if such Person or Persons shall be allocated a majority of partnership, limited liability company, association or other business entity gains or losses or shall be or control the managing director, managing member, general partner or other managing Person of such partnership, limited liability company, association or other business entity.

“Tax” or “Taxes” means any federal, state, provincial, municipal, land transfer, local or foreign income, gross receipts, franchise, estimated, alternative minimum, add-on minimum, sales, goods and services, harmonized sales, Quebec sales, use, transfer, real property gains, registration, value added, excise, natural resources, severance, stamp, occupation, windfall profits, customs, duties, real property, personal property, capital stock, social security (or similar), unemployment, disability, payroll, license, employee or other withholding, or other tax, of any kind whatsoever, including any interest, penalties or additions to tax or similar items in respect of the foregoing (whether disputed or not) and shall include any liability for such amounts as a result of (i) being a member of a combined, consolidated, unitary or affiliated group (including non-arm’s length, affiliated or combined group), (ii) a contractual obligation to indemnify any person or other entity or (iii) being a “transferee” (within the meaning of section 160 of the Tax Act or any other laws) of another taxpayer or entity.

“Tax Act” means the Income Tax Act (Canada), as amended.

“Tax Contest” means any audit, action, suit, proceeding, claim, examination, assessment investigation, claim, litigation, dispute or controversy related to Taxes.

“Tax Return” means any return, report, declaration, election, filing, claim for refund, information return or other document (including any related or supporting schedule, statement or information) filed or required to be filed in connection with the determination, assessment or collection of any Tax of any party or the administration of any laws, regulations or administrative requirements relating to any Tax (including any amendment thereof).

“Tail Policy” has the meaning set forth in Section 6.6.

“Third Party Claim” has the meaning set forth in Section 7.3.1.

“VAT Legislation” means laws of any Governmental Authority relating to or otherwise imposing Taxes levied on, or measured by, or referred to as sales, goods and services, use, value-added or excise, including all custom duties and import and export taxes, together with all interest, penalties, fines, additions to tax or other additional amounts imposed in respect thereof.

Section 1.2 *Interpretive Provisions* . Unless otherwise indicated to the contrary herein by the context or use thereof: (a) the words, “herein,” “hereto,” “hereof” and words of similar import refer to this Agreement as a whole and not to any particular Section or paragraph hereof; (b) the word “including” means “including, but not limited to”, whether or not such words appear; (c) the masculine gender shall also include the feminine and neutral genders, and vice versa; and (d) words importing the singular shall also include the plural, and vice versa. All references to “dollar” or “\$” mean the lawful currency of the United States of America. Unless otherwise specified, all accounting terms and principles shall be interpreted in accordance with GAAP. All calculations of all amounts payable by Seller, Purchaser or any of their Affiliates under this Agreement (including Losses, any Proposed Closing Date Calculations, the Final Statement of Purchase Price, the Actual Adjustment and all amounts payable by either Seller or Purchaser under Article VII) shall be calculated in United States dollars. If any such amounts are determined initially by reference to a foreign currency, such amounts will be converted into dollars based on the currency conversion rate published in *The Wall Street Journal* on (i) with respect to any Proposed Closing Date Calculations, the Final Statement of Purchase Price, the Actual Adjustment or any amount in Section 2.4, the date hereof and (ii) with respect to all other amounts, the date such amount is paid by the applicable party to the other party. The conversion of any amount determined initially by reference to a foreign currency into dollars for purposes of testing such amount against the thresholds contained in Section 3.16 (*Contracts*) shall be made based on the currency conversion rate published in *The Wall Street Journal* on the date hereof.

ARTICLE II —PURCHASE AND SALE

Section 2.1 *Purchase and Sale of the Shares.*

Section 2.1.1 Upon the terms and subject to the conditions of this Agreement, at the Closing, Seller shall sell to Purchaser the Shares, free and clear of all Liens, and Purchaser shall purchase such Shares from Seller.

Section 2.2 *Purchase Price.*

Section 2.2.1 The consideration due to Seller for the Shares to be purchased by Purchaser pursuant to Section 2.1.1 from Seller shall be a cash amount equal to the Purchase Price.

Section 2.2.2 The amount due pursuant to this Section 2.2 shall be a cash amount paid by Purchaser to Seller in accordance with, and as adjusted pursuant to, the provisions set forth in Section 2.3.

Section 2.3 *Adjustment to Purchase Price and Closing Deliverables.*

Section 2.3.1 Estimated Purchase Price. Schedule 2.3.1 sets forth a calculation of the Estimated Purchase Price prepared by the Company. On the Closing Date, the following payments shall be made:

Section 2.3.1.1 Purchaser shall pay a cash amount equal to, in the aggregate, the Escrow Amount to Citibank, N.A., as escrow agent (the “Escrow Agent”), which amount shall be deposited into the Adjustment Escrow Account and the Indemnity Escrow Account pursuant to the Escrow Agreement by and among Seller, Purchaser and the Escrow Agent attached as Exhibit B hereto (the “Escrow Agreement”);

Section 2.3.1.2 Purchaser shall withhold from the Estimated Purchase Price and pay a cash amount equal to, in the aggregate, the Section 116 Escrow Amount to the Escrow Agent, which amount shall be deposited into the Section 116 Escrow Account pursuant to the Section 116 Escrow Agreement by and among Seller, Purchaser and the Escrow Agent attached as Exhibit C hereto (the “Section 116 Escrow Agreement”);

Section 2.3.1.3 Purchaser shall pay a cash amount equal to the aggregate amount due to Seller in accordance with Section 2.2.1 minus the Escrow Amount and minus the Section 116 Escrow Amount, which amount shall be paid by wire transfer of immediately available funds to the account designated on Schedule 2.3.1.2;

Section 2.3.1.4 Purchaser shall pay, or cause the Company to pay, to the respective holders thereof, such holder’s respective portion of the estimated Closing Date Funded Indebtedness set forth on Schedule 2.3.1;

Section 2.3.1.5 Purchaser shall pay, or cause the Company to pay, the respective payees thereof such payee's applicable portion of the estimated Seller Expenses set forth on Schedule 2.3.1, and in the case of any respective Seller Expenses owed or otherwise payable in connection with the transaction to any employee of the Company with respect to any Employee Benefit Plan (including any transaction bonuses or similar amounts), Purchaser shall pay or cause the Company to pay, such amounts directly to the respective payee (and shall pay or withhold, or cause to be withheld or paid, as the case may be, any Taxes required to be withheld from such amount to the extent required in accordance with applicable Law and remitted to the applicable Tax authority), in each case in accordance with customary payroll practices; and

Section 2.3.1.6 Purchaser shall pay to the R&W Policy Provider (or its designee), an amount equal to one hundred percent (100%) of the premium for the R&W Insurance Policy and all other amounts payable with respect thereto.

Section 2.3.2 Actions at Closing. Upon the terms of this Agreement, at the Closing, the following shall occur:

Section 2.3.2.1 Purchaser shall deliver or cause to be delivered to Seller (i) a certificate executed by the secretary or other authorized Person of Purchaser attaching, and attesting to, (1) the Governing Documents of Purchaser, (2) the resolutions adopted by the Board of Directors of Purchaser with respect to the transactions contemplated by this Agreement and (3) the identities and signatures of the officers or other authorized Persons of Purchaser authorized to execute this Agreement and any other agreements to be executed by Purchaser in connection with the transactions contemplated by this Agreement; (ii) counterparts to the Escrow Agreement and the Section 116 Escrow Agreement duly executed by Purchaser or its applicable Affiliate; and (iii) a copy of the R&W Insurance Policy, accompanied by evidence that it has been bound; and

Section 2.3.2.2 Seller shall deliver or cause to be delivered to Purchaser (i) share certificates representing all of the Shares, duly endorsed in blank or accompanied by stock transfer powers or a lost certificate affidavit representing stock certificates which have been lost, stolen, or destroyed, (ii) letters of resignation from each of the officers and directors of the Company whose resignation Purchaser has requested prior to Closing, (iii) good standing certificates for each of Seller and the Company, in each case, dated no later than five (5) Business Days prior to Closing Date, (iv) customary payoff letters (to the extent applicable) from the applicable lenders with respect to all Funded Indebtedness set forth on Schedule 2.3.2.2(iv), together with all lien and mortgage releases as are reasonably necessary to release as of record all Liens securing any such Funded Indebtedness (in form and substance reasonably satisfactory to Purchaser), (v) a certificate executed by the secretary or other authorized Person of the Company attaching, and attesting to, (1) the Governing Documents of the Company, (2) the resolutions adopted by the Board of Directors of the Company with respect to the transactions contemplated by this Agreement and (3) the identities and signatures of the officers or other authorized Persons of the Company authorized to execute any agreements to be executed by the Company in connection with the transactions contemplated by this Agreement; (vi) a certificate executed by the secretary or other authorized Person of Seller attaching, and attesting to, (1) the Certificate of Formation of Seller, (2) the resolutions adopted by the Board of Managers of Seller with respect to the transactions contemplated by this Agreement and (3) the identities and signatures of the officers or other authorized Persons of Seller authorized to execute the Agreement and any other agreements to be executed by Seller in connection with the transactions contemplated by this Agreement, (vii) evidence reasonably satisfactory to Purchaser of the termination of any related party agreements between the Company, on one hand, and Seller or an Affiliate of Seller (other than the Company) on the other hand, (viii) an executed consent in connection with the transactions contemplated by this Agreement from each of the parties described on Schedule 2.3.2.2(viii), (ix) executed employment agreements from each of the individuals listed on Schedule 2.3.2.2(ix), (x) counterparts to the Escrow Agreement and the Section 116 Escrow Agreement duly executed by Seller or its applicable Affiliate, and (xi) evidence reasonably satisfactory to Purchaser of a fully-paid Tail Policy effective as of Closing.

Section 2.3.3 Preparation of the Final Statement of Purchase Price.

Section 2.3.3.1 As soon as practicable, but no later than ninety (90) days after the Closing Date, Purchaser shall prepare in good faith and deliver to Seller (A) a proposed calculation of the Net Working Capital (the “Proposed Closing Date Statement of Net Working Capital”), (B) a proposed calculation of the amount of Cash and Cash Equivalents (the “Proposed Cash and Cash Equivalents”), (C) a proposed calculation of the amount of Closing Date Funded Indebtedness (the “Proposed Closing Date Funded Indebtedness”), (D) a proposed calculation of the amount of Seller Expenses (the “Proposed Seller Expenses”), (E) a proposed calculation of Closing Liabilities (the “Proposed Closing Liabilities”) and (F) a proposed calculation of the Purchase Price (the “Proposed Purchase Price Calculation”) and, in each case, the components thereof. The Proposed Closing Date Statement of Net Working Capital, the Proposed Cash and Cash Equivalents, the Proposed Closing Funded Indebtedness, the Proposed Seller Expenses, the Proposed Closing Liabilities and the Proposed Purchase Price Calculation shall collectively be referred to herein from time to time as the “Proposed Closing Date Calculations.” Notwithstanding anything to the contrary set forth herein, if Purchaser fails to timely deliver any of the Proposed Closing Date Calculations, then the calculation of the Estimated Purchase Price shall represent the Final Statement of Purchase Price and shall be conclusive and binding on the parties hereto.

Section 2.3.3.2 Upon the delivery of the Proposed Closing Date Calculations to Seller, Purchaser shall provide reasonable access to Seller, Seller’s accountants, and Seller’s advisors during normal business hours to the Company’s accounting personnel, including the chief financial officer, the Company’s and/or Purchaser’s accountants (subject to customary access and indemnification letters), and the books and records of the Company solely as the foregoing relates to the preparation of the Proposed Closing Date Calculations for the sole purpose of completing the Final Statement of Purchase Price. Purchaser agrees that following the Closing Date and prior to the completion of the Final Statement of Purchase Price, Purchaser shall, and shall cause the Company to, preserve and not alter or destroy any of the books and records of the Company on which the calculation of the Purchase Price or any component thereof are to be based.

Section 2.3.3.3 If Seller does not give written notice of dispute (a “Purchase Price Dispute Notice”) to Purchaser within forty-five (45) days of receiving the Proposed Closing Date Calculations, Seller and Purchaser agree that (A) the Proposed Closing Date Statement of Net Working Capital shall be deemed to set forth the Net Working Capital, (B) the Proposed Cash and Cash Equivalents shall be deemed to set forth the Cash and Cash Equivalents, (C) the Proposed Closing Date Funded Indebtedness shall be deemed to set forth the Closing Date Funded Indebtedness, (D) the Proposed Seller Expenses shall be deemed to set forth the Seller Expenses, (E) the Proposed Closing Liabilities shall be deemed to set forth the Closing Liabilities and (F) the Proposed Purchase Price Calculation shall be deemed to set forth the Purchase Price; *provided* that, in the event Purchaser and the Company do not provide any papers or documents reasonably requested by Seller within five (5) days of request therefor (or such shorter period as may remain in such forty-five (45) day period), such forty-five (45) day period shall be extended by one day for each additional day required for Purchaser and the Company to fully respond to such request. If Seller gives a Purchase Price Dispute Notice to Purchaser within such forty-five (45)-day period (including, for the avoidance of doubt, any extended period pursuant to the preceding sentence), Purchaser and Seller will use commercially reasonable efforts to resolve the dispute during the forty-five (45)-day period (the “Discussions Period”) commencing on the date Purchaser receives the Purchase Price Dispute Notice from Seller. During the Discussions Period, each of Purchaser and Seller and their respective accountants shall have reasonable access during normal business hours to the working papers of the other prepared in connection with the Proposed Closing Date Calculations or the Purchase Price Dispute Notice, as the case may be, its accountants (subject to customary access and indemnification letters), if any, and to the books and records of the Company solely as the foregoing relates to the Proposed Closing Date Calculations or the Purchase Price Dispute Notice. If Seller and Purchaser do not obtain a final resolution within the Discussion Period, then the items remaining in dispute (as set forth by Seller in the Purchase Price Dispute Notice or by Purchaser in the Proposed Closing Date Calculations) may be submitted thereafter by Seller or Purchaser to Ernst & Young LLP or another nationally-recognized, independent accounting firm reasonably acceptable to Seller and Purchaser (the “Accounting Firm”). The terms of appointment and engagement of the Accounting Firm shall be as agreed upon between Seller and Purchaser, and any associated fees and expenses shall initially be borne fifty percent (50%) by Seller and fifty percent (50%) by Purchaser; *provided*, that such fees shall ultimately be allocated in accordance with Section 2.3.3.4. Seller and Purchaser will use their respective commercially reasonable best efforts to cause the Accounting Firm to render a determination of the applicable dispute within forty-five (45) days after referral of the matter to the Accounting Firm, which determination must be in writing and must set forth, in reasonable detail, the basis therefor. In making its determination regarding such applicable dispute, the Accounting Firm shall select, with respect to each item in dispute, an amount between or equal to Purchaser’s position as set forth in the Proposed Closing Date Calculations or Seller’s position as set forth in the Purchase Price Dispute Notice. In connection with the resolution of any dispute, the Accounting Firm shall have reasonable access during normal business hours to all documents, records, work papers, facilities and personnel necessary to make its determination. Each party will be afforded the opportunity to present to the Accounting Firm any material such party deems relevant to the determination and shall have a continuing opportunity to discuss the matter and its position with the Accounting Firm, but no such presentation of materials or communication shall be on an *ex parte* basis and each party shall be afforded access to copies of all materials presented by each other party. The determination of the Accounting Firm shall be conclusive and binding upon Seller, Purchaser and the other parties hereto and, subject to Section 8.5, Section 8.6 and Section 8.14, each of the parties hereto shall be entitled to enforce such determination in a court of competent jurisdiction. The Accounting Firm’s function shall be to act as an expert and not as an arbitrator and to review only those items which are in dispute, and such review shall be limited to whether the disputed items (as set forth by Seller in the Purchase Price Dispute Notice or by Purchaser in the Proposed Closing Date Calculations), including the related calculations thereto, were prepared in accordance with this Agreement. The “Final Statement of Purchase Price” shall mean the Proposed Purchase Price Calculations together with any revisions thereto pursuant to this Section 2.3.3.3.

