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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 June 30, 2020

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

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission File Number 001-31812

**ANI PHARMACEUTICALS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of  
incorporation or organization)

**58-2301143**

(IRS Employer  
Identification Number)

**210 Main Street West**

**Baudette, Minnesota 56623**

(Address of principal executive offices)

**(218) 634-3500**

(Registrant's telephone number including area code)

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

<u>Title of each class:</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered:</u>
Common Stock	ANIP	NASDAQ Global Market

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

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Emerging growth company

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

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

As of July 31, 2020, there were 12,304,193 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

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**ANI PHARMACEUTICALS, INC.**  
**FORM 10-Q — Quarterly Report**  
**For the Quarterly Period Ended June 30, 2020**

**TABLE OF CONTENTS**

	<u>Page</u>
<b>PART I — FINANCIAL INFORMATION</b>	
Item 1. Financial Statements (unaudited)	1
<a href="#">Condensed Consolidated Balance Sheets — As of June 30, 2020 and December 31, 2019</a>	5
<a href="#">Condensed Consolidated Statements of Operations — For the Three and Six Months Ended June 30, 2020 and 2019</a>	6
<a href="#">Condensed Consolidated Statements of Comprehensive Income — For the Three and Six Months Ended June 30, 2020 and 2019</a>	7
<a href="#">Condensed Consolidated Statements of Changes in Stockholders' Equity — For the Three and Six Months Ended June 30, 2020 and 2019</a>	8
<a href="#">Condensed Consolidated Statements of Cash Flows — For the Six Months Ended June 30, 2020 and 2019</a>	10
<a href="#">Notes to Condensed Consolidated Financial Statements</a>	11
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	35
Item 3. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	46
Item 4. <a href="#">Controls and Procedures</a>	47
<b>PART II — OTHER INFORMATION</b>	
Item 1. <a href="#">Legal Proceedings</a>	47
Item 1A. <a href="#">Risk Factors</a>	47
Item 2. <a href="#">Recent Sales of Unregistered Securities and Use of Proceeds from Registered Securities</a>	49
Item 3. <a href="#">Defaults upon Senior Securities</a>	49
Item 4. <a href="#">Mine Safety Disclosures</a>	49
Item 5. <a href="#">Other Information</a>	49
Item 6. <a href="#">Exhibits</a>	49
<a href="#">Signatures</a>	50

## 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, the revenue potential (licensing, royalty and sales) of products we sell, development timelines, financial position, operating results, prospects, pipeline or potential markets therefor, accounting principles, litigation expenses, liquidity and capital resources, the impact of the novel coronavirus (“COVID-19”) global pandemic on our business, 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. Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the “SEC”), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, as well as those discussed elsewhere in this Quarterly Report on Form 10-Q, and the following factors:

- risks that we may face with respect to importing raw materials;
- delays or failure in obtaining approvals by the U.S. Food and Drug Administration (the “FDA”) of the products we sell;
- changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls;
- the ability of our manufacturing partners to meet our product demands and timelines;
- our dependence on single source suppliers of ingredients due to the time and cost to validate a second source of supply;
- acceptance of our products at levels that will allow us to achieve profitability;
- our ability to develop, license or acquire, and commercialize new products;
- the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products;
- our ability to protect our intellectual property rights;
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- the impact of any litigation to which we are, or may become a party;
- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries;
- our ability to maintain the services of our key executives and other personnel; and
- general business and economic conditions and the effects and duration of outbreak of public health emergencies, such as COVID-19.

*These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2019, including the factors described in “Item 1A. Risk Factors.” Other risks may be described from time to time in our filings made under the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.*

**NOTE REGARDING TRADEMARKS**

Cortenema®, Cortrophin® Gel, Cortrophin-Zinc®, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, and Vancocin® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries. Atacand® and Atacand HCT® are the property of AstraZeneca AB and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Arimidex® and Casodex® are the property of AstraZeneca UK Limited and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products.

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

	<u>June 30, 2020</u>	<u>December 31, 2019</u>
<b>Assets</b>		
<b>Current Assets</b>		
Cash and cash equivalents	\$ 27,702	\$ 62,332
Accounts receivable, net of \$72,469 and \$59,946 of adjustments for chargebacks and other allowances at June 30, 2020 and 2019, respectively	73,162	72,129
Inventories, net	52,563	48,163
Prepaid income taxes	—	1,076
Prepaid expenses and other current assets	3,117	3,995
<b>Total Current Assets</b>	<u>156,544</u>	<u>187,695</u>
Property and equipment, net	39,937	40,551
Restricted cash	5,002	5,029
Deferred tax assets, net of deferred tax liabilities and valuation allowance	53,488	38,326
Intangible assets, net	205,745	180,388
Goodwill	3,580	3,580
Other non-current assets	1,095	1,220
<b>Total Assets</b>	<u>\$ 465,391</u>	<u>\$ 456,789</u>
<b>Liabilities and Stockholders' Equity</b>		
<b>Current Liabilities</b>		
Current debt, net of deferred financing costs	\$ 12,329	\$ 9,941
Accounts payable	14,209	14,606
Accrued expenses and other	3,066	2,362
Accrued royalties	6,004	5,084
Accrued compensation and related expenses	5,349	3,736
Current income taxes payable, net	8,286	—
Accrued government rebates	9,717	8,901
Returned goods reserve	20,003	16,595
Deferred revenue	125	451
<b>Total Current Liabilities</b>	<u>79,088</u>	<u>61,676</u>
<b>Non-current Liabilities</b>		
Non-current debt, net of deferred financing costs and current component	177,879	175,808
Other non-current liabilities	17,080	6,514
<b>Total Liabilities</b>	<u>\$ 274,047</u>	<u>\$ 243,998</u>
<b>Commitments and Contingencies (Note 11)</b>		
<b>Stockholders' Equity</b>		
Common Stock, \$0.0001 par value, 33,333,334 shares authorized; 12,379,711 shares issued and 12,321,820 outstanding at June 30, 2020; 12,104,875 shares issued and 12,089,565 shares outstanding at December 31, 2019	1	1
Class C Special Stock, \$0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	—	—
Treasury stock, 57,891 shares of common stock, at cost, at June 30, 2020 and 15,310 shares of common stock, at cost, at December 31, 2019	(2,246)	(723)
Additional paid-in capital	209,409	200,800
(Accumulated deficit)/retained earnings	(1,771)	17,584
Accumulated other comprehensive loss, net of tax	(14,049)	(4,871)
<b>Total Stockholders' Equity</b>	<u>191,344</u>	<u>212,791</u>
<b>Total Liabilities and Stockholders' Equity</b>	<u>\$ 465,391</u>	<u>\$ 456,789</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 June 30,</i>		<i>Six Months Ended June 30,</i>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net Revenues	\$ 48,470	\$ 54,357	\$ 98,244	\$ 107,244
<b>Operating Expenses</b>				
Cost of sales (excluding depreciation and amortization)	20,695	15,632	42,499	30,357
Research and development	3,035	5,773	9,379	10,146
Selling, general, and administrative	21,213	14,188	34,896	27,472
Depreciation and amortization	11,198	9,472	22,381	25,575
Cortrophin pre-launch charges	3,636	—	8,238	—
Total Operating Expenses	<u>59,777</u>	<u>45,065</u>	<u>117,393</u>	<u>93,550</u>
Operating (Loss)/Income	(11,307)	9,292	(19,149)	13,694
<b>Other Expense, net</b>				
Interest expense, net	(2,356)	(3,406)	(4,388)	(6,760)
Other (expense)/income, net	<u>(116)</u>	<u>46</u>	<u>(106)</u>	<u>(84)</u>
(Loss)/Income Before Benefit for Income Taxes	(13,779)	5,932	(23,643)	6,850
Benefit for income taxes	<u>1,443</u>	<u>653</u>	<u>4,296</u>	<u>184</u>
Net (Loss)/Income	<u>\$ (12,336)</u>	<u>\$ 6,585</u>	<u>\$ (19,347)</u>	<u>\$ 7,034</u>
<b>Basic and Diluted (Loss)/Earnings Per Share:</b>				
Basic (Loss)/Earnings Per Share	\$ (1.03)	\$ 0.55	\$ (1.62)	\$ 0.59
Diluted (Loss)/Earnings Per Share	\$ (1.03)	\$ 0.53	\$ (1.62)	\$ 0.57
Basic Weighted-Average Shares Outstanding	11,967	11,851	11,935	11,799
Diluted Weighted-Average Shares Outstanding	<u>11,967</u>	<u>12,269</u>	<u>11,935</u>	<u>12,046</u>

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

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

	<i>Three Months Ended June 30,</i>		<i>Six Months Ended June 30,</i>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net (loss)/income	\$ (12,336)	\$ 6,585	\$ (19,347)	\$ 7,034
Other comprehensive (loss)/income, net of tax:				
Change in fair value of interest rate swap, net of tax	<u>(2,360)</u>	<u>(2,814)</u>	<u>(9,178)</u>	<u>(4,634)</u>
Total other comprehensive loss, net of tax	<u>(2,360)</u>	<u>(2,814)</u>	<u>(9,178)</u>	<u>(4,634)</u>
Total comprehensive (loss)/income, net of tax	<u>\$ (14,696)</u>	<u>\$ 3,771</u>	<u>\$ (28,525)</u>	<u>\$ 2,400</u>

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

**ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Changes in Stockholders' Equity**  
**For the Three Months Ended June 30, 2020 and 2019**  
*(in thousands)*  
*(unaudited)*

	<b>Common Stock Par Value</b>	<b>Common Stock Shares</b>	<b>Class C Special Stock</b>	<b>Additional Paid-in Capital</b>	<b>Treasury Stock Shares</b>	<b>Treasury Stock</b>	<b>Accumulated Other Comprehensive Loss, Net of Tax</b>	<b>Retained Earnings (Accumulated Deficit)/</b>	<b>Total</b>
Balance, March 31, 2019	\$ 1	12,024	\$ —	\$ 189,971	2	\$ —	\$ (2,199)	\$ 11,939	\$199,712
Stock-based Compensation Expense	—	—	—	2,593	—	—	—	—	2,593
Treasury stock purchases for restricted stock vests	—	—	—	—	10	(723)	—	—	(723)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	62	—	2,303	—	—	—	—	2,303
Change in Fair Value of Interest Rate Swap, Net of Tax	—	—	—	—	—	—	(2,814)	—	(2,814)
Net Income	—	—	—	—	—	—	—	6,585	6,585
Balance, June 30, 2019	<u>\$ 1</u>	<u>12,086</u>	<u>\$ —</u>	<u>\$ 194,867</u>	<u>12</u>	<u>\$ (723)</u>	<u>\$ (5,013)</u>	<u>\$ 18,524</u>	<u>\$207,656</u>
Balance, March 31, 2020	\$ 1	12,112	\$ —	\$ 203,505	28	\$ (1,211)	\$ (11,689)	\$ 10,565	\$201,171
Stock-based Compensation Expense	—	—	—	5,736	—	—	—	—	5,736
Treasury stock purchases for restricted stock vests	—	—	—	—	30	(1,035)	—	—	(1,035)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	7	—	168	—	—	—	—	168
Issuance of Restricted Stock Awards	—	261	—	—	—	—	—	—	—
Change in Fair Value of Interest Rate Swap, Net of Tax	—	—	—	—	—	—	(2,360)	—	(2,360)
Net Loss	—	—	—	—	—	—	—	(12,336)	(12,336)
Balance, June 30, 2020	<u>\$ 1</u>	<u>12,380</u>	<u>\$ —</u>	<u>\$ 209,409</u>	<u>58</u>	<u>\$ (2,246)</u>	<u>\$ (14,049)</u>	<u>\$ (1,771)</u>	<u>\$191,344</u>



**ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES**  
**Condensed Consolidated Statements of Changes in Stockholders' Equity**  
**For the Six Months Ended June 30, 2020 and 2019**  
*(in thousands)*  
*(unaudited)*

	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Other Comprehensive Loss, Net of Tax	Retained Earnings (Accumulated Deficit)/	Total
Balance, December 31, 2018	\$ 1	11,863	\$ —	\$ 186,812	11	\$ (659)	\$ (379)	\$ 11,488	\$197,263
Cumulative Effect of Change in Accounting Principle, net of tax	—	—	—	—	—	—	—	2	2
Stock-based Compensation Expense	—	—	—	4,303	—	—	—	—	4,303
Treasury stock purchases for restricted stock vests	—	—	—	—	17	(1,031)	—	—	(1,031)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	117	—	4,719	—	—	—	—	4,719
Issuance of Restricted Stock Awards	—	106	—	(967)	(16)	967	—	—	—
Change in Fair Value of Interest Rate Swap, Net of Tax	—	—	—	—	—	—	(4,634)	—	(4,634)
Net Income	—	—	—	—	—	—	—	7,034	7,034
Balance, June 30, 2019	\$ 1	12,086	\$ —	\$ 194,867	12	\$ (723)	\$ (5,013)	\$ 18,524	\$207,656
Balance, December 31, 2019	\$ 1	12,105	\$ —	\$ 200,800	15	\$ (723)	\$ (4,871)	\$ 17,584	\$212,791
Cumulative Effect of Change in Accounting Principle	—	—	—	—	—	—	—	(8)	(8)
Stock-based Compensation Expense	—	—	—	8,160	—	—	—	—	8,160
Treasury stock purchases for restricted stock vests	—	—	—	—	43	(1,523)	—	—	(1,523)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	14	—	449	—	—	—	—	449
Issuance of Restricted Stock Awards	—	261	—	—	—	—	—	—	—
Change in Fair Value of Interest Rate Swap, Net of Tax	—	—	—	—	—	—	(9,178)	—	(9,178)
Net Loss	—	—	—	—	—	—	—	(19,347)	(19,347)
Balance, June 30, 2020	\$ 1	12,380	\$ —	\$ 209,409	58	\$ (2,246)	\$ (14,049)	\$ (1,771)	\$191,344

*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>Six Months Ended June 30,</i>	
	<i>2020</i>	<i>2019</i>
<b>Cash Flows From Operating Activities</b>		
Net (loss)/income	\$ (19,347)	\$ 7,034
Adjustments to reconcile net income/(loss) to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	8,160	4,303
Deferred taxes	(14,100)	(2,705)
Depreciation and amortization	22,381	25,575
Acquired in-process research and development ("IPR&D")	3,753	2,324
Non-cash interest relating to convertible notes and loan cost amortization	705	3,766
Changes in operating assets and liabilities:		
Accounts receivable, net	(1,033)	(11,432)
Inventories, net	4,055	(4,793)
Prepaid expenses and other current assets	878	1,204
Accounts payable	665	1,332
Accrued royalties	920	(2,191)
Current income taxes, net	9,362	(8,464)
Accrued government rebates	816	1,969
Returned goods reserve	3,408	2,104
Accrued expenses, accrued compensation, and other	1,967	(991)
<b>Net Cash and Cash Equivalents Provided by Operating Activities</b>	<b>22,590</b>	<b>19,035</b>
<b>Cash Flows From Investing Activities</b>		
Acquisition of product rights, IPR&D, and other related assets	(58,130)	(20,834)
Acquisition of property and equipment, net	(2,264)	(3,409)
<b>Net Cash and Cash Equivalents Used in Investing Activities</b>	<b>(60,394)</b>	<b>(24,243)</b>
<b>Cash Flows From Financing Activities</b>		
Payments on Term Loan and Delayed Draw Term Loan agreements	(3,279)	(902)
Borrowings under Revolver agreement	15,000	—
Payments on Revolver agreement	(7,500)	—
Proceeds from stock option exercises and ESPP purchases	449	4,719
Treasury stock purchases for restricted stock vests	(1,523)	(1,031)
<b>Net Cash and Cash Equivalents Provided by Financing Activities</b>	<b>3,147</b>	<b>2,786</b>
<b>Net Change in Cash and Cash Equivalents</b>	<b>(34,657)</b>	<b>(2,422)</b>
Cash and cash equivalents, beginning of period	67,361	48,029
Cash and cash equivalents, end of period	\$ 32,704	\$ 45,607
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	62,332	43,008
Restricted cash	5,029	5,021
Cash, cash equivalents, and restricted cash, beginning of period	67,361	48,029
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	27,702	40,589
Restricted cash	5,002	5,018
Cash, cash equivalents, and restricted cash, end of period	32,704	45,607
<b>Supplemental disclosure for cash flow information:</b>		
Cash paid for interest, net of amounts capitalized	\$ 3,541	\$ 2,937
Cash paid for income taxes	\$ 523	\$ 8,723
<b>Supplemental non-cash investing and financing activities:</b>		
Property and equipment purchased and included in accounts payable	\$ 161	\$ 133

*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 (oncology), hormones and steroids, and complex formulations. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. Our strategy is to use our assets to develop, acquire, manufacture, and market branded and generic specialty prescription pharmaceuticals. By executing this strategy, we believe we will be able to continue to grow our business, expand and diversify our product portfolio, and create long-term value for our investors.

**Basis of Presentation**

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations, comprehensive income, and cash flows. The consolidated balance sheet at December 31, 2019, has been derived from audited financial statements of that date. The unaudited interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the United States Securities and Exchange Commission. We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our Annual Report on Form 10-K for the year ended December 31, 2019.