Section 2.3.3.4 In the event Seller and Purchaser submit any disputes to the Accounting Firm for resolution as provided in Section 2.3.3.3, Purchaser shall pay a portion of the fees and expenses of the Accounting Firm equal to 100% multiplied by a fraction, (x) the numerator of which is the disputed items that are resolved in favor of Seller (that being the difference between the Accounting Firm's determination and the Seller's position set forth in the Purchase Price Dispute Notice), and (y) the denominator of which is the total disputed items (that being the sum total by which Purchaser's disputed items as set forth in the Proposed Closing Date Calculations and Seller's position set forth in the Purchase Price Dispute Notice differ from the determination of the Accounting Firm), and Seller will be responsible for and shall pay the remainder of the fees and expenses of the Accounting Firm from the Adjustment Escrow Funds (and Seller and Purchaser shall instruct the Escrow Agent accordingly). For example, should the amount of the disputed items total \$1,000 and the Accounting Firm awards \$600 in favor of Seller's position, 60% of the Accounting Firm's fees and expenses would be borne by Purchaser and 40% of the Accounting Firm's fees and expenses would be borne by Seller.

Section 2.3.4 Adjustment to Estimated Purchase Price.

Section 2.3.4.1 If the Actual Adjustment is a positive amount, subject to payment of any Additional Section 116 Escrow Amount in accordance with the Section 116 Escrow Agreement, Purchaser will pay to Seller such positive amount by wire transfer or delivery of immediately available funds, in each case, within three (3) Business Days after the date on which the Purchase Price is finally determined pursuant to Section 2.3.3.

Section 2.3.4.2 If the Actual Adjustment is a negative amount, Purchaser and Seller will instruct the Escrow Agent to pay to Purchaser such amount from the Adjustment Escrow Funds by wire transfer or delivery of immediately available funds, in each case, within three (3) Business Days after the date on which the Purchase Price is finally determined pursuant to Section 2.3.3.

Section 2.3.4.3 Within three (3) Business Days after the date on which the Purchase Price is finally determined pursuant to this Section 2.3, Purchaser and Seller shall deliver joint written instructions to the Escrow Agent instructing the Escrow Agent to deliver any Adjustment Escrow Funds not distributed to Purchaser pursuant to Section 2.3.4.2 to Seller.

Section 2.3.4.4 For the avoidance of doubt, recovery from the Adjustment Escrow Account shall be the sole and exclusive remedy available to Purchaser and its Affiliates for any negative Actual Adjustment under Section 2.3.4.2 and Seller shall not have any liability or obligation under this Section 2.3 for any portion of the Actual Adjustment in excess of the amount of the then-remaining Adjustment Escrow Funds.

Section 2.4 **Closing**. The closing of the transactions contemplated hereby (the “Closing”) shall take place at the offices of Covington & Burling LLP, The New York Times Building, 620 Eighth Avenue, New York, New York 10018, at 10:00 A.M. Eastern Time on the date hereof, or at such other place (including remotely) or on such other date and time as Seller and Purchaser shall mutually agree. The time and date of the Closing is herein called the “Closing Date.” The Closing shall be effective as of 12:00 A.M. Eastern Time on the Closing Date.

Section 2.5 **Section 116 of the Tax Act.**

Section 2.5.1 Seller will apply for a certificate pursuant to section 116 of the Tax Act in respect of the sale of the Shares by Seller to Purchaser (the “Section 116 Certificate”).

Section 2.5.2 In order to satisfy the requirements under section 116 of the Tax Act in respect of the sale of the Shares and without duplication of amounts withheld pursuant to Section 2.3.1.2, Purchaser will be entitled to withhold from amounts payable at Closing in respect of such Shares \$3,822,636.63 (together with any Additional Section 116 Escrow Amount, the “Section 116 Escrow Amount”), which represents the amount that it may be required to remit pursuant to subsection 116(5) of the Tax Act in connection with the purchase of such Shares (being an amount equal to 25% of the Purchase Price) and shall deposit such amount with the Section 116 Escrow Agent to be held by the Section 116 Escrow Agent in a segregated account (the “Section 116 Escrow Account”) pursuant to the terms of the Section 116 Escrow Agreement in accordance with Section 2.3.1.2.

Section 2.5.3 Contemporaneously with the signing of this Agreement, the parties are entering into the Section 116 Escrow Agreement pursuant to which the Escrow Agent will hold and disburse the Section 116 Escrow Amount.

Section 2.5.4 Purchaser, the Company and their respective Affiliates shall cooperate with Seller in obtaining the Section 116 Certificate and none of Purchaser or any of its Affiliates shall take any action which would interfere with, or cause a delay in, Seller obtaining the Section 116 Certificate or the release of the Section 116 Escrow Amount. If the Purchaser or any of its Affiliates unreasonably takes or omits to take any action which causes a delay in receipt of the Section 116 Certificate or causes the Section 116 Escrow Amount to fail to be released when and as required pursuant to the Section 116 Escrow Agreement, then (a) any such amount which is not released shall accrue interest for the period commencing on the date such amount would have otherwise been released and ending on the date when such amount is released, at a rate per annum equal to 5% plus the rate of interest publicly announced by JPMorgan Chase Bank, N.A. in New York, New York as its Prime Lending Rate on the date on which such amount’s release becomes past due and Purchaser shall pay such interest to Seller (or its designees) and (b) Purchaser shall pay all of the Sellers and their respective Affiliates’ reasonable costs and expenses (including reasonable any penalties, fines and interest payable to the CRA, any amounts due to the Escrow Agent and attorney’s fees) in connection with all measures to collect such amount and interest. It is understood and agreed that none of the Purchaser, the Company or any of their respective Affiliates shall have any right to, or interest in, the Section 116 Escrow Amount and none of them shall have any right to receive any amounts from the Section 116 Escrow Account, including as an offset to other Claims that the Purchaser or its Affiliates may have against Seller or its Affiliates. Notwithstanding the immediately foregoing clause, Seller and Purchaser agree and acknowledge that an amount remitted to the Receiver General of Canada pursuant to Section 5(a), (b), (d) or (e) of the Section 116 Escrow Agreement shall be remitted on behalf of Seller in respect of Purchaser’s obligations pursuant to subsection 116(5) of the Tax Act.

ARTICLE III —REPRESENTATIONS AND WARRANTIES OF THE COMPANY

The Company hereby represents and warrants to Purchaser that except as set forth on the disclosure schedule attached hereto (the “Schedules” and each individually a “Schedule”), which exceptions or disclosures shall be deemed to be part of the representations and warranties made hereunder, that the following are true and correct as of the date of this Agreement (except to the extent expressly relating to a specific date, in which event such representation or warranty shall be made as of such date):

Section 3.1 *Organization; Good Standing; Qualification and Power* . The Company is a company limited by shares duly organized, validly existing and in good standing under the laws of Nova Scotia and has the requisite power and authority to own or lease its material properties and material assets and to carry on its business as presently conducted. The Company is duly qualified to transact business and is in good standing in each jurisdiction where the nature of its business or the ownership of its assets make such qualification necessary except where failure to so qualify or be in good standing would not be material to the Company. The Company has previously made available to Purchaser true and complete copies of the Governing Documents of the Company as currently in effect.

Section 3.2 *Authority; Execution and Delivery; Enforceability* . The Company has the requisite power and authority to execute and deliver this Agreement and the other Documents to which it is a party and to perform its obligations hereunder and thereunder, all of which have been duly authorized by all requisite corporate action on the part of the Company. The Company has duly executed and delivered this Agreement and each other Document to which it is a party. Each of the Documents to which the Company is or will be a party is, or upon its execution and delivery will be (assuming that this Agreement and each other Document has been duly and validly authorized, executed and delivered by the other parties hereto and thereto), a valid and binding agreement of the Company, enforceable against the Company in accordance with its terms, except as the enforceability hereof or thereof may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting the enforcement of creditors’ rights generally or (ii) applicable equitable principles (whether considered in a proceeding at law or in equity).

Section 3.3 **Non-contravention** . Neither the execution and delivery of this Agreement or the other Documents to which the Company is a party nor the fulfillment of and the performance by the Company of its obligations hereunder and thereunder will (i) contravene any provision contained in its Governing Documents, (ii) conflict with, violate or result in a breach (with or without the lapse of time, the giving of notice or both) of, or constitute a default (with or without the lapse of time, the giving of notice or both) under (A) any contract, agreement, commitment, indenture, mortgage, lease, pledge, note, bond, license, permit or other instrument or obligation or (B) any judgment, order, decree, statute, law, rule or regulation or other restriction of any Governmental Authority, in each case to which the Company is a party or by which it is bound or to which any of its assets or properties are subject, (iii) except as contemplated herein or with respect to Permitted Liens, result in the creation or imposition of any Lien on any of the assets or properties of the Company, or (iv) result in the acceleration of, or permit any Person to terminate, modify, cancel, accelerate or declare due and payable prior to its stated maturity, any obligation of the Company, which in the case of any of clauses (ii) through (iv) above, would have a Material Adverse Effect.

Section 3.4 **Consents** . No notice to, filing with, or authorization, registration, consent or approval of any Governmental Authority or other Person is necessary for the execution, delivery or performance of this Agreement or the other Documents to which the Company is a party or the consummation of the transactions contemplated hereby or thereby by the Company, except for notices, filings and approvals set forth on Schedule 3.4.

Section 3.5 **Capitalization** . As of the date of this Agreement, the authorized, issued and outstanding share capital of the Company is as set forth on Schedule 3.5 . All of the outstanding Shares have been validly issued. There are (a) no other issued or outstanding equity securities of the Company, (b) no other issued and outstanding securities of the Company convertible into or exchangeable for, at any time, equity securities of the Company, and (c) no issued and outstanding stock appreciation, phantom stock, profit participation or similar rights with respect to the Company. There are no (i) outstanding obligations of the Company to repurchase, redeem or otherwise acquire any securities of the Company or (ii) voting trusts, proxies or other agreements with respect to the voting or transfer of the Shares. The Company has no Subsidiaries and does not own or have any interest in any equity securities or convertible securities of, or have an ownership interest in, any other Person.

Section 3.6 **Financial Statements.**

Section 3.6.1 Attached hereto as Schedule 3.6.1 are true and complete copies of the following financial statements (such financial statements including the notes thereto, the “Financial Statements”):

Section 3.6.1.1 the audited balance sheet of the Company as of December 31, 2017, the related audited statement of operations and comprehensive loss of the Company for the year ended December 31, 2017, the related audited statement for changes in stockholder's equity of the Company for the year ended December 31, 2017, and the related audited statement of cash flows of the Company for the year ended December 31, 2017 (the “2017 Audited Financial Statements”), and the unaudited balance sheet of the Company as of December 31, 2016 and the related unaudited income statement of the Company for the year ended December 31, 2016; and

Section 3.6.1.2 the unaudited balance sheet of the Company as of June 30, 2018 (the “Latest Balance Sheet”); and together with the 2017 Audited Financial Statements, the “GAAP Financial Statements”), the related unaudited statement of operations and comprehensive loss of the Company for the six (6)-month period ending on such date, the related unaudited statement for changes in stockholder's equity of the Company for the six (6)-month period ending on such date, and the related unaudited statement of cash flows of the Company for the six (6)-month period ending on such date.

Section 3.6.2 The GAAP Financial Statements have been prepared in all material respects accordance with GAAP, applied on a consistent basis throughout the periods covered thereby, except as may be indicated in the notes thereto and except, in the case of unaudited interim Financial Statements, for the absence of footnotes and subject to normal year-end adjustments. The Financial Statements fairly present, in all material respects, the financial position, results of operations and cash flows of the Company as of the dates and for the periods indicated (subject, in the case of the unaudited interim Financial Statements, to the absence of footnotes and to normal year-end adjustments).

Section 3.6.3 The accounts receivable of the Company shown on the Latest Balance Sheet and the accounts receivable arising since the Latest Balance Sheet (a) arose from bona fide transactions engaged in or entered into by the Company relating to the Business in the ordinary course of business substantially consistent with past practices, and (b) subject to a reserve for bad debts shown on the Latest Balance Sheet, are valid obligations payable to the Company in accordance with their terms. The Company has not received any written notice or, to the Knowledge of the Company, oral notice, that any of its accounts receivable will not be collectible in full, net of any reserves shown on the Latest Balance Sheet (to the extent such reserve is not since released).

Section 3.6.4 The books of account and other financial records of the Company (a) reflect all material items of income and expense and all material assets and Liabilities required to be reflected therein in accordance with GAAP applied on a basis consistent with the Latest Balance Sheet, and (b) are in all material respects complete and correct.

Section 3.6.5 The Company maintains a system of internal accounting controls of a type that are customary for similarly sized privately owned companies in its jurisdiction of incorporation that are designed to (a) provide reasonable assurances regarding the reliability of the GAAP Financial Statements in accordance with GAAP applied on a basis consistent with the Latest Balance Sheet, and (b) communicate to the Company's principal executive officer and principal financial officer the type of information that would be required to be disclosed in the Financial Statements. The Company believes that such controls are functioning as intended in all material respects.

Section 3.6.6 The Company is not subject to any “off-balance sheet arrangement” (as defined in Item 303(a)(4)(ii) of Regulation S-K promulgated under the United States Securities Exchange Act of 1934, as amended).

Section 3.7 *Absence of Undisclosed Liabilities* . The Company has no material obligation or liability except for obligations and liabilities which are disclosed on the Latest Balance Sheet or which would not be required to be disclosed on the Latest Balance Sheet in accordance with GAAP.