**Principles of Consolidation**

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

**Foreign Currency**

We have a subsidiary located in Canada. The subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar. The results of any non-U.S. dollar transactions are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income/(loss). Our gain or loss on transactions denominated in foreign currencies was immaterial for the three and six months ended June 30, 2020 and 2019. Unless otherwise noted, all references to “\$” or “dollar” refer to the U.S. dollar.

**Use of Estimates**

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and

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

liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, revenue recognition, allowance for credit losses, variable consideration determined based on accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, income tax provision, deferred taxes and valuation allowance, determination of right-of-use assets and lease liabilities, purchase price allocations, and the depreciable lives of long-lived assets. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates. Management periodically evaluates estimates used in the preparation of the financial statements for reasonableness.

We are subject to risks and uncertainties as a result of the novel coronavirus (“COVID-19”) pandemic. We are unable to predict the impact that the COVID-19 pandemic will have on our future business, financial condition and results of operations due to numerous uncertainties. These uncertainties include the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. While we experienced a negative impact to our net revenues during the three months ended June 30, 2020 in part due to the COVID-19 pandemic, we remain unable to predict the impact on our estimates and assumptions. There was not a material impact to these estimates or assumptions in our condensed and consolidated financial statements as of and for the three and six months ended June 30, 2020. Actual results could differ from those estimates, which may change our estimates in future periods. We continue to closely monitor the impact of the COVID-19 pandemic on our business

#### **Accounts Receivable**

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

#### **Geographic Information**

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

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

(in thousands) Location of Operations	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
United States	\$ 46,277	\$ 52,144	\$ 94,508	\$ 103,062
Canada	2,193	2,213	3,736	4,182
Total Revenue	\$ 48,470	\$ 54,357	\$ 98,244	\$ 107,244

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

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

<i>(in thousands)</i>	<b>June 30, 2020</b>	<b>December 31, 2019</b>
United States	\$ 26,077	\$ 26,708
Canada	13,860	13,843
Total property and equipment, net	\$ 39,937	\$ 40,551

### **Recent Accounting Pronouncements**

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

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

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

#### ***Recently Adopted Accounting Pronouncements***

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

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

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

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

## 2. REVENUE RECOGNITION AND RELATED ALLOWANCES

### Revenue Recognition

We recognize revenue using the following steps:

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

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

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

Products and Services (in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Sales of generic pharmaceutical products	\$ 33,400	\$ 36,255	\$ 70,895	\$ 67,854
Sales of branded pharmaceutical products	10,633	13,996	19,790	31,539
Sales of contract manufactured products	2,900	3,687	4,874	6,124
Royalties from licensing agreements	491	(251)	781	326
Product development services	885	411	1,462	731
Other <sup>(1)</sup>	161	259	442	670
Total net revenues	<u>\$ 48,470</u>	<u>\$ 54,357</u>	<u>\$ 98,244</u>	<u>\$ 107,244</u>

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

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

The following table depicts revenue recognized during the following periods:

<u>Timing of Revenue Recognition</u> <u>(in thousands)</u>	<u>Three Months Ended</u>		<u>Six Months Ended</u>	
	<u>June 30,</u> <u>2020</u>	<u>June 30,</u> <u>2019</u>	<u>June 30,</u> <u>2020</u>	<u>June 30,</u> <u>2019</u>
Performance obligations transferred at a point in time	\$ 47,585	\$ 53,946	\$ 96,782	\$ 106,513
Performance obligations transferred over time	885	411	1,462	731
<b>Total</b>	<b>\$ 48,470</b>	<b>\$ 54,357</b>	<b>\$ 98,244</b>	<b>\$ 107,244</b>

In the three and six months ended June 30, 2020 and 2019, we did not incur, and therefore did not defer, any material incremental costs to obtain contracts. We recognized a decrease of \$5.7 million to net revenue from performance obligations satisfied in prior periods during the six months ended June 30, 2020, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We recognized a decrease of \$3.5 million of net revenue from performance obligations satisfied in prior periods during the six months ended June 30, 2019, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales, partially offset by royalties from licensing agreements. We provide technical transfer services to customers, for which services are transferred over time. As a result, we had less than \$0.1 million of contract assets related to revenue recognized based on a percentage of completion but not yet billed at both June 30, 2020 and December 31, 2019 and \$0.1 million and \$0.5 million of deferred revenue at June 30, 2020 and December 31, 2019, respectively. For the six months ended June 30, 2020, we recognized \$0.3 million of revenue that was included in deferred revenue as of December 31, 2019.

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

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

Sales of our pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative and other rebates, and cash discounts. Estimates for these elements of variable consideration require significant judgment. A comprehensive discussion of variable consideration is included in Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2019.

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

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the six months ended June 30, 2020 and 2019, respectively:

(in thousands)	Accruals for Chargebacks, Returns, and Other Allowances				
	Chargebacks	Government Rebates	Returns	Administrative Fees and Other Rebates	Prompt Payment Discounts
Balance at December 31, 2018 (1)	\$ 39,007	\$ 8,974	\$ 12,552	\$ 7,353	\$ 2,009
Accruals/Adjustments	120,706	7,650	8,248	17,123	5,174
Credits Taken Against Reserve	(122,344)	(5,681)	(6,144)	(16,971)	(4,909)
Balance at June 30, 2019 (1)	\$ 37,369	\$ 10,943	\$ 14,656	\$ 7,505	\$ 2,274
Balance at December 31, 2019 (1)	\$ 49,882	\$ 8,901	\$ 16,595	\$ 8,281	\$ 2,549
Accruals/Adjustments	181,986	7,519	14,103	17,392	6,551
Credits Taken Against Reserve	(169,345)	(6,703)	(10,695)	(17,161)	(6,277)
Balance at June 30, 2020 (1)	\$ 62,523	\$ 9,717	\$ 20,003	\$ 8,512	\$ 2,823

- (1) Chargebacks are included as an offset to accounts receivable, net of chargebacks and other allowances in the unaudited condensed consolidated balance sheets. Administrative Fees and Other Rebates and Prompt Payment Discounts are included accrued expenses and other in the unaudited condensed consolidated balance sheets. Returns are included in returned goods reserve in the unaudited condensed consolidated balance sheets. Government Rebates are included in accrued government rebates in the unaudited condensed consolidated balance sheets.

#### ***Contract Manufacturing Product Sales Revenue***

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

As of June 30, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was \$5.8 million, which consists of firm orders for contract manufactured products. We will recognize revenue for these performance obligations as they are satisfied, which is anticipated within 12 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.

Pursuant to a 2012 Tripartite Agreement (the "Tripartite Agreement") between the Company, The Regents of the University of California ("The Regents"), and Cabaret Biotech Ltd., an Israeli corporation ("Cabaret") (as assignee



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

of Dr. Zelig Eshhar's rights under the Tripartite Agreement), and subsequent amendments thereto and assignments thereof, we are entitled to receive a percentage of the milestone and sales royalty payments paid to Cabaret by Kite Pharma, Inc. ("Kite"), a subsidiary of Gilead Sciences, Inc., under a license agreement. Under such license agreement, Kite licensed from Dr. Eshhar and Cabaret the patent rights covered by the Tripartite Agreement and agreed to make certain payments to Cabaret based on, among other things, Kite's sales of Yescarta®. Under the Tripartite Agreement, portions of these payments are to be distributed to The Regents and to us.

We record royalty income related to Yescarta® on an accrual basis utilizing our best estimate of royalties earned based upon information available in the public domain, our understanding of the various agreements governing the royalty, and other information received from time to time from the relevant parties. Generally, cash is received directly from Cabaret once a year. Currently, the agreements governing this royalty are subject to multiple litigations in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, the Company and Cabaret. In addition, the Israeli Tax Authority has taken the position that any payments from Cabaret to us are subject to mandatory withholding tax. The Company and its tax counsel have disputed this position and are actively seeking to resolve the issue. The ultimate outcome of these matters, either individually or in the aggregate, may impact the amount of cash due to us, and may result in the termination of future payments or further claims that royalties received by us in the past be repaid.

***Product Development Services Revenue***

We provide product development services to customers, which are performed over time. These services primarily relate to the technical transfer of product development to our facility in Oakville, Ontario. The duration of these technical transfer projects can be up to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a percentage of completion basis, which results in contract assets on our balance sheet. As of June 30, 2020, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open product development services contracts was \$3.0 million. We will recognize revenue for these performance obligations as they are satisfied, which is anticipated within 6 to 15 months.

***Credit Concentration***

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

During the three months ended June 30, 2020, three customers represented 33%, 22%, and 19% of net revenues, respectively. During the six months ended June 30, 2020, the same three customers represented 32%, 23%, and 19% of net revenues, respectively. As of June 30, 2020, accounts receivable from these customers totaled 83% of accounts receivable, net. During the three months ended June 30, 2019, three customers represented 30%, 26%, and 24% of net revenues, respectively. During the six months ended June 30, 2019, the same three customers represented 32%, 24%, and 25% of net revenues, respectively.

**3. INDEBTEDNESS**

***Credit Facility***

In December 2018, we refinanced our previous \$125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the "Credit Facility") for up to \$265.2 million. The five-year Credit Facility is comprised of a \$72.2 million Term Loan (the "Term Loan"), a \$118.0 million Delayed Draw Term Loan (the "DDTL") and a \$75.0 million revolving credit facility (the "Revolver"), all of which mature in December 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse event. The Term Loan includes

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

a repayment schedule, pursuant to which \$5.4 million of the loan will be paid in quarterly installments during the 12 months ended June 30, 2021. As of June 30, 2020, \$5.4 million of the loan is recorded as current borrowings in the unaudited condensed consolidated balance sheets. The DDTL includes a repayment schedule, pursuant to which \$7.4 million will be paid in quarterly installments during the 12 months ended June 30, 2021. As of June 30, 2020, \$7.4 million of the loan is recorded as current borrowings in the unaudited condensed consolidated balance sheets. In March 2020, we drew \$15.0 million under the Revolver, of which \$7.5 million was repaid during the three months ended June 30, 2020. As of June 30, 2020, \$67.5 million remained available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending on our total leverage ratio. On the Revolver, we incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio.

The Credit Facility is secured by a lien on substantially all of ANI Pharmaceuticals, Inc.'s and its principal domestic subsidiary's assets and any future domestic subsidiary guarantors' assets. The Credit Facility imposes financial covenants consisting of a maximum total leverage ratio, which was, as of June 30, 2020, no greater than 3.50 to 1.00 and a minimum fixed charge coverage ratio, which shall be greater than or equal to 1.25 to 1.00. The primary non-financial covenants under the Credit Facility limit, subject to various exceptions, our ability to incur future indebtedness, to place liens on assets, to pay dividends or make other distributions on our capital stock, to repurchase our capital stock, to conduct acquisitions, to alter our capital structure, and to dispose of assets.

The carrying value of the current and non-current components of the Term Loan and DDTL as of June 30, 2020 and December 31, 2019 are:

(in thousands)	Current	
	June 30, 2020	December 31, 2019
Current borrowing on debt	\$ 12,790	\$ 10,412
Deferred financing costs	(461)	(471)
Current debt, net of deferred financing costs	<u>\$ 12,329</u>	<u>\$ 9,941</u>

  

(in thousands)	Non-Current	
	June 30, 2020	December 31, 2019
Non-current borrowing on debt	\$ 171,412	\$ 177,069
Deferred financing costs	(1,033)	(1,261)
Non-current debt, net of deferred financing costs and current component	<u>\$ 170,379</u>	<u>\$ 175,808</u>

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

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

As of June 30, 2020, we had a \$67.7 outstanding million balance on the Term Loan, a \$116.5 million balance on the DDTL, and a \$7.5 million balance on the Revolver. Of the remaining \$0.9 million of deferred debt issuance costs allocated to the Revolving Credit Facility, \$0.6 million is included in other non-current assets in the unaudited interim condensed consolidated balance sheets and \$0.3 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets. Of the remaining \$0.4 million of deferred debt issuance costs allocated to the DDTL, \$0.1 million is classified as a direct deduction to the current portion of the DDTL in the unaudited condensed consolidated balance sheets and \$0.3 million is classified as a direct reduction to the non-current portion of the DDTL in the unaudited condensed consolidated balance sheets. Of the remaining \$1.1 million of deferred debt issuance costs allocated to the Term Loan, \$0.4 million is classified as a direct deduction to the current portion of the Term Loan in the unaudited condensed consolidated balance sheets and \$0.7 million is classified as a direct deduction to the non-current portion of the Term Loan in the unaudited condensed consolidated balance sheets.

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

(in thousands)	Term Loan	DDTL	Revolver
2020	\$ 2,708	\$ 4,425	\$ —
2021	5,414	5,900	—
2022	5,414	8,850	—
2023	54,141	97,350	7,500
Total	<u>\$ 67,677</u>	<u>\$ 116,525</u>	<u>\$ 7,500</u>

The following table sets forth the components of total interest expense related to the Term Loan, DDTL, and Revolver recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three and six months ended June 30, 2020 and 2019:

(in thousands)	Three Months Ended		Six Months Ended	
	June 30, 2020	June 30, 2019	June 30, 2020	June 30, 2019
Contractual coupon	\$ 2,206	\$ 1,644	\$ 4,099	\$ 3,275
Amortization of debt discount	—	1,534	—	3,047
Amortization of finance fees	180	360	362	720
Capitalized interest	(24)	(36)	(49)	(111)
	<u>\$ 2,362</u>	<u>\$ 3,502</u>	<u>\$ 4,412</u>	<u>\$ 6,931</u>

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

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

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

In December 2018, we refinanced our previous Credit Agreement and, at the same time, entered into an interest rate swap, which was 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. In February 2019, we entered into an interest rate swap, which was considered a derivative financial instrument, with Citizens Bank, N.A. to manage our exposure to

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

changes in LIBOR-based interest rates underlying our DDTL. The hedges had been designated as effective cash flow hedges and qualified for hedge accounting. The interest rate swaps related to the Term Loan and DDTL had a weighted average fixed rate of 2.60% and 2.47%, respectively, with a maturity in December 2023. In April 2020, we terminated the remaining \$184.2 million notional value of these interest rate swaps. We discontinued hedge accounting for these instruments and will recognize the net loss in accumulated other comprehensive loss of \$13.2 million to interest expense over the remaining terms through December 2023.

At the same time in April 2020, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under our Term Loan and DDTL. The interest rate swap matures in December 2026. As of June 30, 2020, the notional amount of the interest rate swap was \$184.2 million and decreases in line with maturities of our Term Loan and DDTL until December 2023, after which it remains static until maturity in 2026. The interest rate swap provides an effective fixed rate of 1.99% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. The interest rate swap effectively provides a fixed rate of interest throughout the life of our Term Loan and DDTL. As of June 30, 2020, the fair value of the interest rate swap liability was valued at \$16.8 million and was recorded in other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of June 30, 2020, \$14.0 million was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets.

During the three and six months ended June 30, 2020, changes in the fair value of the interest rate swaps of \$2.4 million and \$9.2 million, net of tax, were recorded in accumulated other comprehensive loss, net of tax in our unaudited interim condensed consolidated statements of comprehensive (loss)/income. Differences between the hedged LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Loan and DDTL based on the LIBOR rate. In the three and six months ended June 30, 2020, \$1.0 million and \$1.4 million of interest expense was recognized in relation to the interest rate swaps, respectively.

## **5. EARNINGS (LOSS) PER SHARE**

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

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

Our unvested restricted shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; in periods of net income, the calculation of basic and diluted earnings (loss) per share excludes from the numerator net income (but not net loss) attributable to the unvested restricted shares, and excludes the impact of those shares from the denominator.

For purposes of determining diluted earnings (loss) per share in 2019, we elected a policy to settle the principal portion of our 3% Convertible Senior Notes (the “Notes”), which matured and were settled in December 2019, in cash. As such, the principal portion of the Notes had no effect on either the numerator or denominator when determining diluted earnings (loss) per share. Any conversion gain was assumed to be settled in shares and was incorporated in diluted earnings per share using the treasury method. The warrants issued in conjunction with the issuance of the Notes are considered to be dilutive when they are in-the-money relative to our average stock price during the period; the bond hedge purchased in conjunction with the issuance of the Notes was always considered to be anti-dilutive.

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

Earnings (loss) per share for the three and six months ended June 30, 2020 and 2019 are calculated for basic and diluted earnings (loss) per share as follows:

(in thousands, except per share amounts)	Basic		Diluted		Basic		Diluted	
	Three Months Ended June 30, 2020	2019	Three Months Ended June 30, 2020	2019	Six Months Ended June 30, 2020	2019	Six Months Ended June 30, 2020	2019
Net (loss)/income	\$ (12,336)	\$ 6,585	\$ (12,336)	\$ 6,585	\$ (19,347)	\$ 7,034	\$ (19,347)	\$ 7,034
Net income allocated to restricted stock	—	(107)	—	(105)	—	(114)	—	(114)
Net (loss)/income allocated to common shares	\$ (12,336)	\$ 6,478	\$ (12,336)	\$ 6,480	\$ (19,347)	\$ 6,920	\$ (19,347)	\$ 6,920
Basic Weighted-Average Shares Outstanding	11,967	11,851	11,967	11,851	11,935	11,799	11,935	11,799
Dilutive effect of stock options and ESPP			—	112			—	94
Dilutive effect of Notes			—	306			—	153
Diluted Weighted-Average Shares Outstanding			11,967	12,269			11,935	12,046
(Loss)/Earnings per share	\$ (1.03)	\$ 0.55	\$ (1.03)	\$ 0.53	\$ (1.62)	\$ 0.59	\$ (1.62)	\$ 0.57

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share was 1.0 million and 2.2 million for the three months ended June 30, 2020 and 2019 and was 1.4 million and 3.2 million for the six months ended June 30, 2020 and 2019, respectively. Anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-the-money common stock options, common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the treasury stock method, underlying shares related to out-of-the-money bonds issued as convertible debt (for 2019 only) and out-of-the-money warrants exercisable for common stock.