Section 3.8 *Absence of Certain Developments* . During the period beginning on the date of the Latest Balance Sheet and ending on the date of this Agreement, (i) there has not been any Material Adverse Effect (ii) the Company has conducted its Business in all material respects in the ordinary course of business substantially consistent with past practices, and (iii) the Company has not:

(a) amended or modified its Governing Documents;

(b) split, combined or reclassified any shares of its capital stock;

(c) (1) issued, sold, granted or otherwise disposed of any of the Company’s capital stock or any other equity security, (2) issued, sold, granted or otherwise disposed of any options, warrants, calls, subscription or other right of any kind, fixed or contingent, that directly or indirectly calls for the issuance, sale, pledge or other disposition of any shares of the Company’s capital stock or any other equity security, (3) entered into of any contract calling for any transaction referred to in preceding clauses (1) or (2), or (4) made any other change in the Company’s capital structure;

(d) declared, set aside or paid any dividends or other distributions (whether in cash, stock, property or any combination thereof) on or in respect of any of its capital stock or any other equity security, or redeemed, purchased or acquired for value any shares of its capital stock or any other equity security;

(e) subjected any of its properties or assets or any leased real property to any Lien, except for, if any, (1) Permitted Liens and (2) Liens incurred in connection with any financing obtained by Purchaser;

(f) changed or modified in any material respect any method of accounting or accounting practice, including for Tax purposes, or Tax calculating or Tax reporting methods or practice, except as required by applicable law, GAAP or as disclosed in the notes to the Latest Balance Sheet;

(g) consented to any extensions or waived any statute of limitations in respect of Taxes or executed or filed with any Governmental Authority any agreement extending the period of assessment or collection of any Taxes;

(h) made or amended any elections for Tax purposes;

(i) adopted a taxable year other than the fiscal year ending December 31;

(j) settled or compromised any material claim or assessment relating to Taxes;

(k) made any payments, become obligated to make any payments, or become a party to any plan, program or agreement that could obligate it to make any payments, separately or in the aggregate, that would not be fully deductible under Code Section 280G;

(l) made any change or modification to the Company's cash management practices and its policies, practices and procedures with respect to (1) billing and collection of accounts receivable or unbilled charges, (2) establishment of reserves for uncollectible accounts, (3) accrual of accounts receivable, inventory control, prepayment of expenses, payment of trade accounts payable, accrual of other expenses, deferral of revenue and acceptance of customer deposits, or (4) discounts, rebates or allowances;

(m) acquired assets, other than in the ordinary course of business substantially consistent with past practices;

(n) sold, assigned or transferred, or granted any license or sublicense to, any patents, trademarks, trade names, copyrights, trade secrets or other material intangible assets;

(o) made or granted any bonus or any compensation or salary increase or entered into any employment Contract to any current (or former) employee of the Company, or other individual who performs services for the Company whose annual base salary is (or was at the time of his or her termination) in excess of \$100,000 (except in the ordinary course of business substantially consistent with past practices or as required under the terms of an applicable contract, which contract has been disclosed on Schedule 3.8 to the extent in effect as of the date of this Agreement);

(p) terminated, hired or transferred any senior management employee of the Company;

(q) made any capital expenditures or appropriations or commitments therefore, except any capital expenditure or appropriations or commitment not in excess of \$50,000 individually or \$100,000 in the aggregate;

(r) made any loans or advances to, or guarantees for the benefit of, any Persons (except advances to employees for business expenses in the ordinary course of business substantially consistent with past practices);

(s) established, adopted, entered into, materially amended or materially increased benefits under, or terminated any material benefit or compensation plan, arrangement or agreement (including, without limitation, bonuses, profit sharing, stock option, restricted stock, pensions, retirement benefits, deferred compensation, severance or termination benefits) for any employees of the Company or other individuals who perform services for or on behalf of the Company;

(t) incurred any damage, destruction or loss (whether or not covered by insurance), ordinary wear and tear excepted, in an amount exceeding \$50,000 individually or \$100,000 in the aggregate affecting the property or assets of the Company;

(u) made any capital investment in any other Person except (1) in the ordinary course of business substantially consistent with past practices or (2) for such capital investments that are reflected in the Company's budget for the fiscal year ending December 31, 2018;

(v) sold, transferred, leased or otherwise disposed of any material assets of the Company, except for sales, transfers, leases and other dispositions of inventory in the ordinary course of business substantially consistent with past practices;

(w) entered into or agreed to enter into any merger, consolidation, reorganization, or similar agreement to acquire or sell any business or any Person, engaged in any new material line of business, invested in, made a capital contribution to, or otherwise acquired the securities of, any other Person, or acquired all or substantially all of the assets of any other Person;

(x) entered into any agreements with any Affiliates of the Company or Seller or any of their respective directors, officers, employees, or stakeholders; or

(y) authorized, approved, agreed or committed to do any of the foregoing.

Section 3.9 ***Compliance with Laws.***

Section 3.9.1 The Business is in compliance with all applicable laws, rules, regulations, codes, ordinances and orders of all Governmental Authorities, including FDA and Health Canada good manufacturing practices and reporting obligations, except where failure to so comply would not have a Material Adverse Effect. This Section 3.9 does not relate to matters with respect to Taxes (which are the subject of Section 3.11), Environmental Matters (which are the subject of Section 3.12), Employee Matters (which are the subject of Section 3.13) and Employee Benefit Plans (which are the subject of Section 3.14).

Section 3.9.2 The Company has all material permits, authorizations, licenses and certificates necessary or required for the conduct of the Business by it and the ownership, use and operation of its assets (the "Material Permits"), and (i) the Material Permits are valid and in full force and effect, and (ii) the Company is not, in any material respect, in breach or violation of, or default under, the Material Permits except for any such breach or violation that would not have a Material Adverse Effect.

Section 3.9.3 Since January 1, 2016, the Company has not been a party to any pending or, to the Knowledge of the Company, threatened Claim relating to any defect (whether of manufacturing, labeling or otherwise) with respect to any Product.

Section 3.9.4 Since January 1, 2016, no warranty or product liability Claim (including any claim alleging personal injury and/or death) has been received by the Company and, to the Knowledge of the Company, no such Claim has been threatened against the Company, in any case relating to any of the Products, and, to the Knowledge of the Company, there is no fact or circumstance that would give rise to a warranty Claim or a Claim for product liability.

Section 3.10 **Litigation** . As of the date of this Agreement, there are no lawsuits, legal actions, proceedings, claims, complaints, injunctions, orders or investigations by or before any Governmental Authority (“Proceedings”) pending or, to the Company’s Knowledge, threatened in writing (i) against the Company, or (ii) seeking to enjoin the transactions contemplated hereby, which in the case of (i) above if determined adversely to the Company would have a Material Adverse Effect. This Section 3.10 does not relate to matters with respect to Taxes (which are the subject of Section 3.11), Environmental Matters (which are the subject of Section 3.12), Employee Matters (which are the subject of Section 3.13) and Employee Benefit Plans (which are the subject of Section 3.14).

Section 3.11 **Taxes** . The Company has duly and timely filed with the appropriate Government Authority all Tax Returns required to be filed by it, all such Tax Returns have been prepared in compliance with all applicable laws and regulations and are true, correct and complete in all respects and have not been amended since filed. All Taxes owed by or with respect to the Company, shown as due on any Tax Return, and all other Taxes due and payable, have been timely paid. Notices of assessment have been issued or self-assessments have been made (as applicable) in respect of all liabilities for all taxable periods ending on or before December 31, 2016. The Company is resident in Canada, and not resident in any other country, for purposes of the Tax Act.

Section 3.11.1 In addition:

Section 3.11.1.1 the Company is not and has never been the subject of any Tax Contest;

Section 3.11.1.2 the Company has not consented to extend the time, or is the beneficiary of any extension of time, in which any Tax may be assessed or collected by any taxing authority and no such extension has been requested by any taxing authority;

Section 3.11.1.3 the Company has not received from any taxing authority any notice of proposed adjustment, deficiency or underpayment of Taxes which has not been satisfied by payment or been withdrawn.

Section 3.11.1.4 the Company is not a party to, bound by or obligated under any Tax allocation, Tax indemnification or Tax sharing agreement or similar contract or arrangement, has any liability for the Taxes (or any portion thereof) of any other Person, or has any contractual obligation to pay the amount of any Tax benefits or Tax refunds (or an amount determined by reference thereto) realized or received by it to any former shareholder(s) or other Person(s);

Section 3.11.1.5 the Company has never been a party to a reportable transaction within the meaning of Section 6707A(c)(1) of the Code and Treasury Regulation Section 1.6011-4(b). All accruals or reserves for Taxes reflected in the GAAP Financial Statements are adequate to cover Taxes accruing with respect to or payable by the Company for all Pre-Closing Tax Periods and the Company has not incurred or accrued any liability for Taxes subsequent to the date of the GAAP Financial Statements other than in the ordinary course of business substantially consistent with past practices;

Section 3.11.1.6 there are no Encumbrances for Taxes upon the assets of the Company;

Section 3.11.1.7 no Claim has been made by any taxing authority in a jurisdiction where the Company does not file Tax Returns that the Company is or may be subject to taxation by that jurisdiction;

Section 3.11.1.8 to the Knowledge of the Company, the Company is not required to file a Tax Return in any jurisdiction other than the jurisdictions listed in Schedule 3.11.1.8;

Section 3.11.1.9 the Company has not, directly or indirectly, transferred property to or supplied services to, or acquired property or services from, any Person with whom it was not dealing at arm's length (for purposes of the applicable Tax laws) for consideration other than consideration equal to the fair market value of the property or services at the time of the transfer, supply or acquisition or such property or services, failed to make or obtain, where required, records or documents that meet the requirements of any applicable transfer pricing laws, or entered into any advance pricing agreement with any Governmental Authority;

Section 3.11.1.10 the Company is registered under the VAT Legislation of each jurisdiction where and to the extent it is required to be so registered, has duly and timely complied with all applicable VAT Legislation, and has paid and collected, and remitted to the appropriate Governmental Authority, all amounts required by such legislation;

Section 3.11.1.11 the Company has not (a) granted a power-of-attorney relating to Tax matters to any person or (b) applied for and/or received a ruling or determination from a taxing authority regarding a past or prospective transaction of the Company;

Section 3.11.1.12 all Taxes that the Company was required by law to withhold or collect have been withheld or collected and, to the extent required by law, have been paid over to the proper taxing authority;

Section 3.11.1.13 neither the Company, the Purchaser nor any of their Affiliates will be required to include any item of income in, or exclude any item of deduction from, taxable income for any taxable period (or part thereof) ending after the Closing Date as a result of: (a) any change in accounting method adopted by or on behalf of the Company on or prior to the Closing Date, (b) any closing agreement as described in Section 7121 of the Code (or any similar or corresponding provision of state, local, provincial, territorial, federal or foreign law) entered into by or on behalf of the Company on or prior to the Closing Date, (c) any installment sale entered into by the Company on or prior to the Closing Date, (d) election by the Company under Section 108(i), (e) Section 965 of the Code, or (f) a reserve, deduction, prepaid amount, advance payment or tax credit;

Section 3.11.1.14 Seller has delivered or made available to Purchaser copies of each of the Tax Returns filed on behalf of the Company since December 31, 2014;

Section 3.11.1.15 the Company has not applied for, been granted, or agreed to any accounting method change for which it will be required to take into account any adjustment under Section 481 of the Code (or any similar provision of the corresponding tax laws of any nation, state or locality), and no taxing authority has proposed or purported to require any such adjustment or change in accounting method, and no such adjustment under Section 481 of the Code or the corresponding tax laws of any nation, state or locality will be required of the Company upon the completion of, or by reason of, the transactions contemplated by this Agreement;

Section 3.11.1.16 the Company has never been a member of any consolidated, combined, unitary or other similar group of companies and does not have any liability for Taxes of another person as a transferee or successor;

Section 3.11.1.17 the Shares of the Company are not considered taxable Canadian property for Canadian Tax purposes;

Section 3.11.1.18 the Company has complied with all applicable transfer pricing requirements; and

Section 3.11.2 Notwithstanding anything herein to the contrary, the representations and warranties in this Section 3.11 are the sole and exclusive representations and warranties of the Company concerning Tax matters.

Section 3.12 *Environmental Matters.*

Section 3.12.1 The Company is and, within the past six (6) years, has been, in compliance with all Environmental Laws, except for any such failure to comply as would not reasonably be expected to have a Material Adverse Effect.

Section 3.12.2 The Company is in compliance with all permits, licenses and other authorizations that are required for its current operations by Environmental Laws, except for any such failure to have or comply as would not reasonably be expected to have a Material Adverse Effect and the Company has received no written notice which may require the modification, cancellation, suspension or limitation of any such required permits, licenses or other authorizations or the addition of any conditions of compliance which would reasonably be expected to have a Material Adverse Effect.

Section 3.12.3 As of the date of this Agreement, there are no Proceedings pending or, to the Company's Knowledge, threatened in writing against the Company pursuant to Environmental Laws which, if determined adversely to the Company, would reasonably be expected to have a Material Adverse Effect.

Section 3.12.4 The Company has not released or disposed of any toxic or hazardous material, substance or waste in violation of any Environmental Laws except for any such violations as would not reasonably be expected to have a Material Adverse Effect.

Section 3.12.5 The Company has provided the Purchaser with true, correct and complete copies of all material documents, records and information in its possession or control concerning any environmental or health and safety matter relevant to the Company including documentation, if any, regarding waste disposal, reports, correspondence, permits related to environmental or health and safety matters issued by any Governmental Authority, and analyses and monitoring data, if any, for soil, groundwater and surface water and all material third party reports pertaining to any environmental assessments or audits that were obtained by, or are in the possession or control of, the Company.

Section 3.12.6 The representations and warranties in this Section 3.12 are the sole and exclusive representations and warranties of the Company concerning matters arising under Environmental Laws and any other environmental matters.

Section 3.13 *Employee Matters.*

Section 3.13.1 Schedule 3.13.1 contains a list of the following information for each full-time, part-time or temporary employee, manager, or officer of the Company, including each employee on leave of absence or layoff status: job title; current employment status; current compensation; start date; age; and fringe benefits (if any). There are no service providers to the Company who have not but should have been characterized and treated by the Company as employees of the Company.

Section 3.13.2 The Company is not party to any collective bargaining agreement with respect to its employees and no trade union, employee association or other similar entity has any bargaining rights, acquired by certification, voluntary recognition or otherwise with respect to any of the employees or former employees of the Company. In addition, (a) there is no labor union strike, work stoppage, walkout, lockout, or other material labor dispute pending or, to the Company's Knowledge, threatened in writing against the Company and since the date of the Latest Balance Sheet there has been no such dispute, (b) there is no unfair labor practice charge, investigation or claim relating to any employment-related matter or termination of employment pending against the Company, including any charge or complaint filed by an employee with the Ontario Labour Relations Board, the Ontario Human Rights Commission, or any comparable Governmental Authority, (c) the Company has properly characterized retained individuals as either employees or independent contractors for the purposes of Tax and other applicable laws and the Company has not received any notice from any Governmental Authority disputing such classification, and (d) each employee has executed an employment agreement pursuant to which such employee has agreed, in the event such employee is terminated for any reason or for no reason at any time, to accept the statutory minimum notice of termination (or payment in lieu of notice), or severance payment (if applicable) and benefits continuance (if applicable) required pursuant to the *Employment Standards Act, 2000* (Ontario) or any other applicable employment legislation.

Section 3.13.3 The Business is materially in compliance with all applicable federal, provincial and local laws in respect of labor and employment matters. All amounts payable to or liabilities in respect of the employees of the Company for services provided up to the Closing Date shall have been paid or accrued to the Closing Date, including payment of wages, commissions, bonuses or other compensation, vacation with pay, sick or personal days, benefits under the Employee Benefit Plans, including premium contributions, remittances and assessments for income tax, employment insurance, employer health tax, workers' compensation and any other employment-related legislation.

Section 3.14 *Employee Benefit Plans.*

Section 3.14.1 Schedule 3.14.1 lists all Employee Benefit Plans. The Purchaser has been provided with true, correct and complete copies of all Employee Benefit Plans (or if unwritten, summaries thereof), together with all material related documentation including (i) where applicable, copies of any trust agreements or other funding arrangements, custodial agreements, insurance policies and contracts, administration agreements, stop loss arrangements and similar agreements, and investment management or investment advisory agreements, now in effect or required in the future as a result of the transactions contemplated by this Agreement or otherwise; (ii) copies of any summary plan descriptions, summaries of material modifications, summaries of benefits and coverage, employee handbooks and any other material written communications (or a description of any oral communications) relating to any Employee Benefit Plan; and (iii) copies of material notices, letters or other correspondence from any Governmental Authority relating to the Employee Benefit Plan.

Section 3.14.2 The Company does not sponsor, maintain or contribute to, and has no obligation to contribute to, any Employee Benefit Plan that is required to be registered as a "registered pension plan" or a "retirement compensation arrangement" as those terms are defined in subsection 248(1) of the Tax Act, nor any Employee Benefit Plan with respect to which there are any material unfunded obligations.

Section 3.14.3 The Employee Benefit Plans have been established, registered, administered, invested and communicated in all material respects in accordance with their terms and the requirements of all applicable laws, rules, regulations, codes, ordinances and orders of all Governmental Authorities. All contributions or premiums required to be made by the Company with respect to the period prior to and ending on the Closing Date under the terms of each Employee Benefit Plan have been made or accrued to the Closing Date.

Section 3.14.4 None of the Employee Benefit Plans provide benefits beyond retirement or other termination of service to employees or former employees or to their beneficiaries or dependents.

Section 3.14.5 Excluding any agreement, contract, arrangement or plan entered into by or at the direction of Purchaser on or after the Closing Date (but excluding any documents specifically contemplated hereunder), the execution of this Agreement and the completion of the transactions contemplated hereby will not (either alone or in conjunction with any subsequent events) constitute an event under any Employee Benefit Plan or collective bargaining agreement, or under any employment agreement, offer letter or other agreement relating to employees or employment that, as the case may be, will result in any payment, acceleration of payment or vesting of benefits, forgiveness of indebtedness, vesting, distribution, increase in benefits or obligation to fund benefits, or grant or trigger any benefits or obligation, in any such case with respect to any director, officer or employee or other service provider of the Company.

Section 3.14.6 No insurance policy or any other agreement affecting any Employee Benefit Plan requires or permits a retroactive increase in contributions, premiums or other payments due thereunder. The level of reserves under each Employee Benefit Plan which provides group benefits and contemplates the holding of such reserves is reasonable and sufficient to provide for all incurred but unreported claims.

Section 3.14.7 Other than routine claims for benefits, no Employee Benefit Plan, neither the Company, nor, to the Knowledge of the Company, any administrator of any Employee Benefit Plan, is subject to any pending action, investigation, examination, claim (including claims for Taxes or claims for a breach of a fiduciary obligation) or any other proceeding initiated by any Person, and there exists no state of facts which could reasonably be expected to give rise to any such action, investigation, examination, claim or other proceeding.

Section 3.14.8 Only employees or former employees (or any spouses, domestic partners, dependents, survivors or beneficiaries of any such employees or former employees) of the Company are entitled to participate in the Employee Benefit Plans and no entity other than the Company is a participating employer under any Employee Benefit Plan.

Section 3.14.9 Section 3.13 and Section 3.14 contain the sole and exclusive representations and warranties of the Company with respect to any employee benefit or benefit or compensation plan matters.

Section 3.14.10 Without limiting any other provision of this Agreement to the contrary, no Person shall be a third-party beneficiary or have any rights with respect any provision, or matter described in, Section 3.13 or Section 3.14.

Section 3.15 *Intellectual Property Rights*. The Company owns all right, title and interest in, free and clear of all Liens (other than Permitted Liens), or have a license or other right to use, all of the material Intellectual Property Rights necessary for the conduct of the Business as currently conducted (collectively, the “Company Intellectual Property Rights”). Schedule 3.15 sets forth a list of all patents and patent applications, trademark registrations and applications, domain names, URLs and copyright registrations and applications owned by the Company. There is not pending against the Company any Proceeding (other than, for clarity, office actions or other similar proceedings) by any third party contesting the ownership or use by the Company of any Company Intellectual Property Right, except as would not be expected to have a Material Adverse Effect. To the Company’s Knowledge, the Company has not infringed or misappropriated any Intellectual Property Rights of any third party since the date of the Latest Balance Sheet, which such infringement or misappropriation would have a Material Adverse Effect. This Section 3.15 contains the sole and exclusive representations and warranties of the Company with respect to any Intellectual Property Right matters.

Section 3.16 **Contracts** . **Schedule 3.16** sets forth all material contracts, agreements, leases, permits or licenses (in each case excluding purchase orders in the ordinary course of business substantially consistent with past practices, insurance policies, Employee Benefit Plans, or any contracts or agreements with any customer), to which, as of the date of this Agreement, the Company is a party or is otherwise bound, of the type described below (the “Contracts”):

Section 3.16.1 all manufacturing and supply agreements and proposals with customers of the Company, and other agreements (or group of related agreements with respect to a single transaction or series of related transactions) that cannot be terminated without cause on less than one hundred and eighty (180) days’ notice (and, in the aggregate with all such other agreements, without a material monetary penalty) and involve future payments, performance or services or delivery of goods or materials to or by the Company of any amount or value reasonably expected to exceed \$250,000 during any future twelve (12)-month period;

Section 3.16.2 all agreements or commitments for the purchase or lease by the Company of machinery, equipment or other personal property other than those that are for amounts not to exceed \$100,000 annually;

Section 3.16.3 all employment agreements pursuant to which an employee or officer is entitled to receive base annual compensation in excess of \$150,000, and all consulting or severance agreements that are likely to involve consideration in excess of \$150,000 during the current fiscal year, in each case, that are not terminable by the Company without an obligation to pay severance;

Section 3.16.4 all license agreements pursuant to which the Company grants to, or obtains from, any Person the right to use any Company Intellectual Property Rights owned by, or licensed to, the Company (other than (i) non-exclusive license agreements granted in the ordinary course of business substantially consistent with past practices, and (ii) off-the shelf and other commercially available software licenses);

Section 3.16.5 all agreements that prohibit the Company from, directly or indirectly, (i) freely engaging in any business, (ii) competing in any line of business, or (iii) formulating, developing, manufacturing, or selling any product for any person not party to such agreement, including any Contract that requires the Company to work exclusively with any Person;

Section 3.16.6 all Contracts that require the Company to purchase its total requirements of any product or service from a third party or that contains “take or pay” provisions;

Section 3.16.7 all Contracts creating a partnership, limited liability company, joint venture, strategic alliance, collaboration, co-promotion, profit or revenue sharing, research or development project, or similar Contract;

- Section 3.16.8 any stockholders, voting, investors rights, registration rights or similar agreement or arrangement;
- Section 3.16.9 any contract that grants to the other party or such other party's Affiliates "most favored nation" status or that grants to the other party or such other party's Affiliates any exclusive right or rights or in which any third party grants the Company any exclusive right or rights;
- Section 3.16.10 any contract relating to the acquisition or disposition of any business, stock or assets of any other Person or real property;
- Section 3.16.11 any contract imposing any restriction or limitation on the sale or other transfer of the Shares or of any of the assets of the Company;
- Section 3.16.12 any contract involving the settlement of any legal proceeding entered into in the past three (3) years or under which the Company has any ongoing liabilities or obligations other than confidentiality;
- Section 3.16.13 any contract that provides for the assumption of any environmental liability of any Person; or
- Section 3.16.14 any contract for the provision of goods or services to any Governmental Authority.

Each Contract set forth on Schedule 3.16 is a valid and binding agreement of the Company enforceable in accordance with its terms (subject to proper authorization and execution of such Contract by the other party thereto and the applicable bankruptcy, insolvency, reorganization, moratorium or other laws affecting generally the enforcement of creditors' rights and subject to general principles of equity). The Company is not in material breach of or in material default under the terms of any Contract required to be set forth on Schedule 3.16. The Company has not received written notice prior to the date hereof of any default under any Contract required to be set forth on Schedule 3.16, except for defaults that would not have a Material Adverse Effect. No event or circumstance has occurred that, with notice or lapse of time or both, would constitute an event of default under any Contract or result in a termination thereof or would cause or permit the acceleration or other changes of any right or obligation or the loss of any benefit thereunder. Complete and correct copies of each Contract (including all material modifications, amendments and supplements thereto and material waivers thereunder) have been made available to the Purchaser. For the avoidance of doubt, expiration or termination of any Contract in accordance with its terms after the date of this Agreement shall not be a breach of this Section 3.16.

Section 3.17 Insurance . Schedule 3.17 contains a list of all material policies of fire, liability, property, casualty owned or held by the Company as of the date of this Agreement (other than Employee Benefit Plans). All such policies are, as of the date of this Agreement, in full force and effect, all premiums with respect thereto covering all periods up to and including the Closing will have been paid, and as of the date of this Agreement no written notice of cancellation or termination has been received by the Company with respect to any such policy.

Section 3.18 ***Real Property.***

Section 3.18.1 Schedule 3.18.1 sets forth the address of all land, together with all buildings, structures, and improvements located thereon, owned by the Company as of the date hereof (such real property, the “Owned Real Property”). With respect to each Owned Real Property, as of the date hereof: (A) the Company has registered and beneficial fee simple title to such Owned Real Property, free and clear of all Liens, except Permitted Liens, (B) the Company has not leased, licensed or otherwise granted to any Person the right to use or occupy such Owned Real Property or any portion thereof; (C) other than the right of Purchaser pursuant to this Agreement, there are no outstanding options, rights of first offer or rights of first refusal to purchase such Owned Real Property or any portion thereof or interest therein; (D) no written notice has been received by the Company of outstanding work orders, permit violations, or deficiency notices of any Governmental Authority with respect to the Owned Real Property and to the Knowledge of the Company, no such orders, violations or deficiency notices are pending or threatened; (E) no part of the Owned Real Property has been condemned, taken or expropriated by any Governmental Authority, nor has any notice or proceeding in respect thereof been received by the Company; (F) there are no pending actions, appeals or complaints to seek either a reduction or increase in the value of the Owned Real Property for real estate tax purposes and there are no appeals, suits, audits, investigations, requests for information or similar proceedings for real estate taxes now pending or, to the Company’s Knowledge, threatened against the Company with respect to the Owned Real Property; (G) no written notice has been received by the Company of any boundary or water drainage disputes or any other disputes with an owner of any property adjacent to the Owned Real Property; (H) to the Knowledge of the Company, all of the plants, buildings, structures, erections, improvements, appurtenances and fixtures situated on or forming part of the Owned Real Property are in good operating condition and in a state of good maintenance and repair (reasonable wear and tear excepted), are adequate and suitable for the purposes for which they are currently being used and the Company has adequate rights of ingress and egress to and from the Owned Real Property as reasonably required in the ordinary course of business substantially consistent with past practices; (I) there are no amounts owing by the Company in respect of the supply to or the use by it of water, gas, electrical power or energy, steam or hot water, or other utilities (except for current accounts, the payment dates of which have not yet passed); (J) none of the buildings and structures situated on or forming part of the Owned Real Property violate any restrictive covenant or any applicable law or encroaches on any property owned by others in any material respect and no buildings or structures from neighboring properties encroach onto any part of the Owned Real Property; (K) the present use of the Owned Real Property is lawful and the Company has received no notice from any municipal, provincial or other authority having jurisdiction that the Owned Real Property and its current use does not comply with any applicable law or regulation; and (L) the Permitted Liens affecting the Owned Real Property are in good standing in all material respects and no notice of material default or purported termination or surrender has been received or given by the Company in respect of any of the Permitted Liens. There are no existing material defaults under any of the Permitted Liens and all consents and assumption agreements required for the transfer of the Permitted Liens have been received or will have been received prior to the Closing Date.

Section 3.18.2 The Company is not a party to any leases, licenses or other occupancy agreements of real property (whether as lessee or lessor). The Company has never owned any real property other than the Owned Real Property and has never leased, licensed or otherwise similarly occupied any real property.

Section 3.19 **Transaction with Affiliates** . None of the Company’s stockholders, directors or officers nor, to the Company’s Knowledge, any of their respective Affiliates is involved in any business arrangement or relationship with the Company other than employment arrangements and severance arrangements set forth on Schedule 3.14.1, and none of the Company’s stockholders, directors or officers nor, to the Company’s Knowledge, any of their respective Affiliates owns any property or right, tangible or intangible, which is used by the Company.

Section 3.20 **Title and Condition of Assets; Sufficiency of Assets** .

Section 3.20.1 The Company has good and marketable title to, a valid leasehold interest in, or valid rights under a contract to use, all material items of personal property, whether tangible or intangible, owned by them and used in the Business, and a valid and enforceable right to use all material tangible items of personal property, leased by or licensed to them and used in the Business (collectively, the “Personal Property”), in each case, free and clear of all Liens (other than Permitted Liens).

Section 3.20.2 All Personal Property necessary for, and material to, the operation or conduct of the Business as conducted on the date hereof are in reasonably good operating condition and repair, normal wear and tear excepted and having regard to the age of the equipment and other Personal Property, other than machinery and equipment under repair or out of service in the ordinary course of business substantially consistent with past practices.

Section 3.20.3 The assets, properties and rights owned or leased by the Company collectively (a) constitute in all material respects all assets, properties and rights which are used in or reasonably necessary to enable the current operation of the Business and (b) are reasonably sufficient in the aggregate to permit the Company to continue to conduct the Business as currently conducted in all material respects, in each case based on current customer forecasts and orders and applicable regulatory requirements as of the date hereof. No Subsidiary or Affiliate of Seller holds any assets that are reasonably necessary to enable the current operation of the Business.

Section 3.21 **Customers** . Schedule 3.21 lists each of the Material Customers and the aggregate dollar revenues received by the Company from each such Material Customer for the twelve months ended May 31, 2018.

Section 3.22 **Anti-Bribery** . Within the past six (6) years, none of the Seller (with respect to the Company), the Company, or any of their directors, officers, or to the Company’s Knowledge, any employees, agents or consultants, or any other Person acting for, or on behalf of, the Seller (with respect to the Company) or the Company, directly or indirectly:

Section 3.22.1 has violated or is in violation of the Corruption of Foreign Public Officials Act (Canada), the U.S. Foreign Corrupt Practices Act (the “FCPA”) or any other laws regarding corruption or illegal payments applicable to the Seller (with respect to the Company) or the Company (collectively with the FCPA, the “Improper Payment Laws”);

Section 3.22.2 has made, undertaken, offered to make, promised to make or authorized the payment or giving of any bribe, rebate, payoff, influence payment, kickback or other payment, gift or other transfer of money or anything of value (including meals or entertainment) to (i) any officer, employee or ceremonial office holder of any government, instrumentality thereof, government-controlled legal entity or supra-national organization (such as the United Nations), (ii) any political party, (iii) any political candidate, or (iv) any royal family member, that is prohibited under any Improper Payment Law or otherwise for the purpose of influencing any act or decision of such payee in his or her official capacity, inducing such payee to do or omit to do any act in violation of his or her lawful duty, securing any improper advantage or inducing such payee to use his or her influence with a government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality in violation of his or her lawful duty (any of the foregoing a “Prohibited Payment”);

Section 3.22.3 has used funds or other assets, or made any promise or undertaking, for establishment or maintenance of a secret, unrecorded or improperly recorded fund (a “Prohibited Fund”); or

Section 3.22.4 has made any false or fictitious entries in any books or records of the Company relating to any Prohibited Payment or Prohibited Fund.

Section 3.23 *International Trade Matters; Export Control and Import Laws.*

Section 3.23.1 Each of the Seller (with respect to the Company) and the Company is in compliance and, within the past six (6) years, has complied, in all material respects with all applicable export control and trade and economic sanctions laws (“Export Controls”), including, without limitation, the Export Administration Regulations maintained by the U.S. Department of Commerce, trade and economic sanctions maintained by the Treasury Department’s Office of Foreign Assets Control (“OFAC”), and International Traffic in Arms Regulations (the “ITAR”) maintained by the Department of State and any applicable anti-boycott compliance regulations.

Section 3.23.2 None of (i) the Seller; (ii) the Company, or (iii), to the Knowledge of the Company, any director, officer, employee, agent or consultant of, or any other Person acting for, or on behalf of, the Company is a Prohibited Person. “Prohibited Person” shall mean (A) a Person who is on the List of Specially Designated Nationals and Blocked Persons or any other list of sanctioned persons administered by OFAC; (B) any other similar list of sanctioned persons administered by a Governmental Entity in any other jurisdiction; (C) where relevant under applicable Export Controls, any legal entity that is 50%-or-more owned or controlled by one or more Persons identified in the foregoing clauses (A) or (B); or (D) a segment of the government of Crimea, Cuba, Iran, North Korea or Syria or any resident thereof.

Section 3.23.3 The Company is not conducting and has not within the past six (6) years conducted business, directly or indirectly, with any Prohibited Person, where such business would be prohibited under applicable Export Controls. The Company is not conducting and has not since July 7, 2015 conducted business, directly or indirectly, in, with or involving, Crimea, Cuba, Iran, North Korea or Syria.

Section 3.23.4 No good, service, software or technical information that the Company sells, exports, possesses or works with is subject to ITAR control. The Company is not engaging, and has not within the past six (6) years engaged, in activities that are subject to the ITAR.