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

**6. INVENTORIES**

Inventories consist of the following as of:

<i>(in thousands)</i>	<b>June 30, 2020</b>	<b>December 31, 2019</b>
Raw materials	\$ 37,703	\$ 34,881
Packaging materials	3,038	2,902
Work-in-progress	733	361
Finished goods	18,514	16,750
	<u>59,988</u>	<u>54,894</u>
Reserve for excess/obsolete inventories	(7,425)	(6,731)
Inventories, net	<u>\$ 52,563</u>	<u>\$ 48,163</u>

**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 June 30, 2020, we purchased approximately 13% of our inventory from one supplier. As of June 30, 2020, our accounts payable to this supplier was \$1.9 million. During the three months ended June 30, 2019, no vendors represented at least 10% of inventory purchases. During the six months ended June 30, 2020, no vendors represented at least 10% of inventory purchases. During the six months ended June 30, 2019, we purchased approximately 15% of our inventory from one supplier.

**7. PROPERTY, PLANT, AND EQUIPMENT**

Property and equipment consist of the following as of:

<i>(in thousands)</i>	<b>June 30, 2020</b>	<b>December 31, 2019</b>
Land	\$ 4,566	\$ 4,566
Buildings	10,391	10,275
Machinery, furniture, and equipment	36,708	34,984
Construction in progress	3,358	3,496
	<u>55,023</u>	<u>53,321</u>
Less: accumulated depreciation	(15,086)	(12,770)
Property and equipment, net	<u>\$ 39,937</u>	<u>\$ 40,551</u>

Depreciation expense was \$1.2 million and \$1.1 million for the three months ended June 30, 2020 and 2019, respectively. Depreciation expense was \$2.3 million and \$2.2 million for the six months ended June 30, 2020 and 2019, respectively. During the three months ended June 30, 2020 and 2019, there was less than \$0.1 million of interest capitalized into construction in progress. During the six months ended June 30, 2020 and 2019, there was less than \$0.1 million of interest capitalized into construction in progress. 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)*

**8. GOODWILL AND INTANGIBLE ASSETS**

**Goodwill**

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. ("BioSante"), we recorded goodwill of \$1.8 million. As a result of our acquisition of WellSpring, we recorded additional goodwill of \$1.7 million in 2018. We assess the recoverability of the carrying value of goodwill as of October 31<sup>st</sup> 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 six months ended June 30, 2020. No impairment losses were recognized during the three and six months ended June 30, 2020 and 2019.

**Definite-lived Intangible Assets**

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

(in thousands)	June 30, 2020		December 31, 2019		Weighted Average Amortization Period
	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
Acquired ANDA intangible assets	\$ 103,394	\$ (36,155)	\$ 64,704	\$ (30,169)	8.9 years
NDA and product rights	230,974	(99,918)	230,974	(87,352)	10.0 years
Marketing and distribution rights	17,657	(10,452)	10,923	(8,982)	5.7 years
Non-compete agreement	624	(379)	624	(334)	7.0 years
	\$ 352,649	\$ (146,904)	\$ 307,225	\$ (126,837)	

Definite-lived intangible assets are stated at cost, net of amortization, generally using the straight-line method over the expected useful lives of the intangible assets. In the case of certain New Drug Application ("NDA") and product rights assets, we use an accelerated amortization method to better match the anticipated economic benefits expected to be provided. Amortization expense was \$10.0 million and \$8.4 million for the three months ended June 30, 2020 and 2019, respectively. Amortization expense was \$20.1 million and \$23.4 million for the six months ended June 30, 2020 and 2019, respectively. Refer to Note 12 for more details on acquired definite-lived intangible assets.

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 six months ended June 30, 2020 and 2019 and therefore no impairment loss was recognized in the three and six months ended June 30, 2020 and 2019.

Expected future amortization expense is as follows:

(in thousands)	
2020	\$ 19,593
2021	38,223
2022	34,818
2023	34,070
2024	31,093
2025 and thereafter	47,948
Total	\$ 205,745

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

**9. STOCK-BASED COMPENSATION**

**Employee Stock Purchase Plan**

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of June 30, 2020, we have 0.2 million shares of common stock available under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount.

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of sales	\$ 7	\$ 3	\$ 11	\$ 6
Research and development	12	4	19	9
Selling, general, and administrative	38	23	56	45
	<u>\$ 57</u>	<u>\$ 30</u>	<u>\$ 86</u>	<u>\$ 60</u>

**Stock Incentive Plan**

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"). As of June 30, 2020, 1.1 million shares of our common stock are 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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Cost of sales	\$ 33	\$ 28	\$ 59	\$ 49
Research and development	146	219	333	332
Selling, general, and administrative	5,500	2,316	7,682	3,862
	<u>\$ 5,679</u>	<u>\$ 2,563</u>	<u>\$ 8,074</u>	<u>\$ 4,243</u>



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

A summary of stock option and restricted stock activity under the 2008 Plan during the six months ended June 30, 2020 and 2019 is presented below:

<b>(in thousands)</b>	<b>Options</b>	<b>RSAs</b>
Outstanding at December 31, 2018	759	117
Granted	160	122
Options Exercised/RSAs Vested	(114)	(42) <sup>(1)</sup>
Forfeited	(18)	(2)
Expired	(1)	—
Outstanding at June 30, 2019	<u>786</u>	<u>195</u>
Outstanding at December 31, 2019	757	192
Granted	7	261
Options Exercised/RSAs Vested	(8)	(121) <sup>(2)</sup>
Forfeited	(13)	(17)
Expired	—	—
Outstanding at June 30, 2020	<u>743</u>	<u>315</u>

(1) Includes 15 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 \$1.0 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

(2) Includes 43 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 \$1.6 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

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

In May 2020, our former President and Chief Executive Officer, Arthur S. Przybyl, departed the Company. The departure constituted a Termination Without Good Cause as defined in his employment agreement, and he will receive separation payments and benefits under his employment agreement in respect of a termination without good cause, including those related to his non-statutory stock options and restricted stock awards as discussed above. This action was accounted for as a modification of the underlying awards and the full expense related to the modified awards was recognized in the second quarter 2020. As part of the benefits, 48,448 previously unvested restricted stock awards and 63,305 previously unvested non-statutory stock options vested upon the termination. Additionally, these 63,305 previously unvested non-statutory stock options that vested upon termination and 101,376 previously vested and unexercised non-statutory stock options held by Mr. Przybyl will retain their original contractual term.

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

During the three months ended June 30, 2020, we recognized \$3.4 million of stock-based compensation expense associated with this termination and modification of awards.

**10. INCOME TAXES**

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

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of June 30, 2020, we have provided a valuation allowance against consolidated net deferred tax assets of \$0.4 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any such amounts accrued as of June 30, 2020 and December 31, 2019. We are subject to taxation in various U.S. jurisdictions and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate, calculated on a worldwide consolidated basis, expected for the entire year. If we project taxable losses in any specific taxing jurisdiction, those losses are excluded from the calculation of the worldwide estimated annual effective tax rate and a resulting tax benefit is not recognized. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and estimated permanent differences, and excludes certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discrete items result in variances to the effective tax rate from period to period. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. During periods when we incur net losses before income taxes, our annual estimated effective tax rate may be adjusted based on the "loss limitation" requirements applicable to interim tax provisions, resulting in a limited income tax benefit recognized in that period. Our estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discrete items occur. Global Intangible Low-Taxed Income ("GILTI"), as defined in the Tax Cuts and Jobs Act of 2017, generated from our Canadian operations is subject to U.S. taxes, with certain defined exemptions, thresholds and credits. For financial reporting purposes we have elected to treat GILTI inclusions as a period cost.

For the three months ended June 30, 2020, we recognized an income tax benefit of \$1.4 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 10.5% to pre-tax consolidated loss of \$13.8 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2020.

For the three months ended June 30, 2019, we recognized an income tax benefit of \$0.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 16.8% to pre-tax consolidated

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

income of \$5.9 million reported during the period, reduced by the net effects of certain discrete items occurring in 2019 which impact our income tax provision in the period in which they occur. Discrete items occurring during the three months ended June 30, 2019 include the impact of the release of ANI Canada's net valuation allowance, retroactive application of our newly adopted transfer pricing policy to 2018, awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options.

For the six months ended June 30, 2020, we recognized an income tax benefit of \$4.3 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 18.2% to pre-tax consolidated loss of \$23.6 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2020.

For the six months ended June 30, 2019, we recognized an income tax benefit of \$0.2 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 21.4% to pre-tax consolidated income of \$6.9 million reported during the period, reduced by the net effects of certain discrete items occurring in 2019 which impact our income tax provision in the period in which they occur. Discrete items occurring during the six months ended June 30, 2019 include the impact of the release of ANI Canada's net valuation allowance, retroactive application of our newly adopted transfer pricing policy to 2018, awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options.

## 11. COMMITMENTS AND CONTINGENCIES

### Operating Leases

All our existing leases as of June 30, 2020 are classified as operating leases. As of June 30, 2020, we have thirteen material operating leases for facilities and office equipment with remaining terms expiring from 2021 through 2025 and a weighted average remaining lease term of 2.2 years. Many of our existing leases have fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. Discount rates used in the calculation of our lease liability ranged between 3.99% and 8.95%.

Rent expense for the six months ended June 30, 2020 and 2019 consisted of the following:

(in thousands)	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Operating lease costs	\$ 57	\$ 42	\$ 109	\$ 81
Variable lease costs	14	17	29	41
Total lease costs	<u>\$ 71</u>	<u>\$ 59</u>	<u>\$ 138</u>	<u>\$ 122</u>

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

A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2020	\$ 117
2021	172
2022	132
2023	61
2024 and thereafter	31
Total	<u>\$ 513</u>
Discount	(30)
Lease liability	483
Current lease liability	<u>(201)</u>
Non-current lease liability	<u>\$ 282</u>

### Government Regulation

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

### Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone ("EEMT") and Opium Tincture, are marketed without approved NDAs or Abbreviated New Drug Applications ("ANDAs"). During the six months ended June 30, 2020 and 2019, net revenues for these products totaled \$8.1 million and \$10.9 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.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for these unapproved products for the six months ended June 30, 2020 and 2019 were \$1.6 million and \$1.5 million, respectively.

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

**Legal Proceedings**

We are involved, and from time to time may become involved, in various disputes, governmental and/or regulatory inquiries, investigations, government reimbursement related actions and litigation. These matters are complex and subject to significant uncertainties. As such, we cannot accurately predict the outcome, or the effects of the legal proceedings described below. While we believe that we have valid claims and/or defenses in the litigation and other matters described below, litigation is inherently unpredictable, and the outcome of the proceedings could result in losses, including substantial damages, fines, civil or criminal penalties and injunctive or administrative remedies. We intend to vigorously prosecute and/or defend these matters, as appropriate, however, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations, and legal proceedings, individually or in the aggregate, could have a material adverse effect on our results of operations and/or cash flows in any given accounting period or on our overall financial condition.

Some of these matters with which we are involved are described below, and unless otherwise disclosed, we are unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. We record accruals for loss contingencies to the extent we conclude it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

From time to time, we are also involved in other pending proceedings for which, in our opinion based upon facts and circumstances known at the time, either the likelihood of loss is remote or any reasonably possible loss associated with the resolution of such proceedings is not expected to be material to our results, and therefore remain undisclosed. If and when any reasonably possible losses associated with the resolution of such other pending proceedings, in our opinion, become material, we will disclose such matters.

Furthermore, like all pharmaceutical manufacturers, we are periodically exposed to product liability claims. The prevalence of these claims 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. Recent trends in the product liability and D&O insurance markets is to exclude matters related to certain classes of drugs, such as opioids. Our policies have been subject to such exclusions which place further potential risk of financial loss on the Company.

***Commercial Litigation – Arbor Pharmaceuticals, LLC***

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, under the premise that we sold an unapproved Erythromycin Ethylsuccinate (“EES”) product during the period between September 27, 2016 and November 2, 2018. The complaint seeks a trial by jury and monetary damages (inclusive of actual and consequential damages, treble damages, disgorgement of ANI profit, and legal fees) of an unspecified amount. Discovery in this action closed on March 31, 2019. Trial has been postponed due to COVID-19 and is currently expected to be re-scheduled sometime in 2021. We continue to defend this lawsuit vigorously.

***Industry Related Litigation***

In July 2020, we were served with a complaint brought by the Office of the Attorney General of the State of New Mexico against manufacturers and sellers of ranitidine products. The complaint asserts a public nuisance claim and a negligence claim against the generic ranitidine manufacturer defendants, including the Company. The public nuisance claim asserts that the widespread sale of ranitidine products in the state created a public nuisance that requires a state-wide medical monitoring program of New Mexico residents for the development of colorectal cancer, stomach cancer, gastrointestinal disorders and liver disease. As damages, New Mexico asks that the

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

defendants fund this medical monitoring program. The negligence claims assert that the defendants were negligent in selling the product, essentially alleging that it was unreasonable to have the product on the market. With respect to that claim, New Mexico asserts that it paid for ranitidine products through state-funded insurance and health-care programs. We dispute any liability in this matter and intend to vigorously defend ourselves in the litigation.

***Product Liability Related Litigation***

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, have faced allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA's February 2009 Black Box warning requirement ("legacy claims"). All these original legacy claims were settled or closed out, including a series of claims in California that were resolved by coordinated proceeding and settlement. Our insurance company assumed the defense of the legacy claims and paid all losses in settlement of the California legacy claims. In March 2019, we were served with a lawsuit in the Superior Court of California, County of Riverside, adding us as a defendant in a complaint filed in July 2017 that is alleged not to have been part of the original settled legacy claims. This new claim, as well as the impact of the prior settlements on this claim, is currently being evaluated by the Company, its insurers, and its legal counsel.

In June 2020, we were served with a personal injury complaint in the case of Koepsel v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-80882-RLR, filed in the Southern District of Florida, in which the plaintiff alleges that he developed kidney cancer in 2018 as a result of taking over the counter medication containing ranitidine. The Koepsel action was filed within an existing multidistrict litigation concerning ranitidine-containing drugs pending in the Southern District of Florida before Judge Robin L. Rosenberg, In re Zantac MDL, 20 MDL 2924. A Master Personal Injury Complaint in that MDL that was filed on June 22, 2020 also names the Company as a defendant. We have informed counsel for the Koepsel plaintiff that we did not sell an over the counter ranitidine product, and have asked to be voluntarily dismissed from that action as well as the Master Personal Injury Complaint. We sold a generic prescription ranitidine product for a two-month period of time, from July 2019 to September 2019. Our product was voluntarily recalled in January 2020. We dispute any liability in this matter and intend to vigorously defend ourselves in the litigation.

***Other Industry Related Matters***

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. We have been cooperating and intend to continue cooperating with the investigation. However, no assurance can be given as to the timing or outcome of the investigation.

**12. FAIR VALUE DISCLOSURES**

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Loan, DDTL, and Revolver bear an interest rate that fluctuates with the changes in LIBOR and, because the variable interest rates approximate market borrowing rates available to us, we believe the carrying values of these borrowings approximated their fair values at June 30, 2020.

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

**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 June 30, 2020 and December 31, 2019. We also determined that the changes in such fair value were immaterial in the three and six months ended June 30, 2020 and 2019.

In April 2020, we terminated two interest rate swaps used to manage interest rate exposure on underlying interest payments for our Term Loan and DDTL and entered into one new interest rate swap agreement to manage our total exposure under these borrowings (Note 4). The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 4, the fair value of the interest rate swap was a \$16.8 million liability at June 30, 2020.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of June 30, 2020 and December 31, 2019, by level within the fair value hierarchy:

(in thousands) Description	Fair Value at June 30, 2020	Level 1	Level 2	Level 3
<b>Liabilities</b>				
Interest rate swaps	\$ 16,797	\$ —	\$ 16,797	\$ —

  

Description	Fair Value at December 31, 2019	Level 1	Level 2	Level 3
<b>Liabilities</b>				
Interest rate swaps	\$ 6,215	\$ —	\$ 6,215	\$ —

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

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

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

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

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

We measure our long-lived assets, including property, plant, and equipment, ROU assets, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three and six months ended June 30, 2020 and 2019.

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

In May 2020, we entered into an agreement with a private company to purchase an ANDA and API for one currently marketed generic drug product and certain API for \$0.2 million using cash on hand. We also incurred and paid \$7 thousand in transaction costs directly related to the acquisition. We accounted for this transaction as an asset



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

acquisition and capitalized the transaction costs directly related to the acquisition. The API inventory was recognized at fair value. The ANDA will be amortized in full over its useful life of seven years 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 June 30, 2020 and therefore no impairment loss was recognized for the six months ended June 30, 2020.

In January 2020, we completed the acquisition of the U.S. portfolio of 23 generic products and API and finished goods related to certain of those products from Amerigen Pharmaceuticals, Ltd. ("Amerigen") for a purchase consideration of \$56.8 million and up to \$25.0 million in contingent payments over the next four years. The product portfolio included ten commercial products, three approved products with launches pending, four filed products and four in-development products as well as a license to commercialize two approved products. Payments of \$48.9 million were made using cash on hand. We also incurred and paid \$0.7 million in transaction costs directly related to the acquisition. We accounted for the transaction as an asset acquisition and capitalized the transactions costs directly related to the acquisition. We recognized \$38.5 million as acquired ANDA intangible assets and \$6.7 million as acquired marketing and distribution rights related to the licensed products, which will be amortized over their useful lives of seven years. We also recognized \$3.8 million of the purchase price as research and development expense because certain of the generic products have significant remaining work required in order to be commercialized and the products do not have an alternative future use. The payment was allocated to the two asset categories and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. To determine the fair value of the acquired intangible assets and in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 8%. We also recognized \$8.4 million in inventory at fair value, including \$1.7 million of API and \$6.7 million of finished goods. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. Contingent liabilities are accrued when they are both estimable and probable. As of June 30, 2020, we accrued \$0.2 million in contingent payments due to Amerigen. The intangible assets will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to June 30, 2020 and therefore no impairment loss was recognized for the six months ended June 30, 2020.

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

In April 2019, we entered into an agreement with PII and BAS, under which a previously-commercialized product will be developed and marketed. Per the agreement, we paid PII a series of licensing fees in conjunction with the achievement of certain development and commercial milestones. In the fourth quarter of 2019, the product was launched, triggering a \$0.5 million payment due to PII. The payment was capitalized as an intangible asset and will be amortized in full over its useful life of 10 years 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 and therefore no impairment loss was recognized for the six months ended June 30, 2020.

In March 2019, we entered into an agreement with Teva Pharmaceutical Industries Ltd. to purchase a basket of ANDAs for 35 previously-marketed generic drug products for \$2.5 million in cash. We made the \$2.5 million cash payment using cash on hand and capitalized \$10 thousand of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The \$2.5 million of ANDAs were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the product rights intangible assets, we used the present value of the estimated cash flows related to the product rights, using a



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

discount rate of 15%. The ANDAs will be amortized in full over their 10 year useful lives and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to June 30, 2020 and therefore no impairment loss was recognized for the six months ended June 30, 2020.

In January 2019, we entered into an amendment to asset purchase agreements with Teva related to three purchases of baskets of ANDAs. Under the terms of the Asset Purchase Agreement Amendment, all royalty obligations of the Company owed to Teva with respect to products associated with ten ANDAs under the original asset purchase agreements ceased being effective as of December 31, 2018. As consideration for the termination of such future royalty obligations, we paid Teva a sum of \$16.0 million in cash. Upon payment of \$16.0 million, the purchase price of each basket of ANDAs was increased to reflect the subsequent payment as if that payment had been made on the initial acquisition date. As a result, in addition to increasing the carrying value of the acquired ANDA intangible assets by \$9.2 million, we recognized cumulative amortization expense of \$6.8 million. The payment was allocated to the three ANDA baskets based on the relative fair value of the ANDA baskets, which were determined using Level 3 unobservable inputs. In order to determine the fair value of the acquired ANDA intangible assets, we used the present value of the estimated cash flows related to the ANDAs, using a discount rate of 12%. The additional carrying value will be amortized over the remaining useful lives of the three ANDA baskets and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to June 30, 2020 and therefore no impairment loss was recognized for the six months ended June 30, 2020.

In April 2018, we entered into an agreement with Impax Laboratories, Inc. (now Amneal) to purchase the approved ANDAs for three previously-commercialized generic drug products, the approved ANDAs for two generic drug products that have not yet been commercialized, the development package for one generic drug product, a license, supply, and distribution agreement for a generic drug product with an ANDA that is pending approval, and certain manufacturing equipment required to manufacture one of the products, for \$2.3 million in cash. At the same time, we entered into a supply agreement with Amneal under which we may elect to purchase the finished goods for one of the products for up to 17 months beginning October 1, 2019, under certain conditions. If we elected to purchase the finished goods from Amneal for this period, we could have been required to pay a milestone payment of up to \$10.0 million upon launch, depending on the number of competitors selling the product at the time of launch. The payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. The launch of one of the acquired products had the potential to trigger a milestone payment of \$25.0 million to Teva, depending on the number of competitors selling the product at the time of launch. We launched this product in 2019 and the payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. Additionally, depending on the number of competitors selling the product one year after the launch date, we could have been required to pay a second milestone of \$15.0 million to Teva. The one-year anniversary of the launch occurred during the six months ended June 30, 2020 and the payment was not triggered. As a result, no payment was made, and this contingent liability has been resolved. We made the \$2.3 million cash payment using cash on hand and capitalized \$0.1 million of costs directly related to the asset purchase. We accounted for this transaction as an asset purchase. The \$1.0 million acquired ANDA intangible assets were recorded at their relative fair value, determined using Level 3 unobservable inputs. In order to determine the fair value of the acquired ANDA intangible assets, we used the present value of the estimated cash flows related to the approved ANDAs, using discount rates of 10% to 15%. The acquired ANDAs will be amortized in full over their 10 year useful lives and will be tested for impairment when events or circumstances indicate that the carrying value of the assets may not be recoverable. The \$58 thousand of manufacturing equipment used to manufacture one of the products was recorded at its relative fair value, based on the estimated net book value of the equipment purchased. The equipment will be amortized in full over its five 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 June 30, 2020 and therefore no impairment loss was recognized for the six months ended June 30, 2020. The \$1.3 million of in-process research and development related to products with significant further work required in order to commercialize the products, and for which there is no alternative future use. The in-process research and development was recorded at its relative fair value, determined

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

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.

**13. CORTROPHIN PRE-LAUNCH CHARGES**

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

Prior to the third quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts have been consumed in research and development activities and recognized as research and development expense in the period in which they were incurred. In the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. Under U.S. GAAP, we cannot capitalize these pre-launch purchases of materials as inventory prior to FDA approval, and accordingly, they are charged to expense in the period in which they are incurred. We expect these pre-launch purchases of material to increase significantly in the future as we build raw materials, API and finished goods for the expected launch of this product. During the three and six months ended June 30, 2020, we incurred related charges for the purchase of materials of \$3.6 million and \$8.2 million, respectively. Due to the inherent uncertainty of the timing of FDA approval for this product, we cannot reasonably predict whether these materials will ultimately be eligible for use in commercial finished goods inventory. In the future, we also expect to incur other charges directly related to the Cortrophin pre-launch commercialization efforts, including, but not limited to, sales and marketing and consulting expenses, which will vary in frequency and impact on our results of operations.

**14. CEO DEPARTURE**

In May 2020, our former President and Chief Executive Officer, Arthur S. Przybyl, departed the Company. The departure constituted a Termination Without Good Cause as defined in his employment agreement, and he receives separation payments and benefits under his employment agreement in respect of a termination without good cause, including cash payments for salary continuation, bonus and fringe benefits for two years, and benefits related to his non-statutory stock options and restricted stock awards. During the three months ended June 30, 2020, we recognized \$6.5 million of expense associated with his termination. This amount was comprised of \$3.1 million for salary continuation, bonus, and fringe benefits and \$3.4 million of stock-based compensation expense (Note 9). As of June 30, 2020, \$3.0 million of the cash compensation remains accrued and will be cash settled in future periods.

**15. SUBSEQUENT EVENT**

In July 2020, we acquired an ANDA for Fluconazole Tablets USP from a private company for \$3.0 million. The transaction was funded from cash on hand.

In August 2020, we announced that Nikhil Lalwani has been named our President and Chief Executive Officer, effective September 8, 2020 and that he will join our Board of Directors on his start date.

In August 2020, we announced the appointments of Jeanne Thoma, President and Chief Executive Officer of SPI Pharma, Inc.; and Antonio (“Tony”) Pera, former President of Par Pharmaceutical to our Board of Directors.

## 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, the audited consolidated financial statements and the accompanying notes thereto in our Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (the "2019 Annual Report"), as well as the information contained under Management's Discussion and Analysis of Financial Condition and Results of Operations and "Risk Factors" contained in the 2019 Annual Report, and Part II, Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q, and other information provided from time to time in our other filings with the SEC. 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 2019 Annual Report.*

### EXECUTIVE OVERVIEW

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

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

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

- **Formulation Complexity.** Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that we intend to leverage in selecting products to develop or manufacture.
- **Patent Status.** We seek to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.
- **Market Size.** When determining whether to develop or acquire an individual product, we review the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. We endeavor to manufacture products with sufficient market size to enable us to enter the market with a strong likelihood of being able to price our products both competitively and at a profit.
- **Profit Potential.** We research the availability and cost of active pharmaceutical ingredients in determining which products to develop or acquire. In determining the potential profit of a product, we forecast our anticipated market share, pricing, including the expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.

- **Manufacturing.** We generally seek to develop and manufacture products at our own manufacturing plants in order to optimize the utilization of our facilities, ensure quality control in our products, and maximize profit potential.
- **Competition.** When determining whether to develop or acquire a product, we research existing and expected competition. We seek to develop products for which we can obtain sufficient market share and may decline to develop a product if we anticipate significant competition. Our specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies are able to compete.

## **Recent Developments**

### ***Product Launches***

In June 2020, we launched Mexiletine Hydrochloride Capsules USP, 150mg, 200mg, and 250mg. Mexiletine Hydrochloride Capsules are indicated for the treatment of documented ventricular arrhythmias, such as sustained ventricular tachycardia, that, in the judgment of the physician, are life-threatening.

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

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

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

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

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

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

In April 2020, the Food and Drug Administration ("FDA") issued a Refusal to File ("RTF") letter for our Supplemental New Drug Application ("sNDA") for Cortrophin Gel. Since this time, our efforts have been focused on the preparation of a complete and timely resubmission of the sNDA. We immediately retained a prominent regulatory consulting firm to support our efforts and augment the capabilities of our internal Cortrophin development team. In addition, we restructured the composition of the internal team. We have performed a comprehensive review of the original sNDA filing and prepared an internal gap assessment. The resultant remediation activities are currently in-progress and we currently anticipate re-submitting the sNDA no later than the first quarter of 2021.

### ***CEO Departure***

On May 10, 2020, our former President and Chief Executive Officer, Arthur S. Przybyl, departed the Company. Our Board of Directors retained an executive search firm to lead the search for a new President and Chief Executive Officer, and appointed Patrick D. Walsh interim President and CEO, effective May 11, 2020, until such time that Mr. Przybyl's

permanent replacement was identified. In August 2020, we announced that Nikhil Lalwani has been named our President and Chief Executive Officer, effective September 8, 2020 and that he will join our Board of Directors on his start date.

**COVID-19 Impact**

We continue to closely monitor the impact of the novel coronavirus (“COVID-19”) pandemic on our business and the geographic regions where we operate. During the three months ended June 30, 2020, per IQVIA/IMS data, overall generic and brand prescriptions in the United States declined when compared to each of the previous calendar quarters during the trailing 12 months. The decline is in part attributable to the COVID-19 pandemic, including but not limited to negative impacts from “shelter-in-place” and quarantine orders in certain states, restrictions on travel, the prohibition of elective medical procedures, and the related downstream impact of the global economic activity during this period. The decline in prescriptions due to the COVID-19 pandemic negatively impacted our generic and brand net revenues during the three months ended June 30, 2020 when compared to the three months ended March 31, 2020 and June 30, 2019. The Company did not experience a significant impact to its manufacturing operations or supply chain from the COVID-19 pandemic during this period. Our manufacturing facilities in Baudette, MN and Oakville, Ontario have remained open throughout this period and have operated in accordance with local, state and national safety guidelines. Additionally, the pandemic has not impacted the Company’s access to capital and has not significantly impacted the Company’s use of funds, including but not limited to capital expenditures, spend on research and development activities and business development opportunities.

We are unable to predict the impact that the COVID-19 pandemic will have on our future financial condition, results of operations and cash flows due to numerous uncertainties. These uncertainties include the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. The outbreak of COVID-19 in many countries, including the United States and Canada, has had a significant adverse impact on global economic activity and has contributed to significant volatility and negative pressure in financial markets. As a result, the COVID-19 pandemic is negatively impacting almost every industry, either directly or indirectly. Further, the impacts of a potential worsening of global economic conditions and the continued disruptions to, and volatility in, the credit and financial markets, pharmaceutical supply chains, patient access to healthcare as well as other unanticipated consequences remain unknown.

GENERAL

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenues	\$ 48,470	\$ 54,357	\$ 98,244	\$ 107,244
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	20,695	15,632	42,499	30,357
Research and development	3,035	5,773	9,379	10,146
Selling, general, and administrative	21,213	14,188	34,896	27,472
Depreciation and amortization	11,198	9,472	22,381	25,575
Cortrophin pre-launch charges	3,636	—	8,238	—
Operating (loss)/income	(11,307)	9,292	(19,149)	13,694
Interest expense, net	(2,356)	(3,406)	(4,388)	(6,760)
Other income/(expense), net	(116)	46	(106)	(84)
(Loss)/income before benefit for income taxes	(13,779)	5,932	(23,643)	6,850
Benefit for income taxes	1,443	653	4,296	184
Net (loss)/income	\$ (12,336)	\$ 6,585	\$ (19,347)	\$ 7,034

[Table of Contents](#)

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 June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Net revenues	100.0 %	100.0 %	100.0 %	100.0 %
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	42.7 %	28.8 %	43.3 %	28.3 %
Research and development	6.3 %	10.6 %	9.5 %	9.5 %
Selling, general, and administrative	43.8 %	26.1 %	35.5 %	25.6 %
Depreciation and amortization	23.1 %	17.4 %	22.8 %	23.8 %
Cortrophin pre-launch charges	7.5 %	— %	8.4 %	— %
Operating (loss)/income	(23.4)%	17.1 %	(19.5)%	12.8 %
Interest expense, net	(4.9)%	(6.3)%	(4.5)%	(6.3)%
Other income/(expense), net	(0.2)%	0.1 %	(0.1)%	(0.1)%
(Loss)/income before benefit for income taxes	(28.5)%	10.9 %	(24.1)%	6.4 %
Benefit for income taxes	3.0 %	1.2 %	4.4 %	0.2 %
Net (loss)/income	(25.5)%	12.1 %	(19.7)%	6.6 %

**RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2020 AND 2019**

**Net Revenues**

(in thousands)	Three Months Ended June 30,		Change	% Change
	2020	2019		
Generic pharmaceutical products	\$ 33,400	\$ 36,255	\$ (2,855)	(7.9)%
Branded pharmaceutical products	10,633	13,996	(3,363)	(24.0)%
Contract manufacturing	2,900	3,687	(787)	(21.3)%
Royalty and other	1,537	419	1,118	266.8 %
Total net revenues	\$ 48,470	\$ 54,357	\$ (5,887)	(10.8)%

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

Net revenues for the three months ended June 30, 2020 were \$48.5 million compared to \$54.4 million for the same period in 2019, a decrease of \$5.9 million, or 10.8%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$33.4 million during the three months ended June 30, 2020, a decrease of 7.9% compared to \$36.3 million for the same period in 2019. The primary drivers of the decrease were declines in revenues of Ezetimibe Simvastatin, Erythromycin Ethylsuccinate (“EES”), Vancomycin Capsules, and Esterified Estrogen with Methyltestosterone (“EEMT”). These decreases were tempered by the January 2020 launch of Miglustat, Mixed Amphetamine Salts, Penicillamine, and Paliperidone, all products acquired from Amerigen Pharmaceuticals, Ltd. (“Amerigen”), and the September 2019 launch of Vancomycin Oral Solution. During the three months ended June 30, 2020, the overall generic pharmaceutical product market and our generic revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in a decline in generic prescriptions during the three months ended June 30, 2020 when compared to the three months ended June 30, 2019.
- Net revenues for branded pharmaceutical products were \$10.6 million during the three months ended June 30, 2020, a decrease of 24.0% compared to \$14.0 million for the same period in 2019. The primary reasons for the

decrease were lower unit sales of Inderal XL, InnoPran XL, and Inderal LA. During the three months ended June 30, 2020, the overall brand pharmaceutical product market and our brand revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in a decline in brand prescriptions during the three months ended June 30, 2020, when compared to the three months ended June 30, 2019.

- Contract manufacturing revenues were \$2.9 million during the three months ended June 30, 2020, a decrease of 21.3% compared to \$3.7 million for the same period in 2019, due to a decreased volume of orders from contract manufacturing customers in the period.
- Royalty and other revenues were \$1.5 million during the three months ended June 30, 2020, an increase of \$1.1 million from \$0.4 million for the same period in 2019, primarily due to increases in product development revenues earned by ANI Canada and an increase in royalty and laboratory service revenues.