Section 3.24 *Indebtedness* . Schedule 3.24(a) sets forth any indebtedness for borrowed money, including indebtedness under any bank credit agreement and any other related agreements but, for the avoidance of doubt, excluding capital leases. Schedule 3.24(a) sets forth a description of each item of indebtedness of the Company (whether incurred pursuant to a written or oral agreement) outstanding as of the date of this Agreement, including (i) the name of each lender or creditor with respect to any indebtedness, (ii) the aggregate amount that the Company owes to such lender or creditor as of the date of this Agreement, and (iii) whether such indebtedness is secured by any Lien on any property or asset of the Company. Schedule 3.24(b) sets forth a description of each loan or advance made by the Company to a third-party (whether pursuant to a written or oral agreement), including (i) the name of the third party, (ii) the aggregate amount loaned or advanced by the Company to such third party as of the date of this Agreement, and (iii) whether such loan or advance is secured by any Lien on any property or asset of such third party.

Section 3.25 *Privacy and Data Security* .

Section 3.25.2 The Company is not, and during the two (2) years prior to the Closing Date, has not been, the subject of an administrative proceeding a Governmental Authority relating to compliance with Privacy Laws, nor is any such administrative proceeding pending or, to the Company's Knowledge, threatened. There are no pending written claims for indemnification received by the Company from any third party for actions arising from unauthorized use, disclosure, or access to customers' Personal Information.

Section 3.25.3 The Company is in compliance with all Data Security Requirements, except where noncompliance would not, individually or in the aggregate, reasonably be expected to be material and adverse to the Company. As of the date of this Agreement, no written claims have been received by, and to the Company's Knowledge, no claims, charges or complaints have been made against, the Company alleging a violation of any Data Security Requirements, and, to the Company's Knowledge, the Company has not been subject to any proceeding with regard to any Data Security Requirements relating to the Business.

Section 3.26 **Information Technology** . The computers and other information technology infrastructure and assets used by the Company (collectively, the “IT Assets”) operate and perform as is necessary to conduct the Business in the manner in which it is currently being conducted, and are sufficient for the current and anticipated future needs of the Business. The Company has taken or caused to be taken all reasonable precautions to ensure that all IT Assets (i) are free from any material defect, bug, virus or programming, design or documentation error or corruption, and (ii) are reasonably functional and operate and run in a reasonably efficient business manner.

Section 3.27 **Regulatory Matters.**

Section 3.27.1 In the last two (2) years, the Company has not received any Form FDA-483, notice of adverse finding, FDA or Health Canada warning letters, notice of violation or “untitled letters,” notice of FDA, Health Canada or Canada Border Service Agency action for import detentions or refusals, or any other written correspondence from the FDA, Health Canada or other Governmental Authority alleging or asserting material noncompliance with any applicable laws, rules, regulations codes, ordinances and orders of Governmental Authorities. The Company is not subject to any obligation arising under an administrative or regulatory action, inspection, warning letter, notice of violation letter, or other notice, response or commitment made to or with the FDA or Health Canada with respect to a violation or FDA action, and to the knowledge of the Company, no such proceedings have been threatened.

Section 3.27.2 The Company has obtained all material permits of the FDA and Health Canada, or any other applicable Governmental Authority necessary to conduct its business as presently conducted (collectively, the “Regulatory Licenses”), such Regulatory License are set out on Schedule 3.9, and all of such Regulatory Licenses are in full force and effect. There has not occurred any revocation, termination, withdrawal or suspension of any Regulatory License, and no proceeding is pending or, to the Knowledge of the Company, threatened to revoke, terminate, withdraw, suspend or adversely modify any such Regulatory License. To the Knowledge of the Company, the Company has, since January 1, 2015, operated the Business in a manner that would not reasonably be expected to result in withdrawal of approval of any Regulatory License.

Section 3.27.3 The Company is, and, to the Knowledge of the Company, has been since January 1, 2015, in material compliance with all provisions of (i) the FDC Act and the implementing regulations promulgated by the FDA that are applicable to the Company and the Business carried on by it, including (A) the manufacture of the Products in compliance in all material respects with the FDC Act and Current Good Manufacturing Practices; and (B) the recordkeeping and reporting requirements applicable to it; and (ii) the Controlled Substances Act and the implementing regulations promulgated by the Drug Enforcement Administration applicable to it, including, to the extent applicable to the Company, requirements regarding the ordering, receipt, labeling, packaging, storage, security, recordkeeping, reporting, manufacture, sale and distribution of Controlled Substances and Listed Chemicals.

Section 3.27.4 No action is pending or threatened to be taken by the FDA or Health Canada against the Company with regard to the integrity of data submitted by the Company to its customers in support of any Product approval sought by such customers.

Section 3.28 *Government Contracts* . During the past three (3) years, neither the Company nor, to the Company's Knowledge, any director, officer, or employee has been suspended or debarred from bidding on Contracts with any Governmental Authorities; no such suspension or debarment has been initiated or, to the Company's Knowledge, threatened; and the consummation of the transactions contemplated by this Agreement will not result in any such suspension or debarment of the Company (assuming that no such suspension or debarment will result solely from the identity of Purchaser). To the Company's Knowledge, the Company has not been and is not now being audited or investigated in relation to the Business by the United States Government Accountability Office, the United States Department of Defense or any of its agencies, the Defense Contract Audit Agency, the contracting or auditing function of any Governmental Authority with which it is contracting, the United States Department of Justice, the Inspector General of the United States Governmental Body or any other Governmental Authority; nor, to the Company's Knowledge, has any such audit or investigation been threatened. Schedule 3.28 contains as of the date of this Agreement a complete list of each Contract with a Governmental Authority that is still in effect, identifying the (i) contracting agency, (ii) contract type and contract number, (iii) name and address, and contact information of contracting office and/or contracting officer, (iv) total dollar value of Contract, and (v) approximate remaining balance.

Section 3.29 *Inventory* . All of the finished Products manufactured and intended for commercial use by the Company have been manufactured, labelled, packaged and tested by the Company, as applicable, in accordance with the applicable specifications provided by the applicable customers, GMPs and other applicable regulatory requirements.

Section 3.30 *Brokers* . Except for the Financial Advisor and the Sponsors, no Person is or will be entitled to a broker's, finder's, investment banker's, financial advisor's or similar fee from the Company in connection with this Agreement or any of the transactions contemplated hereby.

Section 3.31 *Books and Records* .

Section 3.31.1 The minute books and other similar records of the Company as made available to Purchaser prior to the date hereof contain a true, correct and complete record, in all material respects, of all action taken at all meetings and by all written consents in lieu of meetings of the board of directors and committees of the board of directors of the Company. The stock transfer ledgers and other similar records of the Company as made available to Purchaser prior to the date hereof accurately reflect all record transfers prior to the execution of this Agreement in the Shares.

Section 3.31.2 No books and records of the Company are recorded, stored, maintained, operated or otherwise wholly or partly dependent upon or held by any means (including any electronic, mechanical or photographic process, whether computerized or not) which (including all means of access thereto and therefrom) are not under the exclusive ownership and direct control of the Company. At Closing, all of the books and records of the Company will be in the possession or control of the Company.

Section 3.32 ***NO ADDITIONAL REPRESENTATIONS*** . EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN ARTICLE III, THE COMPANY DOES NOT MAKE AND HAS NOT MADE ANY REPRESENTATION OR WARRANTY IN CONNECTION WITH THIS AGREEMENT OR THE TRANSACTIONS CONTEMPLATED HEREBY. THE COMPANY EXPRESSLY DISCLAIMS ANY OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND OR NATURE, EXPRESS OR IMPLIED, NOTWITHSTANDING THE DELIVERY OR DISCLOSURE TO PURCHASER, ITS AFFILIATES OR THEIR RESPECTIVE OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR REPRESENTATIVES OF ANY DOCUMENTATION OR OTHER INFORMATION (INCLUDING ANY FINANCIAL PROJECTIONS OR OTHER SUPPLEMENTAL DATA), INCLUDING AS TO THE CONDITION, VALUE OR QUALITY OF THE BUSINESS OR ITS ASSETS, THE COMPANY SPECIFICALLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF MERCHANTABILITY, USAGE, SUITABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE WITH RESPECT TO ITS ASSETS OR BUSINESS, ANY PART THEREOF, THE WORKMANSHIP THEREOF, AND THE ABSENCE OF ANY DEFECTS THEREIN, WHETHER LATENT OR PATENT, IT BEING UNDERSTOOD THAT SUCH SUBJECT ASSETS AND BUSINESS ARE BEING ACQUIRED “AS IS, WHERE IS” ON THE CLOSING DATE, AND IN THEIR PRESENT CONDITION, AND PURCHASER AND ITS AFFILIATES SHALL RELY SOLELY ON THEIR OWN EXAMINATION AND INVESTIGATION THEREOF.

ARTICLE IV —REPRESENTATIONS AND WARRANTIES OF SELLER

Seller hereby represents and warrants to Purchaser that except as set forth on the disclosure schedule attached hereto, which exceptions or disclosures shall be deemed to be part of the representations and warranties made hereunder, that the following are true and correct as of the date of this Agreement (except to the extent expressly relating to a specific date, in which event such representation or warranty shall be made as of such date):

Section 4.1 ***Shares*** . Seller owns of record and beneficially the Shares. Such Shares are, and when delivered by Seller to Purchaser pursuant to this Agreement will be, free and clear of any and all Liens.

Section 4.2 ***Authority*** . Seller has the authority under its Governing Documents to execute and deliver this Agreement and each other Document to which it is a party and to perform its obligations hereunder and thereunder. Seller has duly executed and delivered this Agreement and each other Document to which it is a party. Each of the Documents to which Seller is or will be a party is, or upon its execution and delivery will be (assuming that this Agreement and the other Documents have been duly authorized, executed and delivered by the other parties thereto), a valid and binding agreement of Seller, enforceable against Seller in accordance with its terms, except as the enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting the enforcement of creditors’ rights generally or (ii) applicable equitable principles (whether considered in a proceeding at law or in equity).

Section 4.3 ***Non-Contravention*** . Neither the execution and delivery of this Agreement or the other Documents to which it is a party nor the performance by Seller of its obligations hereunder and thereunder will (i) contravene any provision contained in Seller's Governing Documents or (ii) conflict with, violate or result in a breach (with or without the lapse of time, the giving of notice or both) of, or constitute a default (with or without the lapse of time, the giving of notice or both) under (A) any contract, agreement, commitment, indenture, mortgage, lease, pledge, note, bond, license, permit or other instrument or obligation or (B) any judgment, order, decree, statute, law, rule or regulation or other restriction of any Governmental Authority, in each case to which Seller is a party or by which it is bound or to which its assets or properties are subject, except, in each case, as would not have a material adverse effect on the ability of Seller to perform its obligations under this Agreement.

Section 4.4 ***Seller Consents*** . No notice to, filing with, or authorization, registration, consent or approval of any Governmental Authority or other Person is necessary for the execution, delivery or performance of this Agreement or the other Documents to which such Seller is a party or the consummation of the transactions contemplated hereby or thereby by such Seller, except for (i) notices, filings and approvals set forth on Schedule 4.4, (ii) those the failure of which to obtain or make would not have a Material Adverse Effect, and (iii) those that may be required solely by reason of Purchaser's (as opposed to any other third party's) participation in the transactions contemplated hereby and by the other Documents.

Section 4.5 ***NO ADDITIONAL REPRESENTATIONS*** . EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN ARTICLE IV, SELLER DOES NOT MAKE AND HAS NOT MADE ANY REPRESENTATION OR WARRANTY IN CONNECTION WITH THIS AGREEMENT AND THE TRANSACTIONS CONTEMPLATED HEREBY. SELLER EXPRESSLY DISCLAIMS ANY OTHER REPRESENTATIONS OR WARRANTIES OF ANY KIND OR NATURE, EXPRESS OR IMPLIED, NOTWITHSTANDING THE DELIVERY OR DISCLOSURE TO PURCHASER, ITS AFFILIATES OR THEIR RESPECTIVE OFFICERS, DIRECTORS, EMPLOYEES, AGENTS OR REPRESENTATIVES OF ANY DOCUMENTATION OR OTHER INFORMATION (INCLUDING ANY FINANCIAL PROJECTIONS OR OTHER SUPPLEMENTAL DATA), INCLUDING AS TO THE CONDITION, VALUE OR QUALITY OF SELLER'S ASSETS, AND SELLER SPECIFICALLY DISCLAIMS ANY REPRESENTATION OR WARRANTY OF MERCHANTABILITY, USAGE, SUITABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE WITH RESPECT TO ITS ASSETS, ANY PART THEREOF, THE WORKMANSHIP THEREOF, AND THE ABSENCE OF ANY DEFECTS THEREIN, WHETHER LATENT OR PATENT, IT BEING UNDERSTOOD THAT SUCH SUBJECT ASSETS ARE BEING ACQUIRED "AS IS, WHERE IS" ON THE CLOSING DATE, AND IN THEIR PRESENT CONDITION, AND PURCHASER AND ITS AFFILIATES SHALL RELY SOLELY ON THEIR OWN EXAMINATION AND INVESTIGATION THEREOF.

ARTICLE V —REPRESENTATIONS AND WARRANTIES OF PURCHASER

Purchaser hereby represents and warrants to Seller:

Section 5.1 *Organization* . Purchaser is a company duly organized, validly existing and in good standing under the laws of its jurisdiction of Nova Scotia and has all requisite corporate power and authority to own, lease and operate its property and assets and to carry on its business as presently conducted. Purchaser is duly qualified or licensed to do business in each jurisdiction where the actions required to be performed by it hereunder make such qualification or licensing necessary, except in those jurisdictions where failure to be so licensed or qualified would not result in a material adverse effect on Purchaser's ability to perform its obligations hereunder. Purchaser has delivered to the Company true and complete copies of its Governing Documents, as currently in effect.

Section 5.2 *Authorization* . Purchaser has the requisite power and authority to execute and deliver this Agreement and each other Document to which it is a party and to perform its obligations hereunder and thereunder, all of which have been duly and validly authorized by all requisite corporate action. This Agreement and each other Document to which Purchaser is a party have been duly authorized, executed and delivered by Purchaser and constitute a valid and binding agreement of Purchaser, enforceable against Purchaser in accordance with its terms except as the enforceability may be limited by (i) applicable bankruptcy, insolvency, reorganization, moratorium or other similar laws affecting the enforcement of creditors' rights generally or (ii) applicable equitable principles (whether considered in a proceeding at law or in equity).

Section 5.3 *Non-contravention* . The execution, delivery and performance by Purchaser of this Agreement and the other Documents to which it is a party and each of the other transactions contemplated hereby and thereby will not (i) contravene any provision contained in Purchaser's Governing Documents, (ii) conflict with, violate or result in a material breach (with or without the lapse of time, the giving of notice or both) of or constitute a material default (with or without the lapse of time, the giving of notice or both) under (A) any contract, agreement, commitment, indenture, mortgage, lease, pledge, note, bond, license, permit or other instrument or obligation or (B) any judgment, order, decree, statute, law, rule or regulation or other restriction of any Governmental Authority, in each case to which Purchaser is a party or by which it is bound or to which any of its assets or properties are subject, (iii) result in the acceleration of, or permit any Person to terminate, modify, cancel, accelerate or declare due and payable prior to its stated maturity any material obligation of such entity or (iv) require any authorization, consent, approval, exemption or other action by or declaration or notice to any Person or Governmental Authority (except for the applicable requirements of any applicable foreign antitrust laws or regulations).

Section 5.4 *Consents* . No notice to, filing with, or authorization, registration, consent or approval of any Governmental Authority or other Person is necessary for the execution, delivery or performance of this Agreement and the other Documents or the consummation of the transactions contemplated hereby or thereby by Purchaser.

Section 5.5 *Litigation* . Purchaser is not party to any pending or, to Purchaser's Knowledge, threatened litigation which would reasonably be expected to question the validity of, affect or prohibit the consummation of the transactions contemplated hereby.