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

(in thousands)	Three Months Ended June 30,		Change	% Change
	2020	2019		
Cost of sales (excl. depreciation and amortization)	\$ 20,695	\$ 15,632	\$ 5,063	32.4 %

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 June 30, 2020, cost of sales increased to \$20.7 million from \$15.6 million for the same period in 2019, an increase of \$5.1 million, or 32.4%, primarily as a result of increased volumes related to a shift in product mix toward generic products, \$1.4 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the period, inventory reserve charges during the current quarter related to excess inventory on hand and discontinued projects, and increased sales of products subject to profit-sharing arrangements. Cost of sales, exclusive of the \$1.4 million net impact related to excess of fair value over the cost of inventory sold during the period, as a percentage of net revenues increased to 39.8% during the three months ended June 30, 2020, from 28.8% during same period in 2019, primarily as a result of a shift in product mix to an increase volume of generic products, which have lower average selling prices, inventory reserve charges in the current quarter, and increased sales of products subject to profit-sharing arrangements during the current quarter.

During the three months ended June 30, 2020, we purchased approximately 13% of our inventory from one supplier. As of June 30, 2020, our amount payable to this supplier was \$1.9 million. During the three months ended June 30, 2019, no vendors represented at least 10% of inventory purchases.

### Other Operating Expenses

(in thousands)	Three Months Ended June 30,		Change	% Change
	2020	2019		
Research and development	\$ 3,035	\$ 5,773	\$ (2,738)	(47.4)%
Selling, general, and administrative	21,213	14,188	7,025	49.5 %
Depreciation and amortization	11,198	9,472	1,726	18.2 %
Cortrophin pre-launch charges	3,636	—	3,636	NM <sup>(1)</sup>
Total other operating expenses	\$ 39,082	\$ 29,433	\$ 9,649	3.3 %

(1) Not Meaningful



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

For the three months ended June 30, 2020, other operating expenses increased to \$39.1 million from \$29.4 million for the same period in 2019, an increase of \$9.7 million, or 3.3%, primarily as a result of the following factors:

- Research and development expenses decreased from \$5.8 million to \$3.0 million, a decrease of 47.4%, primarily due to the non-recurrence of \$2.3 million of expense related to in-process research and development acquired from Coeptis Pharmaceuticals, Inc. (“Coeptis”) in the second quarter of 2019 and a decrease in expense related to the Cortrophin re-commercialization project. These decreases were tempered by \$0.4 million of severance related expense associated with the restructuring of our internal Cortrophin development team. We currently anticipate that Cortrophin-related expenses in the second half of 2020 will approximate those of the first half of 2020, as we continue to focus on our supplemental New Drug Application (“sNDA”) resubmission efforts.
- Selling, general, and administrative expenses increased from \$14.2 million to \$21.2 million, an increase of 49.5%, primarily due to \$6.5 million of termination benefit expenses related to the departure of our former President and CEO, comprised of \$3.4 million of stock-based compensation expense and \$3.1 million of expense for salary continuation, bonus, and fringe benefits. We also incurred recruitment and related legal charges associated with our CEO search.
- Depreciation and amortization increased from \$9.5 million to \$11.2 million, an increase of 18.2%, primarily due to the amortization of the Abbreviated New Drug Applications (“ANDAs”) and marketing and distribution rights acquired in January 2020 from Amerigen.
- As described in Note 13, *Cortrophin Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we recognized Cortrophin pre-launch charges of \$3.6 million in the three months ended June 30, 2020. No Cortrophin pre-launch charges were recognized in the three months ended June 30, 2019.

**Other Expense, net**

(in thousands)	Three Months Ended June 30,		Change	% Change
	2020	2019		
Interest expense, net	\$ (2,356)	\$ (3,406)	\$ (1,050)	30.8 %
Other (expense)/income, net	(116)	46	162	352.2 %
Total other expense, net	\$ (2,472)	\$ (3,360)	\$ (888)	26.4 %

For the three months ended June 30, 2020, we recognized other expense of \$2.5 million versus other expense of \$3.4 million for the same period in 2019, a decrease of \$0.9 million. Interest expense, net for 2020 consists primarily of interest expense on borrowings under our secured term loan (“Term Loan”), delayed draw term loan (“DDTL”), and line of credit (“Revolver”). Interest expense, net for 2019 consists primarily of interest expense on our convertible debt, including amortization of related debt discount, and interest expense on borrowings under our Term Loan. For the three months ended June 30, 2020 and 2019, there was \$24 thousand and \$36 thousand of interest capitalized into construction in progress, respectively.

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

(in thousands)	Three Months Ended June 30,		Change	% Change
	2020	2019		
Benefit for income taxes	\$ 1,443	\$ 653	\$ (790)	(121.0)%



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

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

For the three months ended June 30, 2020, we recognized an income tax benefit of \$1.4 million. The income tax expense resulted from applying an estimated annual worldwide effective tax rate of 10.5% to pre-tax consolidated loss of \$13.8 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2020.

For the three months ended June 30, 2019, we recognized an income tax benefit of \$0.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 16.8% to pre-tax consolidated income of \$5.9 million reported during the period, reduced by the net effects of certain discrete items occurring in 2019 which impact our income tax provision in the period in which they occur. Discrete items occurring during the three months ended June 30, 2019 include the impact of the release of ANI Canada’s net valuation allowance, retroactive application of our newly adopted transfer pricing policy to 2018, awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options.

**RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2020 AND 2019**

(in thousands)	<u>Six Months Ended June 30,</u>		<u>Change</u>	<u>% Change</u>
	<u>2020</u>	<u>2019</u>		
Generic pharmaceutical products	\$ 70,895	\$ 67,854	\$ 3,041	4.5 %
Branded pharmaceutical products	19,790	31,539	(11,749)	(37.3)%
Contract manufacturing	4,874	6,124	(1,250)	(20.4)%
Royalty and other income	2,685	1,727	958	55.5 %
<b>Total net revenues</b>	<b>\$ 98,244</b>	<b>\$ 107,244</b>	<b>\$ (9,000)</b>	<b>(8.4)%</b>

Net revenues for the six months ended June 30, 2020 were \$98.2 million compared to \$107.2 million for the same period in 2019, a decrease of \$9.0 million, or 8.4%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were \$70.9 million during the six months ended June 30, 2020, an increase of 4.5% compared to \$67.9 million for the same period in 2019. The primary reasons for the increase are the January 2020 launch of Miglustat, Mixed Amphetamine Salts, Penicillamine, Bexarotene, and Paliperidone, all products acquired from Amerigen, and the September 2019 launch of Vancomycin Oral Solution. These increases were tempered by decreases in revenues of Ezetimibe Simvastatin, EES, Vancomycin Capsules, EEMT, and Propafenone. During the six months ended June 30, 2020, the overall generic pharmaceutical product market and our generic revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from state “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in a decline in generic prescriptions during the six months ended June 30, 2020 when compared to the six months ended June 30, 2019.

- Net revenues for branded pharmaceutical products were \$19.8 million during the six months ended June 30, 2020, a decrease of 37.3% compared to \$31.5 million for the same period in 2019. The primary reasons for the decrease were lower unit sales of InnoPran XL, Inderal LA, and Inderal XL as well as a decrease in sales of Arimidex and Atacand. These decreases were tempered by an increase in sales of Atacand HCT and Vancocin. During the six months ended June 30, 2020, the overall brand pharmaceutical product market and our brand revenue results were negatively impacted by the COVID-19 pandemic, including but not limited to effects from “shelter-in-place” orders and the prohibition of elective medical procedures. These actions resulted in a decline in brand prescriptions during the six months ended June 30, 2020, when compared to the six months ended June 30, 2019.
- Contract manufacturing revenues were \$4.9 million during the six months ended June 30, 2020, a decrease of 20.4% compared to \$6.1 million for the same period in 2019, due to a decreased volume of orders from contract manufacturing customers in the period.
- Royalty and other were \$2.7 million during the six months ended June 30, 2019, an increase of \$1.0 million from \$1.7 million for the same period in 2019, primarily due to increases in product development revenues earned by ANI Canada and an increase in royalty and laboratory service revenues.

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

(in thousands)	Six Months Ended June 30,		Change	% Change
	2020	2019		
Cost of sales (excl. depreciation and amortization)	\$ 42,499	\$ 30,357	\$ 12,142	40.0 %

For the six months ended June 30, 2020, cost of sales increased to \$42.5 million from \$30.4 million for the same period in 2019, an increase of \$12.1 million or 40.0%, primarily as a result of increased volumes related to a shift in product mix toward generic products, \$4.1 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the period, increased sales of products subject to profit-sharing arrangements, and inventory reserve charges related to excess inventory on hand and discontinued projects, partially offset by the lack of the impact of the January 2019 royalty buy out from the Asset Purchase Agreement Amendment with Teva Pharmaceuticals USA, Inc. Cost of sales, exclusive of the \$4.1 million net impact related to excess of fair value over the cost of inventory sold during the period, as a percentage of net revenues increased to 39.1% during the six months ended June 30, 2020, from 28.3% during same period in 2019, primarily as a result of a shift in product mix to an increased volume of generic products, which have lower average selling prices, increased sales of products subject to profit-sharing arrangements, and inventory reserve charges related to excess inventory on hand and discontinued projects.

During the six months ended June 30, 2020, no vendors represented at least 10% of inventory purchases. During the six months ended June 30, 2019, we purchased 15% of our inventory from one supplier.

**Other Operating Expenses**

(in thousands)	Six Months Ended June 30,		Change	% Change
	2020	2019		
Research and development	\$ 9,379	\$ 10,146	\$ (767)	(7.6)%
Selling, general, and administrative	34,896	27,472	7,424	27.0 %
Depreciation and amortization	22,381	25,575	(3,194)	(12.5)%
Cortrophin pre-launch charges	8,238	—	8,238	NM <sup>(1)</sup>
Total other operating expenses	\$ 74,894	\$ 63,193	\$ 11,701	18.5 %

For the six months ended June 30, 2020, other operating expenses increased to \$74.9 million from \$63.2 million for the same period in 2019, an increase of \$11.7 million, or 18.5%, primarily as a result of the following factors:

- Research and development expenses decreased from \$10.1 million to \$9.4 million, a decrease of 7.6%, primarily due to the non-recurrence of the \$2.3 million of expense related to in-process research and development acquired from Coeptis during the six months ended June 30, 2019 and a decrease in expense related to the Cortrophin re-commercialization project. These decreases were tempered by the \$3.8 million in-process research and development expense from the Amerigen acquisition in January 2020 and \$0.4 million of severance related expense associated with the restructuring of our internal Cortrophin development team. We currently anticipate that Cortrophin-related expenses in the second half of 2020 will approximate those of the first half of 2020, as we continue to focus on our supplemental New Drug Application (“sNDA”) resubmission efforts.
- Selling, general, and administrative expenses increased from \$27.5 million to \$34.9 million, an increase of 27.0%, primarily due to \$6.5 million of termination benefit expenses related to the departure of our former President and CEO, comprised of \$3.4 million of stock-based compensation expense and \$3.1 million of expense for salary continuation, bonus, and fringe benefits. We also incurred recruitment and related legal charges associated with our CEO search.
- Depreciation and amortization decreased from \$25.6 million to \$22.4 million, a decrease of 12.5%, primarily due to the non-recurrence of amortization expense recorded in relation to the January 2019 royalty buy out, partially offset by the amortization of the ANDAs and marketing and distribution rights acquired in January 2020 from Amerigen.
- As described in Note 13, *Cortrophin Pre-Launch Charges*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, we recognized Cortrophin pre-launch charges of \$8.2 million in the six months ended June 30, 2020. No Cortrophin pre-launch charges were recognized in the six months ended June 30, 2019. We currently expect to incur total expense related to this activity of approximately \$14.0-\$16.0 million for 2020.

**Other Expense, net**

(in thousands)	Six Months Ended June 30,		Change	% Change
	2020	2019		
Interest expense, net	\$ (4,388)	\$ (6,760)	\$ (2,372)	35.1 %
Other expense, net	(106)	(84)	22	(26.2)%
Total other expense, net	\$ (4,494)	\$ (6,844)	\$ (2,350)	34.3 %

For the six months ended June 30, 2020, we recognized other expense of \$4.5 million versus other expense of \$6.8 million for the same period in 2019, a decrease of \$2.4 million. Interest expense, net for 2020 consists primarily of interest expense on our Term Loan, DDTL, and Revolver. Interest expense, net for 2019 consists primarily of interest expense on our convertible debt, including amortization of related debt discount, and interest expense on borrowings under our Term Loan. For the six months ended June 30, 2020 and 2019, there was less than \$0.1 million of interest capitalized into construction in progress.

**Benefit for Income Taxes**

(in thousands)	Six Months Ended June 30,		Change	% Change
	2020	2019		
Benefit for income taxes	\$ 4,296	\$ 184	\$ (4,112)	NM <sup>(1)</sup>

(1) Not Meaningful

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 six months ended June 30, 2020, we recognized an income tax benefit of \$4.3 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 18.2% to pre-tax consolidated loss of \$23.6 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2020.

For the six months ended June 30, 2019, we recognized an income tax benefit of \$0.2 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 21.4% to pre-tax consolidated income of \$6.9 million reported during the period, reduced by the net effects of certain discrete items occurring in 2019 which impact our income tax provision in the period in which they occur. Discrete items occurring during the six months ended June 30, 2019 include the impact of the release of ANI Canada's net valuation allowance, retroactive application of our newly adopted transfer pricing policy to 2018, awards of stock-based compensation, stock option exercises, and disqualifying dispositions of incentive stock options.

#### LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	June 30, 2020	December 31, 2019
Cash and cash equivalents	\$ 27,702	\$ 62,332
Accounts receivable, net	73,162	72,129
Inventories, net	52,563	48,163
Prepaid income taxes	—	1,076
Prepaid expenses and other current assets	3,117	3,995
Total current assets	<u>\$ 156,544</u>	<u>\$ 187,695</u>
Current debt, net of deferred financing costs	\$ 12,329	\$ 9,941
Accounts payable	14,209	14,606
Accrued expenses and other	3,066	2,362
Accrued royalties	6,004	5,084
Accrued compensation and related expenses	5,349	3,736
Current income taxes payable, net	8,286	—
Accrued government rebates	9,717	8,901
Returned goods reserve	20,003	16,595
Deferred revenue	125	451
Total current liabilities	<u>\$ 79,088</u>	<u>\$ 61,676</u>

On June 30, 2020, we had \$27.7 million in unrestricted cash and cash equivalents. On December 31, 2019, we had \$62.3 million in unrestricted cash and cash equivalents. We generated \$22.6 million of cash from operations in the six months ended June 30, 2020. In January 2020, we acquired the U.S. portfolio of 23 generic products and certain commercial and

development inventory and materials from Amerigen Pharmaceuticals, Ltd., for which we have used \$57.4 million in cash and could make future payments of up to \$25.0 million in contingent profit share payments over the next four years. The contingent payments are earned if annual gross profit exceeds a minimum threshold and are earned on a subset of the acquired products. The acquired portfolio includes ten commercial products, three approved products with launches pending, four filed products, and four in-development products as well as a license to commercialize two approved products. The transaction was funded from cash on hand.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue and corresponding collections from customers, and our revolving line of credit facility, under which \$67.5 million remains available for borrowing as of June 30, 2020, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months. During the period of uncertainty and volatility related to the COVID-19 outbreak, we will continue to closely monitor our liquidity.

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

(in thousands)	Six Months Ended June 30,	
	2020	2019
Operating Activities	\$ 22,590	\$ 19,035
Investing Activities	\$ (60,394)	\$ (24,243)
Financing Activities	\$ 3,147	\$ 2,786

### Net Cash Provided by Operations

Net cash provided by operating activities was \$22.6 million for the six months ended June 30, 2020, compared to \$19.0 million provided by operating activities during the same period in 2019, an increase of \$3.6 million. The increase was due to changes in working capital, including accounts receivable, as we began to collect on sales of our portfolio of Amerigen products during the second quarter, inventories and income taxes.

### Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2020 was \$60.4 million, principally due to the January 2020 acquisition 23 generic products and inventory and materials from Amerigen Pharmaceuticals, Ltd. for \$57.4 million and \$2.3 million of capital expenditures during the period. Net cash used in investing activities for the six months ended June 30, 2019 was \$24.2 million, principally due to the June 2019 acquisition of in-process research and development related to seven development stage products for \$2.3 million, the March 2019 asset acquisition of ANDAs for \$2.5 million, the January 2019 Asset Purchase Agreement Amendment for \$16.0 million, and \$3.4 million of capital expenditures during the period.

### Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$3.1 million for the six months ended June 30, 2020, principally due to net borrowings of \$7.5 million on the Revolver and \$0.4 million of proceeds from stock option exercises, partially offset by \$3.3 million of maturity payments on the Term Loan and DDTL and \$1.5 million of treasury stock purchased in relation to restricted stock vests. Net cash provided by financing activities was \$2.8 million for the six months ended June 30, 2019, principally due to \$4.7 million of proceeds from stock option exercises, partially offset by \$0.9 million of payments on the Term Loan and \$1.0 million of treasury stock purchased in relation to restricted stock vests.

### CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited interim condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts

of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, allowance for doubtful accounts, accruals for chargebacks, government rebates, returns, and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, fair value of long-lived assets, deferred taxes and valuation allowance, and the depreciable lives of long-lived assets.

A summary of our significant accounting policies is included in Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2019. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Such policies are summarized in Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” of our Annual Report on Form 10-K for the year ended December 31, 2019.

#### RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

#### OFF-BALANCE SHEET ARRANGEMENTS

As of June 30, 2020, 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.

#### CONTRACTUAL OBLIGATIONS

As of June 30, 2020, our contractual obligations have not changed materially from the amounts reported in our most recent Annual Report on Form 10-K.

### **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.

In December 2018, we refinanced our previous \$125.0 million Credit Agreement by entering into an amended and restated Senior Secured Credit Facility (the “Credit Facility”) for up to \$265.2 million. The five-year Credit Facility is comprised of a \$72.2 million Term Loan (the “Term Loan”), a \$118.0 million Delayed Draw Term Loan (the “DDTL”) and a \$75.0 million revolving credit facility (the “Revolver”), all of which mature in December 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse event. In March 2020, we drew \$15.0 million under the Revolver, of which \$7.5 million was repaid during the three months ended June 30, 2020. As of June 30, 2020, \$67.5 million remained available for borrowing under the Revolver. Amounts drawn on the Term Loan, DDTL, and Revolver bear an interest rate equal to, at our option, either a LIBOR rate plus 1.50% to 2.75% per annum, depending on our total leverage ratio or an alternative base rate plus an applicable base rate margin, which varies within a range of 0.50% to 1.75%, depending on our total leverage ratio. On the Revolver, we incur a commitment fee at a rate per annum that varies within a range of 0.25% to 0.50%, depending on our leverage ratio. As of June 30, 2020, we had a \$184.2 million outstanding balance on the Credit Facility.

In April 2020, we entered into an interest rate swap to manage our exposure to the variable interest rate on our Term Loan and DDTL borrowings. The interest rate swap hedges the variable cash flows associated with interest payments on borrowings under the Term Loan and DDTL, effectively providing a fixed rate of interest throughout the life of these borrowings. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

We are exposed to risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the year ended June 30, 2020 by approximately \$1 thousand.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated transactions from our ANI Pharmaceuticals Canada Inc. subsidiary from the Canadian dollar to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the quarter ended June 30, 2020.

#### **Item 4. Controls and Procedures**

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

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of June 30, 2020. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

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

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

#### **Part II — OTHER INFORMATION**

##### **Item 1. Legal Proceedings**

Please refer to Note 11, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Form 10-Q quarterly report, which is incorporated into this item by reference.

##### **Item 1A. Risk Factors**

In addition to the other information set forth in this report, please carefully consider the factors described in our 2019 Annual Report under the heading “Part I — Item 1A. Risk Factors.” The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition, and/or operating results. The following are new significant risk factors known to us after the filing of our 2019 Annual Report that could materially harm our business, financial position, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report.



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

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States and Canada, have imposed unprecedented restrictions on travel, and there have been business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on our operations and on the global economy as a whole.

Demand for the products we sell was negatively impacted by COVID-19 during the three month period ended June 30, 2020, which could continue depending on the duration and severity of the COVID-19 pandemic, the length of time it takes for normal economic and operating conditions to resume, additional governmental actions that may be taken and/or extensions of time for restrictions that been imposed to date, and numerous other uncertainties.

While a majority of government-mandated “shelter-in-place” or similar orders have elapsed at this time, it is possible future similar orders could be reinstated, which could result in fewer patients visiting physicians for conditions treated by our products, as well as fewer elective surgeries and fewer visits to pharmacies to have prescriptions filled. As a result, we could see a negative impact in future product sales.

It is currently not possible to predict how long the pandemic will last, whether “shelter-in-place” orders will be reinstated, or the time that it will take for economic activity to return to pre-pandemic levels. The COVID-19 pandemic has resulted in significant financial market volatility and uncertainty. A continuation or worsening of the levels of market disruption and volatility seen in the recent past could have an adverse effect on our ability to access capital, on our business, results of operations and financial condition, and on the market price of our common stock.

***In January 2016, we acquired two New Drug Applications (“NDAs”) for \$75.0 million and a percentage of future net sales of products under the NDAs. We continue to invest in the NDAs and if we are unable to commercialize these products, it could have a material adverse effect on our business, financial position, and operating results.***

In January 2016, we acquired the right, title, and interest in the NDAs for Cortrophin Gel, 40 units/mL and 80 units/mL and Cortrophin Zinc, 40 units/mL, along with certain documentation and trademark applications, from Merck for \$75.0 million and a percentage of future net sales of the products under the NDAs. We have incurred and intend to continue to incur significant research and development expense with respect to development of the products. In order to commercialize Cortrophin Gel, we have executed long-term commercial supply agreements with a supplier for pig pituitary glands, our primary API raw material. We have also executed long-term supply agreements with a corticotropin active pharmaceutical ingredient (“API”) manufacturer and a Cortrophin Gel fill/finish contract manufacturer. We have continued to advance the manufacturing of the corticotropin API and have manufactured six different commercial scale batches, including registration and process validation batches. All commercial scale API batches have met specifications. We have also continued to advance to manufacturing of Cortrophin Gel and have manufactured four different commercial scale batches, including registration and process validation batches. All commercial scale Cortrophin Gel batches have met specifications. Following the submission of our supplemental New Drug Application (“sNDA”) in March of this year, the U.S. Food and Drug Administration (“FDA”) issued a Refuse to File (“RTF”) letter in April 2020. Upon its preliminary review, the FDA determined that certain portions of the chemistry, manufacturing, and controls section in the sNDA were not sufficiently complete to permit a substantive review. Since that time, a comprehensive review of the sNDA has been performed by a prominent regulatory consulting firm. This remediation plan may include additional costs related to the generation of additional data and/or batches in support of the resubmission. We continue to press forward with the resubmission process and develop a detailed timeline for the completion of all activities related to the remediation efforts. In addition, we will need to market the products directly to physicians and negotiate with third-party payers to provide coverage and adequate levels of reimbursement for the products, none of which is required for our current products. If we are unable to perform any of these steps, we may be unable to commercialize the products, which could have a material adverse effect on our business, financial position, and operating results.



**Item 2. Unregistered Sales of Equity Securities and Use of Proceeds**

- (a) Not applicable
- (b) Not applicable
- (c) Not applicable

**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**

<b>Exhibit No.</b>	<b>Description</b>
10.1	<a href="#">ANI Pharmaceuticals, Inc. Sixth Amended and Restated 2008 Incentive Plan</a>
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).</a>
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).</a>
32.1	<a href="#">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.</a>
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2020 formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Comprehensive Income; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity; (v) Condensed Consolidated Statements of Cash Flows; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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: August 6, 2020

By: /s/ Patrick D. Walsh

Patrick D. Walsh  
Interim President and  
Chief Executive Officer  
(principal executive officer)

Date: August 6, 2020

By: /s/ Stephen P. Carey

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

## ANI PHARMACEUTICALS, INC. SIXTH AMENDED AND RESTATED 2008 INCENTIVE PLAN

(Amended on June 5, 2020)

1. Purpose of Plan.

The purpose of the ANI Pharmaceuticals, Inc. Sixth Amended and Restated 2008 Stock Incentive Plan (this “Plan”) is to advance the interests of ANI Pharmaceuticals, Inc. (the “Company”) and its stockholders by enabling the Company and its Subsidiaries to attract and retain qualified persons to perform services for the Company and its Subsidiaries by providing an incentive to such individuals through opportunities for equity participation in the Company, and by rewarding such individuals who contribute to the achievement of the Company’s economic objectives.

2. Definitions.

The following terms will have the meanings set forth below, unless the context clearly otherwise requires:

- 2.1 “Board” means the Board of Directors of the Company.
- 2.2 “Broker Exercise Notice” means a written notice pursuant to which a Participant, upon exercise of an Option, irrevocably instructs a broker or dealer to sell a sufficient number of shares or loan a sufficient amount of money to pay all or a portion of the exercise price of the Option and/or any related withholding tax obligations and remit such sums to the Company and directs the Company to deliver stock certificates to be issued upon such exercise directly to such broker or dealer or their nominee.
- 2.3 “Cause” means “cause” as defined in any employment or other agreement or policy applicable to the Participant, or if no such agreement or policy exists, will mean (i) dishonesty, fraud, misrepresentation, embezzlement or deliberate injury or attempted injury, in each case related to the Company or any Subsidiary, (ii) any unlawful or criminal activity of a serious nature, (iii) any intentional and deliberate breach of a duty or duties that, individually or in the aggregate, are material in relation to the Participant’s overall duties, or (iv) any material breach of any employment, service, confidentiality, non-compete or non-solicitation agreement entered into with the Company or any Subsidiary.
- 2.4 “Change in Control” means an event described in Section 14.1 of the Plan; provided, however, if under an Incentive Award that is subject to Section 409A of the Code, payment or settlement is triggered by a Change in Control, such that such payment or settlement would subject the Incentive Award to taxation under Section 409A of the Code, the term Change in Control will mean a change in the ownership or effective control of the Company, or in the ownership of a substantial portion of the assets of the Company, as such term is defined in Section 409A of the Code.
- 2.5 “Code” means the Internal Revenue Code of 1986, as amended (including, when the context requires, all regulations, interpretations and rulings issued thereunder).
- 2.6 “Committee” means the group of individuals administering the Plan, as provided in Section 3 of the Plan.
- 2.7 “Common Stock” means the common stock of the Company, par value \$0.0001 per share, or the number and kind of shares of stock or other securities into which such Common Stock may be changed in accordance with Section 4.3 of the Plan.
- 2.8 “Disability” means the disability of the Participant such as would entitle the Participant to receive disability income benefits pursuant to the long-term disability plan of the Company or Subsidiary then covering the Participant or, if no such plan exists or is applicable to the Participant, the permanent and total disability of the Participant within the meaning of Section 22(e)(3) of the Code; provided, however, if distribution of an Incentive Award subject to Section 409A of the Code is triggered by an Eligible Recipient’s Disability, such term will mean that the Eligible Recipient is disabled as defined by Section 409A of the Code and the regulations and rulings issued thereunder.
- 2.9 “Effective Date” means June 5, 2020 or such later date as this Plan is approved by the Company’s stockholders.
- 2.10 “Eligible Recipients” means (a) for the purposes of granting Incentive Stock Options, all employees (including, without limitation, officers and directors who are also employees) of the Company or any Subsidiary and (b) for the purposes of granting Non-Statutory Stock Options and other Incentive Awards, all employees (including, without
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limitation, officers and directors who are also employees) of the Company or any Subsidiary and any non-employee directors, consultants, advisors and independent contractors of the Company or any Subsidiary. Notwithstanding the foregoing, an Eligible Person shall also include any individual who is expected to become an employee of the Company or any Subsidiary or a non-employee director, consultant, advisor or independent contractor of the Company or any Subsidiary within a reasonable period of time after the grant of an Incentive Award (other than an Incentive Stock Option); provided that any Award granted to any such individual shall be automatically terminated and cancelled without consideration if the individual does not begin performing services for the Company or any Subsidiary within twelve (12) months after the date such Incentive Award is granted.

- 2.11 “Exchange Act” means the Securities Exchange Act of 1934, as amended.
- 2.12 “Fair Market Value” means, with respect to the Common Stock, as of any date: (i) the closing sale price of the Common Stock at the end of the regular trading session, as reported by The NASDAQ Stock Market, The New York Stock Exchange, The American Stock Exchange or any national exchange on which the Common Stock is then listed or quoted (or, if no shares were traded on such date, as of the next preceding date on which there was such a trade); or (ii) if the Common Stock is not so listed, admitted to unlisted trading privileges, or reported on any national exchange or, the closing sale price as of such date at the end of the regular trading session, as reported by OTC Bulletin Board or the Pink Sheets LLC, or other comparable service (or, if no shares were traded or quoted on such date, as of the next preceding date on which there was such a trade or quote); or (iii) if the Common Stock is not so listed or reported, such price as the Committee determines in good faith, and consistent with the definition of “fair market value” under Section 409A of the Code.
- 2.13 “Incentive Award” means an Option, Stock Appreciation Right, Restricted Stock Award, Stock Unit Award, Performance Award or Stock Bonus granted to an Eligible Recipient pursuant to the Plan.
- 2.14 “Incentive Stock Option” means a right to purchase shares of Common Stock granted to an Eligible Recipient pursuant to Section 6 of the Plan that qualifies as an “incentive stock option” within the meaning of Section 422 of the Code.
- 2.15 “Non-Statutory Stock Option” means a right to purchase shares of Common Stock granted to an Eligible Recipient pursuant to Section 6 of the Plan that does not qualify as an Incentive Stock Option.
- 2.16 “Option” means an Incentive Stock Option or a Non-Statutory Stock Option.
- 2.17 “Participant” means an Eligible Recipient who receives one or more Incentive Awards under the Plan.
- 2.18 “Performance Award” means a right granted to an Eligible Recipient pursuant to Section 10 of the Plan to receive an amount of cash, a number of shares of Common Stock, or a combination of both, contingent upon achievement of specified performance objectives during a specified period. A Performance Award is also commonly referred to as a “performance unit.”
- 2.19 “Previously Acquired Shares” means shares of Common Stock that are already owned by the Participant or, with respect to any Incentive Award, that are to be issued to the Participant upon the grant, exercise or vesting of such Incentive Award.
- 2.20 “Prior Plan Restatement” means any prior amendment and restatement of ANI Pharmaceuticals, Inc. 2008 Stock Plan.
- 2.21 “Restricted Stock Award” means an award of shares of Common Stock granted to an Eligible Recipient pursuant to Section 8 of the Plan that are subject to restrictions on transferability and/or a risk of forfeiture.
- 2.22 “Retirement” means termination of employment or service at age 55 or older and completion of at least ten years of continuous service.
- 2.23 “Securities Act” means the Securities Act of 1933, as amended.
- 2.24 “Stock Appreciation Right” means a right granted to an Eligible Recipient pursuant to Section 7 of the Plan to receive a payment from the Company, in the form of shares of Common Stock, cash or a combination of both, equal to the difference between the Fair Market Value of one or more shares of Common Stock and a specified exercise price of such shares.

- 2.25 “Stock Bonus” means an award of shares of Common Stock granted to an Eligible Recipient pursuant to Section 11 of the Plan.
- 2.26 “Stock Unit Award” means a right granted to an Eligible Recipient pursuant to Section 9 of the Plan to receive the Fair Market Value of one or more shares of Common Stock, payable in cash, shares of Common Stock, or a combination of both, the payment, issuance, retention and/or vesting of which is subject to the satisfaction of specified conditions, which may include achievement of specified performance objectives. A Stock Unit Award when payable in shares of Common Stock is also commonly referred to as a “restricted stock unit.”
- 2.27 “Subsidiary” means any entity that is directly or indirectly controlled by the Company or any entity in which the Company has a significant equity interest, as determined by the Committee, provided the Company has a “controlling interest” in the Subsidiary as defined in Treas. Reg. Sec. 1.409A-1(b)(5)(iii)(E)(1).
- 2.28 “Tax Date” means the date any withholding tax obligation arises under the Code for a Participant with respect to an Incentive Award.
3. Plan Administration.
- 3.1 The Committee. The Plan will be administered by the Board or by a committee of the Board. So long as the Company has a class of its equity securities registered under Section 12 of the Exchange Act, any committee administering the Plan will consist solely of two or more members of the Board who are “non-employee directors” within the meaning of Rule 16b-3 under the Exchange Act and who are “independent” as required by the listing standards of The NASDAQ Stock Market (or other applicable exchange or market on which the Company’s Common Stock may be traded or quoted). Such a committee, if established, will act by majority approval of the members (but may also take action by the written consent of all of the members of such committee), and a majority of the members of such a committee will constitute a quorum. As used in the Plan, “Committee” will refer to the Board or to such a committee, if established. To the extent consistent with applicable corporate law of the Company’s jurisdiction of incorporation, the Committee may delegate to any officers of the Company the duties, power and authority of the Committee under the Plan pursuant to such conditions or limitations as the Committee may establish; provided, however, that only the Committee may exercise such duties, power and authority with respect to Eligible Recipients who are subject to Section 16 of the Exchange Act. The Committee may exercise its duties, power and authority under the Plan in its sole and absolute discretion without the consent of any Participant or other party, unless the Plan specifically provides otherwise. Each determination, interpretation or other action made or taken by the Committee pursuant to the provisions of the Plan will be final, conclusive and binding for all purposes and on all persons, and no member of the Committee will be liable for any action or determination made in good faith with respect to the Plan or any Incentive Award granted under the Plan.
- 3.2 Authority of the Committee.
- (a) In accordance with and subject to the provisions of the Plan, the Committee will have the authority to determine all provisions of Incentive Awards as the Committee may deem necessary or desirable and as consistent with the terms of the Plan, including, without limitation, the following: (i) the Eligible Recipients to be selected as Participants; (ii) the nature and extent of the Incentive Awards to be made to each Participant (including the number of shares of Common Stock to be subject to each Incentive Award, any exercise price, the manner in which Incentive Awards will vest or become exercisable and whether Incentive Awards will be granted in tandem with other Incentive Awards) and the form of written agreement, if any, evidencing such Incentive Award; (iii) the time or times when Incentive Awards will be granted; (iv) the duration of each Incentive Award; and (v) the restrictions and other conditions to which the payment or vesting of Incentive Awards may be subject. In addition, the Committee will have the authority under the Plan in its sole discretion to pay the economic value of any Incentive Award in the form of cash, Common Stock or any combination of both.
- (b) Subject to Section 3.2(d) of the Plan, the Committee will have the authority under the Plan to amend or modify the terms of any outstanding Incentive Award in any manner, including, without limitation, the authority to modify the number of shares or other terms and conditions of an Incentive Award, extend the term of an Incentive Award, accelerate the exercisability or vesting or otherwise terminate any restrictions relating to an Incentive Award, accept the surrender of any outstanding Incentive Award or, to the extent not previously exercised or vested,

authorize the grant of new Incentive Awards in substitution for surrendered Incentive Awards; provided, however that (i) the amended or modified terms must otherwise be permitted by the Plan as then in effect, and may not subject any Participant to taxation under Section 409A of the Code and (ii) any Participant adversely affected by such amended or modified terms must have consented to such amendment or modification.

- (c) In the event of (i) any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, extraordinary dividend or divestiture (including a spin-off) or any other similar change in corporate structure or shares; (ii) any purchase, acquisition, sale, disposition or write-down of a significant amount of assets or a significant business; (iii) any change in accounting principles or practices, tax laws or other such laws or provisions affecting reported results; (iv) any uninsured catastrophic losses or extraordinary non-recurring items as described in Financial Accounting Standards Board Accounting Standards Codification 225, Income Statement or in management's discussion and analysis of financial performance appearing in the Company's annual report to stockholders for the applicable year; or (v) any other similar change, in each case with respect to the Company or any other entity whose performance is relevant to the grant or vesting of an Incentive Award, the Committee (or, if the Company is not the surviving corporation in any such transaction, the board of directors of the surviving corporation) may, without the consent of any affected Participant, amend or modify the vesting criteria (including any performance objectives) of any outstanding Incentive Award that is based in whole or in part on the financial performance of the Company (or any Subsidiary or division or other subunit thereof) or such other entity so as equitably to reflect such event, with the desired result that the criteria for evaluating such financial performance of the Company or such other entity will be substantially the same (in the sole discretion of the Committee or the board of directors of the surviving corporation) following such event as prior to such event; provided, however, that the amended or modified terms are permitted by the Plan as then in effect, including the limitations in Section 3.2(a) and 3.2(b).
- (d) Notwithstanding any other provision of this Plan other than Section 4.3, the Committee may not, without prior approval of the Company's stockholders, seek to effect any re-pricing of any previously granted, "underwater" Option or Stock Appreciation Right by: (i) amending or modifying the terms of the Option or Stock Appreciation Right to lower the exercise price; (ii) canceling the underwater Option or Stock Appreciation Right in exchange for (A) cash; (B) replacement Options or Stock Appreciation Rights having a lower exercise price; or (C) other Incentive Awards; or (iii) repurchasing the underwater Options or Stock Appreciation Rights and granting new Incentive Awards under this Plan. For purposes of this Section 3.2(d), Options and Stock Appreciation Rights will be deemed to be "underwater" at any time when the Fair Market Value of the Common Stock is less than the exercise price of the Option or Stock Appreciation Right.
- (e) In addition to the authority of the Committee under Section 3.2(b) of the Plan and notwithstanding any other provision of the Plan, the Committee may, in its sole discretion, amend the terms of the Plan or Incentive Awards with respect to Participants resident outside of the United States or employed by a non-U.S. Subsidiary in order to comply with local legal requirements, to otherwise protect the Company's or Subsidiary's interests, or to meet objectives of the Plan, and may, where appropriate, establish one or more sub-plans (including the adoption of any required rules and regulations) for the purposes of qualifying for preferred tax treatment under foreign tax laws. The Committee shall have no authority, however, to take action pursuant to this Section 3.2(e) of the Plan: (i) to reserve shares or grant Incentive Awards in excess of the limitations provided in Section 4.1 of the Plan; (ii) to effect any re-pricing in violation of Section 3.2(d) of the Plan; (iii) to grant Options or Stock Appreciation Rights having an exercise price in violation of Section 6.2 or 7.2 of the Plan, as the case may be; or (iv) for which stockholder approval would then be required pursuant to Section 422 of the Code or the rules of The NASDAQ Stock Market (or other applicable exchange or market on which the Company's Common Stock may be traded or quoted). In addition, the Committee shall have no authority to grant any Incentive Award on or after April 10, 2020 that vests or becomes exercisable earlier than twelve months after such Incentive Award was granted; provided, however, that this minimum vesting condition shall not apply to (x) any Incentive Award that is outstanding on April 9, 2020, or (y) Incentive Awards granted on or after April 10, 2020 with respect to which the aggregate number of shares issuable pursuant to such Incentive Awards do not exceed 5% of the aggregate number of shares of Common Stock reserved for issuance under the Plan as of April 10, 2020 less the sum of the number of shares of Common Stock issued under the Plan prior to April 10, 2020 and the number of shares of Common Stock underlying Incentive Awards that were outstanding as of April 10, 2020 (collectively, "Exempted Awards").

4. Shares Available for Issuance.

- 4.1 Maximum Number of Shares Available; Certain Restrictions on Awards. Subject to adjustment as provided in Section 4.3 of the Plan, the maximum number of shares of Common Stock that will be available for issuance under the Plan will be the sum of:
- (a) 3,000,000;
  - (b) the number of shares of Common Stock subject to Incentive Awards granted under any Prior Plan Restatement that remain outstanding as of the Effective Date but only to the extent that such outstanding Incentive Awards are forfeited, expire or otherwise terminate without the issuance of such shares of Common Stock; and
  - (c) the number of shares issued or Incentive Awards granted under the Plan in connection with the settlement, assumption or substitution of outstanding awards as a condition of the Company and/or any Subsidiary(ies) acquiring, merging or consolidating with another entity.

The shares available for issuance under the Plan may, at the election of the Committee, be either treasury shares or shares authorized but unissued, and, if treasury shares are used, all references in the Plan to the issuance of shares will, for corporate law purposes, be deemed to mean the transfer of shares from treasury.

- 4.2 Accounting for Incentive Awards. Shares of Common Stock that are issued under the Plan or that are potentially issuable pursuant to outstanding Incentive Awards will be applied to reduce the maximum number of shares of Common Stock remaining available for issuance under the Plan. All shares so subtracted from the amount available under the Plan with respect to an Incentive Award (other than Incentive Awards granted pursuant to Section 4.1(c)) that lapses, expires, is forfeited (including issued shares forfeited under a Restricted Stock Award) or for any reason is terminated unexercised or unvested or is settled or paid in cash or any form other than shares of Common Stock will automatically again become available for issuance under the Plan; provided, however, that (i) any shares which would have been issued upon any exercise of an Option but for the fact that the exercise price was paid by a “net exercise” pursuant to Section 6.4(b) of the Plan or the tender or attestation as to ownership of Previously Acquired Shares pursuant to Section 6.4(a) of the Plan will not again become available for issuance under the Plan; (ii) the full number of shares of Common Stock subject to a Stock Appreciation Right granted that are settled by the issuance of shares of Common Stock will be counted against the shares authorized for issuance under this Plan, regardless of the number of shares actually issued upon settlement of such Stock Appreciation Right, and will not again become available for issuance under the Plan; and (iii) shares withheld by the Company to pay the exercise price of any Incentive Award or satisfy any tax withholding obligation will not again become available for issuance under the Plan. Any shares of Common Stock repurchased by the Company on the open market using the proceeds from the exercise of an Incentive Award will not increase the number of shares available for future grant of Incentive Awards. Subject to the foregoing, any shares of Common Stock related to Incentive Awards under this Plan or under any Prior Plan Restatement that terminate by expiration, forfeiture, cancellation or otherwise without the issuance of shares of Common Stock, or are settled in cash in lieu of shares, or are exchanged with the Committee’s permission, prior to the issuance of shares, for Incentive Awards not involving shares, will be available again for grant under this Plan.
- 4.3 Adjustments to Shares and Incentive Awards. In the event that the Committee determines that any reorganization, merger, consolidation, recapitalization, liquidation, reclassification, stock dividend, stock split, combination of shares, rights offering, divestiture or extraordinary dividend (including a spin-off) or any other similar corporate transaction or change in the corporate structure or shares of the Company affects the Common Stock, such that an adjustment is appropriate in order to prevent dilution or enlargement of the benefits or potential benefits intended to be provided or made available under the Plan, then the Committee shall, in such manner as it may deem equitable, adjust any or all of (a) the number and kind of securities or other property with respect to which Incentive Awards may be granted, (b) the number and kind of securities or property subject to outstanding Incentive Awards, and (c) the exercise price of outstanding Options and Stock Appreciation Rights or, if it deems it appropriate, the Committee may make provision for a cash payment to the holders of outstanding Incentive Awards. Notwithstanding the foregoing, no such adjustment shall be authorized with respect to any Options or Stock Appreciation Rights to the extent that such adjustment would cause the Option or Stock Appreciation Rights (determined as if such Option or Stock Appreciation Right was an Incentive Stock Option) to violate Section 424(a) of the Code or otherwise subject any Participant to taxation under Section 409A of the Code; and provided further that the number of Shares subject to any Award denominated in Shares shall always be a whole number.

5. Participation.

Participants in the Plan will be those Eligible Recipients who, in the judgment of the Committee, have contributed, are contributing or are expected to contribute to the achievement of economic objectives of the Company or its Subsidiaries. Eligible Recipients may be granted from time to time one or more Incentive Awards, singly or in combination or in tandem with other Incentive Awards, as may be determined by the Committee in its sole discretion. Incentive Awards will be deemed to be granted as of the date specified in the grant resolution of the Committee, which date will be the date of any related agreement with the Participant.

6. Options.

6.1 Grant. An Eligible Recipient may be granted one or more Options under the Plan, and such Options will be subject to such terms and conditions, consistent with the other provisions of the Plan, as may be determined by the Committee in its sole discretion. The Committee may designate whether an Option is to be considered an Incentive Stock Option or a Non-Statutory Stock Option. To the extent that any Incentive Stock Option (or portion thereof) granted under the Plan ceases for any reason to qualify as an “incentive stock option” for purposes of Section 422 of the Code, such Incentive Stock Option (or portion thereof) will continue to be outstanding for purposes of the Plan but will thereafter be deemed to be a Non-Statutory Stock Option. Options may be granted to an Eligible Recipient for services provided to a Subsidiary only if, with respect to such Eligible Recipient, the underlying shares of Common Stock constitute “service recipient stock” within the meaning of Treas. Reg. Section 1.409A-1(b)(5)(iii).

6.2 Exercise Price. The per share price to be paid by a Participant upon exercise of an Option will be determined by the Committee in its discretion at the time of the Option grant, provided that such price will not be less than 100% of the Fair Market Value of one share of Common Stock on the date of grant (or 110% of the Fair Market Value of one share of Common Stock on the date of grant of an Incentive Stock Option if, at the time the Incentive Stock Option is granted, the Participant owns, directly or indirectly, more than 10% of the total combined voting power of all classes of stock of the Company or any parent or subsidiary corporation of the Company). Notwithstanding the foregoing, to the extent that Options are granted under the Plan as a result of the Company’s assumption or substitution of options issued by any acquired, merged or consolidated entity, the exercise price for such Options shall be the price determined by the Committee pursuant to the conversion terms applicable to the transaction.

6.3 Exercisability and Duration. An Option will become exercisable at such times and in such installments and upon such terms and conditions as may be determined by the Committee in its sole discretion at the time of grant (including without limitation (i) the achievement of one or more specified performance objectives; and/or that (ii) the Participant remain in the continuous employ or service of the Company or a Subsidiary for a certain period); provided, however, that no Option may be exercisable after ten (10) years from its date of grant (five years from its date of grant in the case of an Incentive Stock Option if, at the time the Incentive Stock Option is granted, the Participant owns, directly or indirectly, more than 10% of the total combined voting power of all classes of stock of the Company or any parent or subsidiary corporation of the Company).

6.4 Payment of Exercise Price.

(a) The total purchase price of the shares to be purchased upon exercise of an Option will be paid entirely in cash (including check, bank draft or money order); provided, however, that the Committee, in its sole discretion and upon terms and conditions established by the Committee, may allow such payments to be made, in whole or in part, by (i) tender of a Broker Exercise Notice; (ii) by tender, or attestation as to ownership, of Previously Acquired Shares that are acceptable to the Committee; (iii) by a “net exercise” of the Option (as further described in paragraph (b), below); or (iv) by a combination of such methods.

(b) In the case of a “net exercise” of an Option, the Company will not require a payment of the exercise price of the Option from the Participant but will reduce the number of shares of Common Stock issued upon the exercise by the largest number of whole shares that has a Fair Market Value on the exercise date that does not exceed the aggregate exercise price for the shares exercised under this method. Shares of Common Stock will no longer be outstanding under an Option (and will therefore not thereafter be exercisable) following the exercise of such Option to the extent of (i) shares used to pay the exercise price of an Option under the “net exercise,” (ii) shares actually delivered to the Participant as a result of such exercise and (iii) any shares withheld for purposes of tax withholding pursuant to Section 13.1 of the Plan.



(c) Previously Acquired Shares tendered or covered by an attestation as payment of an Option exercise price will be valued at their Fair Market Value on the exercise date.

- 6.5 Manner of Exercise. An Option may be exercised by a Participant in whole or in part from time to time, subject to the conditions contained in the Plan and in the agreement evidencing such Option, by delivery in person, by facsimile or electronic transmission or through the mail of written notice of exercise to the Company at its principal executive office in Baudette, Minnesota and by paying in full the total exercise price for the shares of Common Stock to be purchased in accordance with Section 6.4 of the Plan.
7. Stock Appreciation Rights.
- 7.1 Grant. An Eligible Recipient may be granted one or more Stock Appreciation Rights under the Plan, and such Stock Appreciation Rights will be subject to such terms and conditions, consistent with the other provisions of the Plan, as may be determined by the Committee in its sole discretion. The Committee will have the sole discretion to determine the form in which payment of the economic value of Stock Appreciation Rights will be made to a Participant (i.e., cash, shares of Common Stock or any combination thereof) or to consent to or disapprove the election by a Participant of the form of such payment. Stock Appreciation Rights may be granted to an Eligible Recipient for services provided to a Subsidiary only if, with respect to such Eligible Recipient, the underlying shares of Common Stock constitute "service recipient stock" within the meaning of Treas. Reg. Section 1.409A-1(b)(5)(iii).
- 7.2 Exercise Price. The exercise price of a Stock Appreciation Right will be determined by the Committee, in its discretion, at the date of grant but may not be less than 100% of the Fair Market Value of one share of Common Stock on the date of grant. Notwithstanding the foregoing, to the extent that Stock Appreciation Rights are granted under the Plan as a result of the Company's assumption or substitution of stock appreciation rights issued by any acquired, merged or consolidated entity, the exercise price for such Stock Appreciation Rights shall be the price determined by the Committee pursuant to the conversion terms applicable to the transaction.
- 7.3 Exercisability and Duration. A Stock Appreciation Right will become exercisable at such time and in such installments as may be determined by the Committee in its sole discretion at the time of grant; provided, however, that no Stock Appreciation Right may be exercisable after ten (10) years from its date of grant. A Stock Appreciation Right will be exercised by giving notice in the same manner as for Options, as set forth in Section 6.5 of the Plan.
- 7.4 Grants in Tandem with Options. Stock Appreciation Rights may be granted alone or in addition to other Incentive Awards, or in tandem with an Option, at the time of grant of the Option. A Stock Appreciation Right granted in tandem with an Option shall cover the same number of shares of Common Stock as covered by the Option (or such lesser number as the Committee may determine), shall be exercisable at such time or times and only to the extent that the related Option is exercisable, have the same term as the Option and shall have an exercise price equal to the exercise price for the Option. Upon the exercise of a Stock Appreciation Right granted in tandem with an Option, the Option shall be canceled automatically to the extent of the number of shares covered by such exercise; conversely, upon exercise of an Option having a related Stock Appreciation Right, the Stock Appreciation Right shall be canceled automatically to the extent of the number of shares covered by the Option exercise.
8. Restricted Stock Awards.
- 8.1 Grant. An Eligible Recipient may be granted one or more Restricted Stock Awards under the Plan, and such Restricted Stock Awards will be subject to such terms and conditions, consistent with the other provisions of the Plan, as may be determined by the Committee in its sole discretion. The Committee may impose such restrictions or conditions, not inconsistent with the provisions of the Plan, to the vesting of such Restricted Stock Awards as it deems appropriate, including, without limitation, (i) the achievement of one or more specified performance objectives; and/or that (ii) the Participant remain in the continuous employ or service of the Company or a Subsidiary for a certain period.
- 8.2 Rights as a Stockholder; Transferability. Except as provided in Sections 8.1, 8.3, 8.4 and 15.3 of the Plan, a Participant will have all voting, dividend, liquidation and other rights with respect to shares of Common Stock issued to the Participant as a Restricted Stock Award under this Section 8 upon the Participant becoming the holder of record of such shares as if such Participant were a holder of record of shares of unrestricted Common Stock.