Section 5.6 *Brokers* . No Person is or will be entitled to broker's, finder's, investment banker's, financial adviser's or similar fees from Purchaser in connection with this Agreement or any of the transactions contemplated hereby.

Section 5.7 *R&W Insurance Policy* . Purchaser has obtained the R&W Insurance Policy bound and effective as of the date hereof. Purchaser has provided Seller with a true, correct and complete copy of the final form of the R&W Insurance Policy and with a binder reflecting placement and effectiveness of the R&W Insurance Policy as of Closing.

Section 5.8 *Acknowledgement by Purchaser* . Purchaser acknowledges and agrees that it has conducted its own independent review and analysis of, and, based thereon, has formed an independent judgment concerning, the Business, assets, condition, operations and prospects of the Company, and Purchaser has been furnished with or given full access to such information about the Company and the Business and operations as it has requested. In entering into this Agreement, Purchaser has relied solely upon its own investigation and analysis and the representations and warranties of the Company and Seller expressly set forth in this Agreement, and Purchaser:

Section 5.8.1 acknowledges that, other than as set forth in Article III and Article IV of this Agreement, none of Seller, the Company, or any of their respective directors, officers, employees, Affiliates, stockholders, members, owners, agents, advisors or representatives makes or has made any representation or warranty, either express or implied, (i) as to the accuracy or completeness of any of the information provided or made available to Purchaser or its agents, advisors, representatives, lenders or Affiliates prior to the execution of this Agreement, and (ii) with respect to any projections, forecasts, estimates, plans or budgets of future revenues, expenses or expenditures, future results of operations (or any component thereof), future cash flows (or any component thereof) or future financial condition (or any component thereof) of the Company heretofore or hereafter delivered to or made available to Purchaser or its agents, advisors, representatives, lenders or Affiliates;

Section 5.8.2 acknowledges and agrees that, other than as expressly set forth in Article III and Article IV of this Agreement, no projections, forecasts and predictions, other estimates, data, financial information, documents, reports, statements (oral or written), summaries, abstracts, descriptions, presentations (including any management presentation or facility tour), memoranda, or offering materials with respect to the Company's business, is or shall be deemed to be a representation or warranty by Seller or any other Person, under this Agreement, or otherwise, and that Purchaser has not relied thereon in determining to execute this Agreement and proceed with the transactions contemplate hereby;

Section 5.8.3 acknowledges that the Shares have not been registered under applicable securities laws; and

Section 5.8.4 represents and warrants that (i) the Shares shall be acquired for Purchaser's own account and not with a view to, or intention of, distribution thereof in violation of the Securities Act, or any applicable state or other securities laws, and the Shares shall not be disposed of in contravention of the Securities Act or any applicable state securities laws, (ii) Purchaser's knowledge and experience in financial and business matters are such that it is capable of evaluating the merits and risks of the investment in the Company, (iii) Purchaser is an "accredited investor" as such term is defined in Rule 501 of Regulation D under the Securities Act, (iv) it has sufficient knowledge and experience in financial and business matters so as to be capable of evaluating the merits and risks of their investment in the Shares, (v) it is capable of bearing the economic risks of such investment, including a complete loss of its investment in the Shares and (vi) it understands and agrees that it may not sell or dispose of any of the Shares other than pursuant to a registered offering or in a transaction exempt from the registration requirements of applicable securities laws and regulations.

ARTICLE VI—COVENANTS AND AGREEMENTS

Section 6.1 *Confidentiality; Reservation of Documents.*

Section 6.1.1 For a period of two (2) years following the Closing, and subject to Section 6.5.2, Seller shall treat and hold as strictly confidential any data or information related to the Company, or to Purchaser or Parent or their direct or indirect shareholders, including information and documents disclosed to Seller (or its respective Affiliates or representatives), whether before or after the date hereof, pursuant to this Agreement or in connection with the transactions contemplated by, or the discussions and negotiations preceding, this Agreement, and Seller will not use any such data or information except in connection with this Agreement, *provided*, that Seller shall not be bound by the confidentiality requirements of this Section 6.1.1 with respect to data or information and documents which (i) are or become generally available to the public other than as a result of a disclosure by Seller after the Closing Date in breach of its obligations hereunder, (ii) relate to Purchaser or any of its Affiliates and were within Seller's possession or control prior to its being furnished to Seller by or on behalf of the Company or Purchaser pursuant hereto, *provided* that the source of such information was not actually known by Seller, after reasonable inquiry, to be bound by a contractual, legal or fiduciary obligation of confidentiality to Seller, the Company or Purchaser with respect to such information, (iii) are provided to or become available to Seller from a source other than the Company or Purchaser, *provided* that such source is not actually known by Seller, after reasonable inquiry, to be bound by a contractual, legal or fiduciary obligation of confidentiality to the Company or Purchaser with respect to such information, (iv) is or was independently developed or on behalf of by Seller or any of its Affiliates without violating its obligations hereunder, (v) in connection with the enforcement of this Agreement and any dispute relating to or in connection with the transactions contemplated by this Agreement, including under this Agreement or (vi) are requested or required to be disclosed by applicable law, regulation or stock exchange rule (including any Proceeding, arbitration, civil investigative demand, subpoena, or other similar process reasonably believed to create a disclosure requirement).

Section 6.1.2 After the Closing, Purchaser shall, and shall cause the Company to, until the seventh (7th) anniversary of the Closing Date, retain all books and records of the Company in existence on the Closing Date and make the same available for inspection and copying by Seller or any representative of Seller at the expense of Seller during normal business hours of the Company upon reasonable request and upon reasonable notice.

Section 6.2 *Personal Information* . Purchaser covenants that it will (i) use and disclose the Personal Information transferred to it under the terms of this Agreement solely for the purposes for which that Personal Information was collected or permitted to be used or disclosed before the transaction was completed and in accordance with applicable Privacy Laws; and (ii) neither use nor disclose any of that Personal Information for any purpose for which its use and disclosure was not permitted before the Closing. The obligations imposed by this Section 6.2 will be perpetual.

Section 6.3 *No Modification of R&W Insurance Policy* . Purchaser has bound the R&W Insurance Policy at or prior to the Closing on terms and in the form provided or made available to Seller prior to the date hereof, which such policy, for the avoidance of doubt, includes terms to the effect that the insurers under the R&W Insurance Policy (a) waives, and agrees not to pursue, directly or indirectly, any subrogation rights against Seller with respect to any claim made by any insured thereunder (except in the case of knowing and intentional fraud of Seller) and (b) agrees that the Purchaser Indemnitees shall have no obligation to pursue any claim against Seller in connection with any Loss. Purchaser shall not, and shall cause its Affiliates and the insureds under the R&W Insurance Policy to not: (a) amend, supplement, modify or otherwise change, terminate or waive any provision of the R&W Insurance Policy with respect to the waiver of subrogation set forth therein without the prior written consent of Seller, or (b) grant any waiver or consent under the R&W Insurance Policy, in each case in a manner that would be inconsistent with the foregoing clause (a) or that otherwise would be adverse to the interests of Seller or its partners, managers, Affiliates, employees and personnel.

Section 6.4 *Reasonable Efforts; Further Assurances* . Subject to the terms and conditions herein provided, each of the parties hereto shall use reasonable best efforts to take, or cause to be taken, all action, and to do, or cause to be done, all things reasonably necessary, proper or advisable under applicable laws and regulations to consummate and make effective the transactions contemplated by this Agreement and each of the Company and Purchaser will use reasonable best efforts to obtain consents or approvals of all Governmental Authorities and third parties necessary to the consummation of the transactions contemplated by this Agreement. All costs incurred in connection with obtaining any such consents or approvals prior to the Closing shall be borne fifty percent (50%) by Seller and fifty percent (50%) by Purchaser. In addition, the Seller agrees to provide or cause the Company to provide any reasonable officer's certificate reasonably required by the Purchaser's title insurer to obtain a title insurance policy or amendment to a title insurance policy with respect to the Owned Real Property provided that such officer's certificate shall be made without personal liability on the part of the officer signing such certificate.

Section 6.5 ***Public Announcements.***

Section 6.5.1 No press release or public announcement related to this Agreement, the documents, certificates and instruments delivered in connection with this Agreement or the transactions contemplated hereby or thereby, shall be issued or made by any party hereto (nor will any party permit any of its advisors or Affiliates to do any thereof) without the prior written approval of Seller and Purchaser; *provided* that the foregoing restriction shall not apply to press releases or public announcements (a) which, in the reasonable opinion of counsel, are required by applicable law or self-regulatory organization such as a stock exchange, in which case Seller and Purchaser shall be afforded a reasonable opportunity to review and comment on such press release, announcement or communication prior to its issuance, distribution or publication, (b) disclosure which is necessary in connection with the enforcement of any right or remedy relating to this Agreement, the documents, certificates and instruments delivered in connection with this Agreement or the transactions contemplated hereby or thereby, or (c) customary disclosures by any party hereto or any Affiliate thereof which is a private equity or other investment fund to its investors or potential investors who are subject to customary confidentiality restrictions. Notwithstanding anything to the contrary herein, promptly following the execution of this Agreement, Purchaser and Parent, as the case may be, shall be permitted to issue a press release and make related disclosures in filings by Parent with the United States Securities Exchange Commission announcing the transactions contemplated by the Documents; provided that, prior to such disclosure, Purchaser or Parent, as the case may be, shall provide Seller with a copy of, and a reasonable opportunity to review and comment on, such disclosure and after such announcement Seller and its Affiliates shall be permitted to make public announcements which are consistent with, and contain no information in addition to, such prior disclosures; provided that, prior to such disclosure, Seller shall provide Parent with a copy of, and a reasonable opportunity to review and comment on, such disclosure.

Section 6.5.2 Notwithstanding anything contained herein to the contrary, the parties hereto acknowledge and agree that each of the Sponsors and their respective Affiliates (except for the Company) and representatives may provide general information about the subject matter of this Agreement and the Company (including its and their performance and improvements) in connection with each Sponsor or its respective Affiliates' fund raising, marketing, informational or reporting activities. Notwithstanding anything contained herein to the contrary, in no event will Purchaser or, after the Closing, the Company or its Affiliates have any right to use either Sponsor's or its respective Affiliates' names or marks, or any abbreviation, variation or derivative thereof, in any press release, public announcement or other public document or communication without the express written consent of such Sponsor or its respective Affiliates, as applicable. Following the Closing, each Sponsor and its respective Affiliates may use and reference the name of the Company and the associated marks and logos for the purpose of describing the current and historical relationship of the Company with such Sponsor and its respective Affiliates (including on their respective web sites). Each Sponsor is express third party beneficiaries of this Section 6.5.2.

Section 6.5.3 For the avoidance of doubt, disclosures resulting from the parties' efforts to obtain any consent, waiver, approval and/or early termination under any applicable Governmental Authority and to make any related filing shall be deemed to not violate this Agreement.

Section 6.6 *Indemnification of Directors and Officers*. The Governing Documents of the Company shall contain provisions no less favorable with respect to the limitation or elimination of liability and indemnification than are set forth in the Governing Documents of the Company as of the date of this Agreement, which provisions shall not be amended, repealed or otherwise modified for a period of six (6) years after the Closing in any manner that would adversely affect the rights thereunder of individuals who at or prior to the Closing were directors, officers, agents or employees of the Company or who were otherwise entitled to indemnification pursuant to the Governing Documents of the Company. Seller has caused the Company to purchase and maintain in effect a directors' and officers' liability insurance tail policy (the "Tail Policy") to be effective for six (6) years from the Closing Date with respect to matters existing or occurring at or prior to the Closing Date (including transactions contemplated by this Agreement). The provisions of this Section 6.6 are (i) intended to be for the benefit of, and shall be enforceable by, each Person entitled to indemnification under this Section 6.6, and each such Person's heirs, legatees, representatives, successors and assigns, it being expressly agreed that such Persons shall be third-party beneficiaries of this Section 6.6 and (ii) in addition to, and not in substitution for, any other rights to indemnification that any such Person may have by contract or otherwise. This Section 6.6 shall survive the consummation of the Closing and shall be binding on all successors and assigns of Purchaser and the Company.

Section 6.7 *Transfer Taxes*. All transfer, documentary, sales, use, stamp, registration and other such Taxes, and all conveyance fees, recording charges and other fees and charges (including any penalties and interest) incurred in connection with consummation of the transactions contemplated by this Agreement shall be paid by Purchaser; *provided* that any Taxes incurred in connection with the transfer of the Shares shall be borne fifty percent (50%) by Seller and fifty percent (50%) by Purchaser.

Section 6.8 *Tax Matters.*

Section 6.8.1 Taxes (other than Transfer Taxes) with respect to any Straddle Period will be allocated to the portion of the period ending on the Closing Date using the following conventions: (A) in the case of income Taxes (however denominated), sales and use Taxes, withholding Taxes and value added Taxes, the amount of Taxes allocated to the portion of the Straddle Period ending on the Closing Date shall be the amount of Taxes payable for such portion of the period determined utilizing the "closing of books" methodology; and (B) in the case of all other Taxes, the amount of Taxes allocated to the portion of the Straddle Period ending on the Closing Date shall equal to the amount of Taxes for the entire Straddle Period multiplied by a fraction, the numerator of which is the number of calendar days in the portion of the Straddle Period ending on the Closing Date and the denominator of which is the number of calendar days in the entire Straddle Period.

Section 6.8.2 Seller shall be entitled to receive (as additional Purchase Price) an amount equal to any Tax refunds, including interest paid by an applicable Tax authority therewith, that are received by the Company during the twelve (12) month period following the Closing Date, in respect of Taxes paid by the Company with respect to any period ending on or prior to the Closing Date, or the portion ending on the Closing Date of any period that begins before and ends after the Closing Date (each, a “Pre-Closing Tax Period”). Purchaser shall forward to or reimburse Seller for any such amounts within ten (10) days after receipt thereof.

Section 6.8.3 Unless otherwise required by law, neither Purchaser nor any of its Affiliates shall file, amend, refile, revoke or otherwise modify any Tax Return or Tax election of the Company with respect to a Pre-Closing Tax Period (including a Code Section 338 election with respect to the sale) without the prior written consent of Seller, which consent shall not be unreasonably withheld, conditioned or delayed.

Section 6.8.4 Purchaser and Seller shall cooperate fully, and after the Closing, Purchaser shall cause the Company to cooperate fully, as and to the extent reasonably requested by the other party, in connection with the preparation and filing of Tax Returns and any audit or other Tax Contest. Such cooperation shall include access to, the retention and (upon the other party’s request) the provision of records and information that are reasonably relevant to any such Tax Return or Tax Contest, and the making available of employees on a mutually convenient basis to provide additional information and explanation of any material provided hereunder.

Section 6.8.5 Purchaser acknowledges and agrees that its sole remedy for claims for indemnification in respect of Taxes will be pursuant to the indemnification provisions set forth in Article VII.

Section 6.9 *Seller Release.*

Effective as of the Closing, Seller knowingly and voluntarily releases and forever discharges the Company from any and all claims, controversies, causes of action, cross-claims, counter-claims, damages, claims for costs and attorneys’ fees, or liabilities, in law and in equity and whether known or unknown, suspected, or claimed against the Company that Seller may have, relating to its ownership of the Shares; *provided, however*, that no release is given hereunder in respect of any obligations required to be performed by the Company under the terms of this Agreement.

Section 6.10 *Use of Name.*

As promptly as practicable following the Closing Date (and in any event within thirty (30) days following the Closing Date), Seller shall, and shall cause its Affiliates to, cease to make any use of the name “Wellspring” and the service marks, trademarks, trade names, identifying symbols, logos, emblems, signs or insignia related thereto or containing or comprising of the foregoing, including any name or mark confusingly similar thereto (the “Company Marks”). Immediately after the Closing, Seller shall, and shall cause its Affiliates to, cease to hold itself out as having any affiliation with the Company or any of its Affiliates. In furtherance thereof, as promptly as practicable but in no event later than the expiration of the relevant period provided above for transitional use of the Company Marks, Seller shall, and shall cause its Affiliates to, remove, strike over or otherwise obliterate all Company Marks from any websites, social media pages, vehicles, storage tanks, business cards, schedules, stationery, packaging materials, displays, signs, promotional materials, manuals, forms, computer software and other property and materials of Seller or its Affiliates. For the avoidance of doubt, nothing in this Section 6.10 shall affect the rights of the Sponsors pursuant to Section 6.5.2.

ARTICLE VII—SURVIVAL OF REPRESENTATIONS AND WARRANTIES; INDEMNIFICATION

Section 7.1 *Survival of Representations and Warranties* . The representations and warranties of Seller, the Company and Purchaser contained in this Agreement (whether or not contained in Article III, Article IV or Article V) shall survive the Closing for a period of twelve (12) months after the Closing Date, other than in the case of fraud on the part of the party making such representation or warranty (in such case, surviving in accordance with the applicable statute of limitations). All covenants set forth herein shall survive the Closing in accordance with their respective terms.

Section 7.2 *General Indemnification* .

Section 7.2.1 If, after the Closing Date, Purchaser and/or its officers, directors, employees, partners, managers, Affiliates (which, upon and after the Closing, shall include the Company) and/or agents (each a “Purchaser Indemnitee” and together the “Purchaser Indemnitees”) suffer, without any duplication, any Losses as a result of, in connection with, or arising out of (a) any breach of any representation or warranty made by Seller or the Company contained in Article III or Article IV, (b) any failure by Seller to perform any of its covenants or agreements contained herein which are to be performed by Seller after the Closing, (c) any claim pursuant to Section 6.6 which directly results from breach of any representation or warranty made by the Company contained in Article III, or (d) any claim made prior to the 12-month anniversary of the Closing with respect to the matters described on Schedule 7.2.1(d), then, subject to the other provisions of this Article VII, Seller agrees to indemnify, defend and hold harmless Purchaser Indemnitees against such Losses.

Section 7.2.2 If, after the Closing Date, Seller and its officers, directors, employees, partners, managers, Affiliates and/or agents (each a “Seller Indemnitee” and together the “Seller Indemnitees”) suffer, without duplication, any Losses as a result of, in connection with, or arising out of (a) any breach of any representation or warranty made by Purchaser in Article V, (b) any failure by Purchaser to perform any of its covenants or agreements contained herein, and (c) any breach by the Company of any of its covenants or agreements contained herein which are to be performed by the Company after the Closing, then, subject to the other provisions of this Article VII, Purchaser agrees to indemnify, defend and hold harmless Seller Indemnitees against such Losses.

Section 7.2.3 The obligations to reimburse, indemnify and hold harmless pursuant to Section 7.2.1 and pursuant to Section 7.2.2 shall survive the consummation of the transactions contemplated hereby for the period set forth in Section 7.1, except for claims for indemnification pursuant to such clauses asserted in writing prior to the end of such period which claims shall survive until final resolution thereof.

Section 7.2.4 All indemnification payments made pursuant to this Article VII shall be treated as adjustments to the Purchase Price for Tax purposes unless otherwise required by a change in law occurring after the date hereof, a closing agreement with an applicable taxing authority or a final non-appealable judgment of a court of competent jurisdiction.

Section 7.3 *Third Party Claims.*

Section 7.3.1 If a claim, action, suit or other proceeding by a third party (a “Third Party Claim”) is made against any Person entitled to indemnification or reimbursement pursuant to Section 7.2 (an “Indemnified Party”), and if such Indemnified Party intends to seek indemnity or reimbursement with respect thereto under this Article VII, such Indemnified Party shall promptly provide written notice to the party obligated to indemnify such Indemnified Party (such notified party, the “Responsible Party”) of such claims; *provided*, that the failure to so notify shall not relieve the Responsible Party of its obligations hereunder, except to the extent that the Responsible Party is actually and materially prejudiced thereby. Such notice shall provide in reasonable detail, to the extent known, the basis of such claim (with reference to the specific provision of this Agreement) under which indemnification or reimbursement is sought pursuant to Section 7.2 and enclose true, correct and complete copies of any written document furnished to the Indemnified Party by the Person that instituted the Third Party Claim.

Section 7.3.2 The Responsible Party shall have the right to elect to control the defense or prosecution of any Third Party Claim in respect of which indemnity or reimbursement may be sought hereunder and shall furnish to the Indemnified Party such records, information and testimony, and shall permit such Indemnified Party the opportunity to attend such conferences, discovery proceedings, hearings, trials and appeals, as may be reasonably requested by such Indemnified Party in connection therewith.

Section 7.3.2.1 The Responsible Party shall have twenty (20) days the receipt of the Indemnified Party’s notice of a claim of indemnity hereunder to assume the conduct and control, through counsel reasonably acceptable to the Indemnified Party at the expense of the Responsible Party (it being understood and agreed by Seller that Orrick, Herrington & Sutcliffe LLP is deemed reasonably acceptable counsel), of the settlement or defense thereof, and the Indemnified Party shall cooperate with it in connection therewith; provided, that the Responsible Party shall permit the Indemnified Party to participate in such settlement or defense through counsel chosen by such Indemnified Party, it being understood and agreed that the fees and expenses of such counsel shall be borne by such Indemnified Party; provided, however, such fees and expenses of the Indemnified Party’s counsel shall be borne by the Responsible Party if in the reasonable opinion of counsel to the Indemnified Party, a conflict or potential conflict exists between such Indemnified Party and such Responsible Party that would make separate representation advisable.

Section 7.3.2.2 If the Responsible Party does not notify the Indemnified Party within twenty (20) days after the receipt of the Indemnified Party's notice of a claim of indemnity hereunder that it elects to undertake the defense thereof, the Indemnified Party shall have the right to contest, settle or compromise the claim but shall not thereby waive any right to indemnity or reimbursement therefor pursuant to this Agreement.

Section 7.3.2.3 If the Responsible Party elects not to assume the defense thereof, fails to timely and properly notify the Indemnified Party of its election as herein provided, or, at any time after assuming such defense, fails to diligently defend against such Third-Party Claim in good faith, or if such Indemnified Party is otherwise entitled pursuant to this Agreement to have control over the defense of any Third-Party Claim, such Indemnified Party may, at such Responsible Party's expense, pay, defend, settle, or compromise such asserted claim (but such Responsible Party shall nevertheless be required to pay in accordance with this Agreement any Losses incurred by such Indemnified Party in connection with such payment, defense, settlement, or compromise thereof which are indemnifiable in accordance with this Article VII).

Section 7.3.2.4 Notwithstanding anything herein to the contrary, the Responsible Party shall not be entitled to have sole control over (and if it so desires, the Indemnified Party shall have sole control over) the defense, settlement, adjustment, or compromise of (but such Responsible Party shall nevertheless be required to pay in accordance with this Agreement all Losses incurred by the Indemnified Party in connection with the defense, settlement, or compromise thereof) (i) any Third-Party Claim that primarily seeks an order, injunction or other equitable relief against any Indemnified Party or any of its Affiliates, (ii) any Third-Party Claim that is reasonably expected to result in damages greater than 120% of the amount of the Indemnity Escrow Funds, (iii) the Third-Party Claim is on behalf of a Material Customer, and (iv) any criminal proceeding, indictment or allegation.

Section 7.3.2.5 No Responsible Party will, without the prior written consent of each such Indemnified Party, settle or compromise or consent to the entry of any judgment in any Third Party Claim in respect of which indemnification may be sought hereunder (whether or not any such Indemnified Party is a party to such action), unless such settlement, compromise or consent by its terms obligates such Responsible Party to pay the full amount of the Losses in connection with such Third-Party Claim and includes an unconditional release of all such Indemnified Parties from all liability arising out of such Third Party Claim.

Section 7.4 *Limitations on Indemnification Obligations* . The rights of Purchaser Indemnitees to indemnification pursuant to the provisions of Section 7.2.1 are subject to the following limitations:

Section 7.4.1 the amount of any and all Losses will be determined net of (i) any amounts recovered by Purchaser Indemnitees under insurance policies or other collateral sources (such as contractual indemnities of any Person which are contained outside of this Agreement) with respect to such Losses, net of any reasonable out-of-pocket expenses incurred in collecting such proceeds or payment and increases in premiums attributable to such recovery, and (ii) any Tax benefit actually realized with respect to such Losses within twelve (12) months following the date on which the Claim is made by Purchaser Indemnitee hereunder (it being understood that any such Tax benefit that actually is realized after the payment pursuant to this section (and within the period specified above) shall not be netted from such payment, but shall be paid by the applicable Purchaser Indemnitee within twenty (20) days after such Tax benefit actually is realized) (for the avoidance of doubt, this Section 7.4 shall in no way be construed to require any Purchaser Indemnitee to make available its Tax Returns (or any other information it deems confidential) to Seller or any other Person);

Section 7.4.2 [Intentionally omitted];

Section 7.4.3 Purchaser Indemnitees will not be entitled to recover Losses pursuant to Section 7.2.1(a) until the total amount which Purchaser Indemnitees would recover under Section 7.2.1(a) (as limited by the provisions of Sections 7.4.1), exceeds \$110,000 (the “Deductible”) and then only for the excess over the Deductible; provided, however, the Deductible will not apply in the case of fraud on the part of the party making such representation or warranty; provided, further, any amounts recovered by Purchaser Indemnitees under Sections 7.2.1(b), (c), or (d) or in the case of fraud shall count when determining whether the Deductible has been exceeded for purposes of claims under Section 7.2.1(a).

Section 7.4.4 the Indemnity Escrow Funds, at any given time, shall be the sole source of recovery with respect to any Losses that the Purchaser Indemnities are entitled to recover from Seller or any of its Affiliates for Losses pursuant to Sections 7.2.1(a), and (d) (except in the case of fraud on the part of Seller or the Company) and in no event shall the Purchaser Indemnitees be entitled to recover from Seller or any of its Affiliates more than the amount of the Indemnity Escrow Funds in respect of Losses pursuant to Sections 7.2.1(a), and (d) (except in the case of fraud on the part of the party making such representation or warranty) (for the avoidance of doubt, notwithstanding anything contained herein to the contrary after the Closing, on the date that the amount of cash in the Indemnity Escrow Account is reduced to zero, Purchaser Indemnitees shall have no further rights to indemnification from Seller under Sections 7.2.1(a), and (d) (except in the case of fraud on the part of the party making such representation or warranty));

Section 7.4.5 In no event shall Seller or any of its Affiliates have any liability pursuant to this Agreement, the Documents or any other certificate or instrument delivered pursuant hereto, or the transactions related hereto or thereto in the aggregate in excess of the proceeds received by such Person directly or indirectly as a result of the payment of proceeds to Seller pursuant to Article II of this Agreement, as adjusted.

Section 7.4.6 Purchaser Indemnitees shall not be entitled to recover Losses to the extent such Losses were included in any item taken into account in the determination of Purchase Price (for which the sole remedy shall be pursuant to Section 2.3);

Section 7.4.7 Purchaser Indemnitees and Seller Indemnitees, as applicable, shall use commercially reasonable efforts to mitigate any of their respective Losses; provided that the costs of any such commercially reasonable mitigation efforts, subject to the limitations set forth in this Agreement, shall constitute indemnifiable Losses hereunder;

Section 7.4.8 in any case where a Purchaser Indemnitee recovers under insurance policies or from other collateral sources any amount in respect of a matter for which such Purchaser Indemnitee was indemnified pursuant to Section 7.2.1 of this Agreement, such Purchaser Indemnitee shall promptly pay over to Seller the amount so recovered (after deducting therefrom all reasonable and out-of-pocket expenses incurred by it in procuring such recovery), but not in excess of the sum of (i) any amount previously so paid by or on behalf of Seller in respect of such matter (taking into account any reduction pursuant to Section 7.4.1), and (ii) any reasonable out-of-pocket expenses incurred by Seller in pursuing or defending any claim arising out of such matter; and

Section 7.4.9 notwithstanding the foregoing, for the purposes of determining whether there has been a breach of a representation or warranty or covenant and for calculating the amount of any Losses related thereto, the representations and warranties and covenants shall be read without regard to any Material Adverse Effect or other materiality qualifiers contained therein; provided that the foregoing shall not apply to the representations and warranties set forth in Section 3.6.2.

Section 7.5 *Release of Indemnity Escrow Funds*. Any funds remaining in the Indemnity Escrow Account, less the amount claimed pursuant to Section 7.2.1 in respect of matters which have not been resolved prior to the date which is twelve (12) months following the Closing Date shall be released to Seller on such date that is twelve (12) months following the Closing Date, provided that Purchaser and Seller shall promptly provide written instruction to the Escrow Agent to make such release. At any time after the date that is twelve (12) months after the Closing Date, if a claim for which funds had been retained in the Indemnity Escrow Account is resolved, Purchaser and Seller shall, within three (3) Business Days following resolution thereof, provide written instructions to the Escrow Agent to release the funds associated therewith to the Party associated with such resolution.

Section 7.6 *Exclusive Remedy*. Notwithstanding anything contained in this Agreement to the contrary, except as provided in Section 2.3, Section 2.5, Section 8.13 and in the case of fraud, after the Closing, indemnification pursuant to the provisions of this Article VII and of the R&W Insurance Policy shall be the sole and exclusive remedy of Purchaser for any misrepresentation or breach of any warranty, covenant or other provision contained in this Agreement, the Documents or in any other certificate or instrument delivered pursuant hereto or otherwise in respect of the transactions contemplated hereby (including with respect to any environmental, health or safety matters, including those arising under CERCLA or any other Environmental Laws (“Environmental Matters”) or Tax matters). Except as provided in Section 8.13 and except for Seller’s obligation (if any) under Section 2.3.4.2 with respect to the Actual Adjustment and in the case of fraud on the part of Seller or the Company, the sole and exclusive remedy available to Purchaser Indemnitees from Seller and its Affiliates for any Loss, Losses or other amounts (including any relating to Environmental Matters or Tax matters) arising under the indemnification obligations set forth in this Agreement, or otherwise in respect of the transactions contemplated hereby (including with respect to any Environmental Matters), shall be the provisions of this Article VII. Purchaser acknowledges that in no event shall any of Seller’s current, former and future equityholders, controlling Persons, directors, managers, officers, employees, agents, representatives, Affiliates, members, managers, general or limited partners, or assignees (or any former, current or future equityholder, controlling Person, director, officer, employee, agent, representative, Affiliate, member, manager, general or limited partner, or assignee of any of the foregoing) (in each case other than the other Seller and the Company as expressly provided herein) have any liability related to this Agreement or the transactions contemplated herein. Any payment made under the R&W Insurance Policy to the Purchaser Indemnitees pursuant to this Article VII shall constitute full satisfaction of any obligation of Seller to make such payment to the Purchaser Indemnitees.

ARTICLE VIII — MISCELLANEOUS

Section 8.1 *Notices* . All notices or other communications required or permitted hereunder shall be in writing and shall be delivered personally, by facsimile, by electronic mail or sent by certified, registered or express air mail, postage prepaid, and shall be deemed given when so delivered personally, or by facsimile or electronic mail, or if mailed, two (2) days after the date of mailing, as follows:

If to Purchaser, Parent or the Company:

ANI Pharmaceuticals, Inc.
210 W Main St
Baudette, MN 56623
Attention: CFO

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

Orrick, Herrington and Sutcliffe LLP
51 West 52nd Street
New York, NY 10019-6142
Facsimile: (212) 506-5151
Email: kmilling@orrick.com, dschwartz@orrick.com
Attention: R. King Milling, David Schwartz

If to Seller:

WSP Pharma Holdings, LLC
c/o Sentinel Capital Partners, L.L.C.
330 Madison Avenue, 27th Floor
New York, NY 10017
Facsimile: (212) 688-6513
Email: bommer@sentinelpartners.com; vansickle@sentinelpartners.com
Attention: Eric D. Bommer; John Van Sickle

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

Covington & Burling LLP
620 Eighth Avenue
New York, NY 10018
Facsimile: (646) 441-9250
Email: awollensack@cov.com
Attention: Amy Wollensack

or to such other address as any party hereto shall notify the other parties hereto (as provided above) from time to time.

Section 8.2 *Exhibits and Schedules* . All exhibits and schedules hereto (including the Schedules), or documents expressly referenced in this Agreement, are hereby incorporated into this Agreement and are hereby made a part hereof as if set out in full in this Agreement. Any matter that is disclosed in a Schedule shall be deemed to have been disclosed for the purposes of each other representation and warranty in this Agreement to which it is reasonably apparent on the face of such disclosure that it is applicable, notwithstanding the omission of an appropriate cross reference thereto. Disclosure of any fact or item in any Schedule shall not necessarily mean that such fact or item is material to Seller or the Company and any such disclosure, or any references to dollar amounts, shall not be deemed to be an acknowledgement or representation that such items are material or would cause a Material Adverse Effect, to establish any standard of materiality or to define further the meaning of such terms for the purposes of this Agreement.

Section 8.3 *Time of the Essence; Computation of Time* . Time is of the essence for each and every provision of this Agreement. In the computation of periods of time from a specified date to a later specified date, the word “from” means “from and including” and the words “to” and “until” mean “to but excluding” and the word “through” means “to and including.” Whenever the last day for the exercise of any privilege or the discharge of any duty hereunder shall fall upon a day that is not a Business Day, the party having such privilege or duty may exercise such privilege or discharge such duty on the next succeeding day that is a Business Day.

Section 8.4 *Expenses* . Except as otherwise set forth in this Agreement, regardless of whether the transactions provided for in this Agreement are consummated, except as otherwise provided herein, each party hereto shall pay its own expenses incident to this Agreement and the transactions contemplated herein. Purchaser understands and acknowledges that all out-of-pocket fees and expenses incurred or to be incurred by Seller or the Company in connection with the transactions contemplated hereby (including the Seller Expenses) will be paid by or on behalf of the Company in the manner set forth Section 2.2.

Section 8.5 *Governing Law* . All issues and questions concerning the construction, validity, enforcement and interpretation of this Agreement and the schedules and exhibits hereto shall be governed by, and construed in accordance with, the laws of the State of New York without giving effect to any choice of law or conflict of law rules or provisions (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York. In furtherance of the foregoing, the internal law of the State of New York shall control the interpretation and construction of this Agreement (and all schedules and exhibits hereto), even though under that jurisdiction’s choice of law or conflict of law analysis, the substantive law of some other jurisdiction would ordinarily apply.

Section 8.6 *Jurisdiction and Venue* . Each of the parties submits to the exclusive jurisdiction of any state or federal court sitting in New York, New York (or any applicable court of appeal thereto), in any action or proceeding arising out of or relating to this Agreement, agrees that all claims in respect of the action or proceeding may be heard and determined in any such court and agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court. Each of the parties waives any defense of inconvenient forum to the maintenance of any action or proceeding so brought and waives any bond, surety or other security that might be required of any other party with respect thereto. Each party agrees that service of summons and complaint or any other process that might be served in any action or proceeding may be made on such party by sending or delivering a copy of the process to the party to be served at the address of the party and in the manner provided for the giving of notices in Section 8.1. Nothing in this Section 8.6, however, shall affect the right of any party to serve legal process in any other manner permitted by law. Each party agrees that a final, non-appealable judgment in any action or proceeding so brought shall be conclusive and may be enforced by suit on the judgment or in any other manner provided by law.

Section 8.7 *Assignment; Successors and Assigns; No Third Party Rights* . Except as otherwise provided herein, this Agreement may not, without the prior written consent of the other parties hereto, be assigned by operation of law or otherwise, and any attempted assignment shall be null and void. Notwithstanding the foregoing, after the Closing Purchaser may assign or delegate any or all of its rights and/or obligations in whole or in part under this Agreement to any Person (other than an Affiliate of Purchaser) acquiring all or substantially all of the assets of Purchaser, in which case Purchaser shall, upon assumption of its obligations under this Agreement by such purchaser, be released from all of its obligations under this Agreement. Subject to the foregoing, this Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective heirs, successors, permitted assigns and legal representatives. Except as expressly set forth in Section 6.5.2 and Section 6.6, this Agreement shall be for the sole benefit of the parties to this Agreement and their respective heirs, successors, permitted assigns and legal representatives and is not intended, nor shall be construed, to give any Person, other than the parties hereto and their respective heirs, successors, assigns and legal representatives, any legal or equitable right, remedy or claim hereunder. Nothing in this Agreement, expressed or implied, is intended to or shall constitute the parties hereto partners or participants in a joint venture.

Section 8.8 *Counterparts* . This Agreement may be executed in any number of counterparts for the convenience of the parties hereto, each of which shall be deemed an original and all of which together will constitute one and the same instrument. Delivery of an executed counterpart of a signature page to this Agreement by facsimile, e-mailed PDF or other electronic transmission shall be effective as delivery of a mutually executed counterpart to this Agreement.

Section 8.9 *Titles and Headings* . The titles, captions and table of contents in this Agreement are for reference purposes only, and shall not in any way define, limit, extend or describe the scope of this Agreement or otherwise affect the meaning or interpretation of this Agreement.

Section 8.10 *Entire Agreement* . This Agreement (including the Schedules and Exhibits attached hereto), the other Documents and the Confidentiality Agreement, constitute the entire agreement among the parties with respect to the matters covered hereby and supersedes all previous written, oral or implied understandings among them with respect to such matters.

Section 8.11 *Severability* . The invalidity of any portion hereof shall not affect the validity, force or effect of the remaining portions hereof. If it is ever held that any restriction hereunder is too broad to permit enforcement of such restriction to its fullest extent, such restriction shall be enforced to the maximum extent permitted by law.

Section 8.12 *No Strict Construction* . Each of the parties hereto acknowledges that this Agreement has been prepared jointly by the parties hereto, and shall not be strictly construed against either party.

Section 8.13 *Specific Performance* . Each of Seller, the Company and Purchaser acknowledges that the rights of each party set forth in this Agreement are unique and recognizes and affirms that in the event of a breach of this Agreement by any party, money damages may be inadequate and the non-breaching party may have no adequate remedy at law. Accordingly, the parties agree that such non-breaching party shall have the right, in addition to any other rights and remedies existing in their favor at law or in equity, to enforce its rights and the other party's obligations not only hereunder but also by an action or actions for specific performance, injunctive and/or other equitable relief (without posting of bond or other security).

Section 8.14 *Waiver Of Jury Trial* . EACH OF THE PARTIES HERETO WAIVES ANY RIGHT IT MAY HAVE TO TRIAL BY JURY IN RESPECT OF ANY LITIGATION BASED ON, ARISING OUT OF, UNDER OR IN CONNECTION WITH OR INCIDENTAL TO THIS AGREEMENT OR ANY COURSE OF CONDUCT, COURSE OF DEALING, VERBAL OR WRITTEN STATEMENT OR ACTION OF ANY PARTY HERETO. THE PARTIES TO THIS AGREEMENT EACH HEREBY AGREES AND CONSENTS THAT ANY SUCH CLAIM, DEMAND, ACTION, OR CAUSE OF ACTION SHALL BE DECIDED BY COURT TRIAL WITHOUT A JURY AND THAT THE PARTIES TO THIS AGREEMENT MAY FILE AN ORIGINAL COUNTERPART OF A COPY OF THIS AGREEMENT WITH ANY COURT AS WRITTEN EVIDENCE OF THE CONSENT OF THE PARTIES HERETO TO THE WAIVER OF THEIR RIGHT TO TRIAL BY JURY.

Section 8.15 *Failure or Indulgence not Waiver* . No failure or delay on the part of any party hereto in the exercise of any right hereunder shall impair such right or be construed to be waiver of, or acquiescence in, any breach of any representation, warranty or agreement herein, nor shall any single or partial exercise of any such right preclude any other or further exercise thereof or any other right. All rights and remedies existing under this Agreement are cumulative to, and not exclusive of, any rights or remedies otherwise available.

Section 8.16 *Amendments* . This Agreement (including the provisions of this Section 8.16) may not be amended or modified except by an instrument in writing signed on behalf of each of Seller and Purchaser.

Section 8.17 *Conflicts; Privileges* . It is acknowledged by each of the parties hereto that Seller and the Company have retained Covington & Burling LLP (“Covington”) and Davies Ward Phillips & Vineberg LLP (together with Covington, the “Legal Counsel”) to act as their counsel in connection with the transactions contemplated hereby and that the Legal Counsel have not acted as counsel for any other Person in connection with the transactions contemplated hereby and that no other party to this Agreement has the status of a client of either Legal Counsel for conflict of interest or any other purposes as a result thereof. Purchaser hereby agrees that, in the event that a dispute arises between Purchaser or any of its Affiliates (including, after the Closing, the Company) and Seller or any of Seller’s direct or indirect equityholders (“Seller’s Equityholders”) under this Agreement or the transactions contemplated hereby, each Legal Counsel may represent Seller or such Seller’s Equityholder in such dispute. Even though the interests of such Seller’s Equityholder may be directly adverse to Purchaser, the Company or any of its Affiliates, and even though such Legal Counsel may have represented Seller or the Company in a matter substantially related to such dispute, Purchaser and the Company hereby waive, on behalf of themselves and each of their Affiliates, any conflict of interest in connection with such representation by such Legal Counsel. Purchaser further agrees that, as to all communications among any Legal Counsel, Seller, the Company and any of Seller’s Equityholders that relate in any way to the transactions contemplated by this Agreement, the attorney-client privilege, the expectation of client confidence and all other rights to any evidentiary privilege belong to Seller and Seller’s Equityholder and may be controlled by Seller or such Seller’s Equityholder and shall not pass to or be claimed by Purchaser or the Company. Purchaser agrees to take, and to cause its Subsidiaries to take, all steps reasonably necessary and within its control to implement the intent of this Section 8.17 .

Section 8.18 *Parent Guarantee.*

Section 8.18.1 Parent hereby unconditionally and irrevocably guarantees, as primary obligor and not merely as surety, the due and punctual payment and discharge of each obligation of Purchaser and the full and timely performance by Purchaser of its obligations, in each case, under the provisions of this Agreement and the other Documents to which Purchaser is a party (collectively, the “Obligations”).

Section 8.18.2 This is a guarantee of payment and performance, and Parent acknowledges and agrees that this guarantee is full and unconditional, and no release or extinguishment of Purchaser’s liabilities and obligations (other than in accordance with the terms of this Agreement or the Documents to which Purchaser is a party, as applicable), whether by decree in any bankruptcy proceeding or otherwise, will affect the continuing validity and enforceability of this guarantee. Parent hereby waives, for the benefit of Seller, (i) any right to require Seller, as a condition of payment or performance of Parent, to proceed against Purchaser or pursue any other remedies whatsoever, and (ii) to the fullest extent permitted by law, any defenses or benefits that may be derived from or afforded by law that limit the liability of or exonerate guarantors or sureties, except to the extent that any such defense is available to Purchaser under this Agreement.

Section 8.18.3 Seller shall not be obligated to file any claim relating to the Obligations in the event that Purchaser becomes subject to an insolvency event, and the failure of Seller to so file shall not affect Parent's obligations hereunder. In the event that any payment to Seller in respect of the Obligations is rescinded or must otherwise be returned for any reason whatsoever, Parent shall remain liable hereunder with respect to the Obligations as if such payment had not been made. This is an unconditional guarantee of payment and not of collectability.

Section 8.18.4 Parent agrees that its obligations hereunder shall remain absolute and unconditional and shall not be released or discharged, in whole or in part, or otherwise affected by (i) the failure of Seller to assert any claim or demand or to enforce any right or remedy against Purchaser (or any of its permitted assignees) or any other Person; (ii) any change in time, place or manner of payment of any of the Obligations or any rescission, waiver, compromise, consolidation or other amendment to or modification of any of the terms or provisions of this Agreement made in accordance with the terms thereof or any other agreement evidencing, securing or otherwise executed in connection with any of the Obligations; (iii) the addition, substitution or release of Purchaser (or any of its permitted assignees) or any other Person; (iv) any change in the corporate existence, structure or ownership of Purchaser (or any of its permitted assignees) or any other Person; (v) any insolvency event or other similar proceeding affecting Purchaser (or any of its successors or permitted assigns) or any other Person; (vi) the existence of any claim, set-off or other right which Parent may have at any time against Purchaser or Seller or any of their respective Affiliates, whether in connection with the Obligations or otherwise; (vii) the adequacy of any other means Seller may have of obtaining repayment of any of the Obligations; (viii) the value, genuineness, validity, regularity, illegality or enforceability of this Agreement; (ix) any assignment by Purchaser of its rights or obligations under this Agreement and (x) any defenses available to Purchaser (or its permitted assignees), other than defenses available under this Agreement. Parent waives promptness, diligence, notice of the acceptance of this guarantee and of the Obligations, presentment, demand for payment, notice of non-performance, default, dishonor and protest, notice of the incurrence of any Obligations and all other notices of any kind, all defenses which may be available by virtue of any valuation, stay, moratorium law or other similar law now or hereafter in effect, any right to require the marshalling of assets of Purchaser or any other Person interested in the transactions contemplated by this Agreement, and all suretyship defenses generally. Parent acknowledges that it will receive substantial direct and indirect benefits from the transactions contemplated by this Agreement and that the waivers set forth in this guarantee are knowingly made in contemplation of such benefits.

Section 8.18.5 As an inducement to Seller to enter into this Agreement, Parent hereby makes the following representations and warranties, as of the Effective Date, to Seller: Parent is a validly existing corporation and is in good standing under the laws of the jurisdiction of its organization; the execution, delivery and performance of this Agreement by Parent has been duly authorized by all requisite corporate action; this Agreement constitutes the legal, valid and binding obligation of Parent, enforceable against Parent in accordance with the terms hereof, subject to the effect of bankruptcy, insolvency, reorganization, receivership, moratorium and other similar laws affecting the rights and remedies of creditors generally and the effect of general principles of equity, whether applied by a court of law or equity; and the execution, delivery and performance of this Agreement will not violate or conflict with any other agreement or instrument to which it is a party.

Section 8.18.6 This guarantee shall remain in full force and effect and shall be binding on Parent and its successors and permitted assigns, and shall inure to the benefit of Seller and its successors and permitted assigns, until all of the Obligations and all amounts payable under this guarantee have been indefeasibly paid, observed, performed or satisfied in full, except to the extent set forth herein. The obligations of Parent hereunder are independent of the obligations of Purchaser and a separate action or actions may be brought and prosecuted against Parent whether or not any action is brought against Purchaser and whether or not Purchaser is joined in any such actions.

* * * * *

IN WITNESS WHEREOF, the parties hereto have caused this Stock Purchase Agreement to be duly executed as of the day and year first above written.

WELLSPRING PHARMA SERVICES INC.

By: /s/ Wendy Shusko
Name: Wendy Shusko
Title: Chief Executive Officer

ANI PHARMACEUTICALS CANADA INC.

By: /s/ Stephen Carey
Name: Stephen Carey
Title: Vice President, Secretary, and Treasurer

ANI PHARMACEUTICALS, INC., solely for purposes of Section 8.18

By: /s/ Stephen Carey
Name: Stephen Carey
Title: Vice President and Chief Financial Officer

[Signature Page to Stock Purchase Agreement]

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

I, Arthur S. Przybyl, certify that:

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

Date: November 6, 2018

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

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

I, Stephen P. Carey, certify that:

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

Date: November 6, 2018

/s/ Stephen P. Carey

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

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

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended September 30, 2018 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

Dated: November 6, 2018

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

Dated: November 6, 2018

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

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