- 8.3 Dividends and Distributions. Unless the Committee determines otherwise in its sole discretion (either in the agreement evidencing the Restricted Stock Award at the time of grant or at any time after the grant of the Restricted Stock Award), any dividends or distributions paid with respect to shares of Common Stock subject to the unvested portion of a Restricted Stock Award will be subject to the same restrictions as the shares to which such dividends or distributions relate. The Committee will determine in its sole discretion whether any interest will be paid on such dividends or distributions.
- 8.4 Enforcement of Restrictions. To enforce the restrictions referred to in this Section 8, the Committee may place a legend on the stock certificates referring to such restrictions and may require the Participant, until the restrictions have lapsed, to keep the stock certificates, together with duly endorsed stock powers, in the custody of the Company or its transfer agent, or to maintain evidence of stock ownership, together with duly endorsed stock powers, in a certificate less book-entry stock account with the Company's transfer agent.
9. Stock Unit Awards.
- An Eligible Recipient may be granted one or more Stock Unit Awards under the Plan, and such Stock Unit Awards will be subject to such terms and conditions, consistent with the other provisions of the Plan, as may be determined by the Committee in its sole discretion. The Committee may impose such restrictions or conditions, not inconsistent with the provisions of the Plan, to the payment, issuance, retention and/or vesting of such Stock Unit Awards as it deems appropriate, including, without limitation, (i) the achievement of one or more specified performance objectives; and/or that (ii) the Participant remain in the continuous employ or service of the Company or a Subsidiary for a certain period.
10. Performance Awards.
- An Eligible Recipient may be granted one or more Performance Awards under the Plan, and such Performance Awards will be subject to such terms and conditions, if any, consistent with the other provisions of the Plan, as may be determined by the Committee in its sole discretion, including, but not limited to, the achievement of one or more specified performance objectives.
11. Stock Bonuses.
- An Eligible Recipient may be granted one or more Stock Bonuses under the Plan, and such Stock Bonuses will be subject to such terms and conditions, if any, consistent with the other provisions of the Plan, as may be determined by the Committee in its sole discretion, including, but not limited to, the achievement of one or more specified performance objectives.
12. Effect of Termination of Employment or Other Service. The following provisions shall apply upon termination of a Participant's employment or other service with the Company and all Subsidiaries, except to the extent that the Committee provides otherwise in an agreement evidencing an Incentive Award at the time of grant or determines pursuant to Section 12.3 of the Plan.
- 12.1 Termination Due to Death, Disability or Retirement. In the event a Participant's employment or other service with the Company and all Subsidiaries is terminated by reason of death, Disability or Retirement:
- (a) All outstanding Options and Stock Appreciation Rights then held by the Participant will, to the extent exercisable as of such termination, remain exercisable in full for a period of one year after such termination (but in no event after the expiration date of any such Option or Stock Appreciation Right). Options and Stock Appreciation Rights not exercisable as of such termination will be forfeited and terminate;
- (b) All Restricted Stock Awards then held by the Participant that have not vested as of such termination will be terminated and forfeited; and
- (c) All outstanding but unpaid Stock Unit Awards, Performance Awards and Stock Bonuses then held by the Participant will be terminated and forfeited.

- 12.2 Termination for Reasons Other than Death, Disability or Retirement. Subject to Section 12.4 of the Plan, in the event a Participant's employment or other service is terminated with the Company and all Subsidiaries for any reason other than death, Disability or Retirement, or a Participant is in the employ or service of a Subsidiary and the Subsidiary ceases to be a Subsidiary of the Company (unless the Participant continues in the employ or service of the Company or another Subsidiary):
- (a) All outstanding Options and Stock Appreciation Rights then held by the Participant will, to the extent exercisable as of such termination, remain exercisable in full for a period of three months after such termination (but in no event after the expiration date of any such Option or Stock Appreciation Right). Options and Stock Appreciation Rights not exercisable as of such termination will be forfeited and terminate;
- (b) All Restricted Stock Awards then held by the Participant that have not vested as of such termination will be terminated and forfeited; and
- (c) All outstanding but unpaid Stock Unit Awards, Performance Awards and Stock Bonuses then held by the Participant will be terminated and forfeited.
- 12.3 Modification of Rights Upon Termination. Notwithstanding the other provisions of this Section 12, upon a Participant's termination of employment or other service with the Company and all Subsidiaries, the Committee may, in its sole discretion (which may be exercised at any time on or after the date of grant, including following such termination), except as provided in clause (ii), below, cause Options or Stock Appreciation Rights (or any part thereof) then held by such Participant to terminate, become or continue to become exercisable and/or remain exercisable following such termination of employment or service, and Restricted Stock Awards, Stock Unit Awards, Performance Awards or Stock Bonuses then held by such Participant to terminate, vest or become free of restrictions and conditions to payment, as the case may be, following such termination of employment or service, in each case in the manner determined by the Committee; provided, however, that any such action adversely affecting any outstanding Incentive Award will not be effective without the consent of the affected Participant (subject to the right of the Committee to take whatever action it deems appropriate under Sections 3.2(c), 4.3 and 14 of the Plan).
- 12.4 Effects of Actions Constituting Cause. Notwithstanding anything in the Plan to the contrary, in the event that a Participant is determined by the Committee, acting in its sole discretion, to have committed any action which would constitute Cause as defined in Section 2.3 of the Plan, irrespective of whether such action or the Committee's determination occurs before or after termination of such Participant's employment with the Company or any Subsidiary, all rights of the Participant under the Plan and any agreements evidencing an Incentive Award then held by the Participant shall terminate and be forfeited without notice of any kind. The Company may defer the exercise of any Option, the vesting of any Restricted Stock Award or the payment of any Stock Unit Award, Performance Award or Stock Bonus for a period of up to forty-five (45) days in order for the Committee to make any determination as to the existence of Cause.
- 12.5 Determination of Termination of Employment or Other Service.
- (a) The change in a Participant's status from that of an employee of the Company or any Subsidiary to that of a non-employee consultant, director or advisor of the Company or any Subsidiary will, for purposes of the Plan, be deemed to result in a termination of such Participant's employment with the Company and its Subsidiaries, unless the Committee otherwise determines in its sole discretion.
- (b) The change in a Participant's status from that of a non-employee consultant, director or advisor of the Company or any Subsidiary to that of an employee of the Company or any Subsidiary will not, for purposes of the Plan, be deemed to result in a termination of such Participant's service as a non-employee consultant, director or advisor with the Company and its Subsidiaries, and such Participant will thereafter be deemed to be an employee of the Company or its Subsidiaries until such Participant's employment is terminated, in which event such Participant will be governed by the provisions of this Plan relating to termination of employment or service (subject to paragraph (a), above).
- (c) Unless the Committee otherwise determines in its sole discretion, a Participant's employment or other service will, for purposes of the Plan, be deemed to have terminated on the date recorded on the personnel or other

records of the Company or the Subsidiary for which the Participant provides employment or other service, as determined by the Committee in its sole discretion based upon such records.

(d) Notwithstanding the foregoing, if payment of an Incentive Award that is subject to Section 409A of the Code is triggered by a termination of a Participant's employment or other service, such termination must also constitute a "separation from service" within the meaning of Section 409A of the Code, and any change in employment status that constitutes a "separation from service" under Section 409A of the Code shall be treated as a termination of employment or service, as the case may be.

12.6 Breach of Employment, Consulting, Confidentiality or Non-Compete Agreements. Notwithstanding anything in the Plan to the contrary and in addition to the rights of the Committee under Section 12.4 of the Plan, in the event that a Participant materially breaches the terms of any employment, consulting, confidentiality or non-compete agreement entered into with the Company or any Subsidiary (including an employment, consulting, confidentiality or non-compete agreement made in connection with the grant of an Incentive Award), whether such breach occurs before or after termination of such Participant's employment or other service with the Company or any Subsidiary, the Committee in its sole discretion may require the Participant to surrender shares of Common Stock received, and to disgorge any profits (however defined by the Committee), made or realized by the Participant in connection with any Incentive Awards or any shares issued upon the exercise or vesting of any Incentive Awards.

13 Payment of Withholding Taxes.

13.1 General Rules. The Company is entitled to (a) withhold and deduct from future wages of the Participant (or from other amounts that may be due and owing to the Participant from the Company or a Subsidiary), or make other arrangements for the collection of, all legally required amounts necessary to satisfy any and all federal, foreign, state and local withholding and employment-related tax requirements attributable to an Incentive Award, including, without limitation, the grant, exercise, vesting or settlement of, or payment of dividends with respect to, an Incentive Award or a disqualifying disposition of stock received upon exercise of an Incentive Stock Option; (b) withhold cash paid or payable or shares of Common Stock from the shares issued or otherwise issuable to the Participant in connection with an Incentive Award; or (c) require the Participant promptly to remit the amount of such withholding to the Company before taking any action, including issuing any shares of Common Stock, with respect to an Incentive Award. Shares of Common Stock issued or otherwise issuable to the Participant in connection with an Incentive Award that gives rise to the tax withholding obligation that are withheld for purposes of satisfying the Participant's withholding or employment-related tax obligation, will be valued at their Fair Market Value on the Tax Date. No withholding will be effected under this Plan which exceeds the minimum statutory withholding requirements.

13.2 Special Rules. The Committee may, in its sole discretion and upon terms and conditions established by the Committee, permit or require a Participant to satisfy, in whole or in part, any withholding or employment-related tax obligation described in Section 13.1 of the Plan by withholding shares of Common Stock underlying an Incentive Award, by electing to tender, or by attestation as to ownership of, Previously Acquired Shares, by delivery of a Broker Exercise Notice or a combination of such methods. For purposes of satisfying a Participant's withholding or employment-related tax obligation, shares of Common Stock withheld by the Company or Previously Acquired Shares tendered or covered by an attestation will be valued at their Fair Market Value on the Tax Date.

14. Change in Control.

14.1 A "Change in Control" shall be deemed to have occurred if the event set forth in any one of the following paragraphs shall have occurred:

(a) the sale, lease, exchange or other transfer, directly or indirectly, of substantially all of the assets of the Company (in one transaction or in a series of related transactions) to a person or entity that is not controlled by the Company;

(b) the approval by the stockholders of the Company of any plan or proposal for the liquidation or dissolution of the Company;

(c) any person becomes after the effective date of the Plan the “beneficial owner” (as defined in Rule 13d-3 under the Exchange Act), directly or indirectly, of (A) 20% or more, but not 50% or more, of the combined voting power of the Company’s outstanding securities ordinarily having the right to vote at elections of directors, unless the transaction resulting in such ownership has been approved in advance by the Continuity Directors, or (B) 50% or more of the combined voting power of the Company’s outstanding securities ordinarily having the right to vote at elections of directors (regardless of any approval by the Continuity Directors);

(d) a merger or consolidation to which the Company is a party if the stockholders of the Company immediately prior to effective date of such merger or consolidation have “beneficial ownership” (as defined in Rule 13d-3 under the Exchange Act), immediately following the effective date of such merger or consolidation, of securities of the surviving corporation representing (A) more than 50%, but less than 80%, of the combined voting power of the surviving corporation’s then outstanding securities ordinarily having the right to vote at elections of directors, unless such merger or consolidation has been approved in advance by the Continuity Directors (as defined below), or (B) 50% or less of the combined voting power of the surviving corporation’s then outstanding securities ordinarily having the right to vote at elections of directors (regardless of any approval by the Continuity Directors);

(e) the Continuity Directors cease for any reason to constitute at least a majority of the Board; or

(f) any other change in control of the Company of a nature that would be required to be reported pursuant to Section 13 or 15(d) of the Exchange Act, whether or not the Company is then subject to such reporting requirements.

For purposes of this Section 14, “Continuity Directors” of the Company will mean any individuals who are members of the Board on the Effective Date and any individual who subsequently becomes a member of the Board whose election, or nomination for election by the Company’s stockholders, was approved by a vote of at least a majority of the Continuity Directors (either by specific vote or by approval of the Company’s proxy statement in which such individual is named as a nominee for director without objection to such nomination).

14.2 Acceleration of Vesting. Without limiting the authority of the Committee under Sections 3.2 and 4.3 of the Plan, if a Change in Control of the Company is to occur, then immediately prior to the occurrence of such Change in Control, unless otherwise provided by the Committee in its sole discretion either in the agreement evidencing an Incentive Award at the time of grant or at any time after the grant of an Incentive Award: (a) all Options and Stock Appreciation Rights will become immediately exercisable in full and will remain exercisable in accordance with their terms; (b) all Restricted Stock Awards will become immediately fully vested and non-forfeitable; and (c) any conditions to the payment of Stock Unit Awards, Performance Awards and Stock Bonuses will lapse.

14.3 Cash Payment.

(a) In the event of a merger or consolidation of the Company with or into another corporation or a sale of substantially all of the stock of the Company (a “Corporate Transaction”), each outstanding Incentive Award (including the portion of the award that is not otherwise exercisable or non-forfeitable) shall automatically lapse without the consent of any Participant, unless pursuant to the terms of such Corporate Transaction the outstanding Incentive Award is required or permitted to remain outstanding or is assumed by the surviving company (or its parent company) or replaced with an equivalent Incentive Award granted by the surviving company (or its parent company) in substitution for such outstanding Incentive Award. If an Incentive Award lapses pursuant to the preceding sentence, the Committee shall not exercise its authority under Section 14.2 to prevent the vesting of, or lapse of conditions to exercise or payment in respect of, any outstanding Incentive Award and shall either (i) allow all Participants to exercise such Options and Stock Appreciation Rights to the extent vested and exercisable as of the consummation of such Corporate Transaction (including any Incentive Award that vests immediately prior to or upon consummation of such Corporate Transaction pursuant to Section 14.2 or the terms of the agreement evidencing such Incentive Award) within a reasonable period prior to the consummation of the Corporate Transaction and cancel any outstanding Incentive Awards that remain unexercised or which are not otherwise vested upon consummation of the Corporate Transaction, or (ii) cancel any or all outstanding Incentive Awards in exchange for a payment (in cash, or in securities or other property) in an amount equal to the amount that the Participant would have received (net of the exercise price) with respect to such vested Incentive Awards had such Options and Stock Appreciation Rights been exercised and such other vested Incentive Awards settled immediately prior to the consummation of the Corporate Transaction. Notwithstanding the foregoing, if an Incentive Award

lapses upon consummation of a Corporate Transaction and such award is not vested and non-forfeitable or the exercise price with respect to any outstanding Option or Stock Appreciation Right exceeds the Fair Market Value of the Common Stock immediately prior to the consummation of the Corporation Transaction, such Incentive Awards shall be cancelled without any payment to the Participant.

(b) Liquidation or Dissolution of the Company. In the event of the proposed dissolution or liquidation of the Company, each Incentive Award will terminate immediately upon consummation of such proposed action, unless otherwise provided by the Committee. Any Incentive Awards that is not vested and non-forfeitable as of the consummation of such proposed action and any Options or Stock Appreciation Rights that remain unexercised upon consummation of such proposed action shall be cancelled without any payment to the Participant.

(c) Special Provisions for Incentive Awards Subject to Section 409A of the Code. Notwithstanding the foregoing provisions of this Section 14.3, if an Incentive Award is subject to Section 409A of the Code, no payment of cash or other property shall be made with respect to such Incentive Award until the earlier of a Change in Control within the meaning of Section 409A of the Code or such time as such Incentive Award would have otherwise settled in the absence of a Corporate Transaction.

15. Rights of Eligible Recipients and Participants; Transferability.

15.1 Employment or Service. Nothing in the Plan will interfere with or limit in any way the right of the Company or any Subsidiary to terminate the employment or service of any Eligible Recipient or Participant at any time, nor confer upon any Eligible Recipient or Participant any right to continue in the employ or service of the Company or any Subsidiary.

15.2 Rights as a Stockholder; Dividends. As a holder of Incentive Awards (other than Restricted Stock Awards), a Participant will have no rights as a stockholder unless and until such Incentive Awards are exercised for, or paid in the form of, shares of Common Stock and the Participant becomes the holder of record of such shares. Except as otherwise provided in the Plan or otherwise provided by the Committee, no adjustment will be made in the amount of cash payable or in the number of shares of Common Stock issuable under Incentive Awards denominated in or based on the value of shares of Common Stock as a result of cash dividends or distributions paid to holders of Common Stock prior to the payment of, or issuance of shares of Common Stock under, such Incentive Awards.

15.3 Restrictions on Transfer.

(a) Except pursuant to testamentary will or the laws of descent and distribution or as otherwise expressly permitted by subsections (b) and (c) below, no right or interest of any Participant in an Incentive Award prior to the exercise (in the case of Options) or vesting or issuance (in the case of Restricted Stock Awards and Performance Awards) of such Incentive Award will be assignable or transferable, or subjected to any lien, during the lifetime of the Participant, either voluntarily or involuntarily, directly or indirectly, by operation of law or otherwise.

(b) A Participant will be entitled to designate a beneficiary to receive an Incentive Award upon such Participant's death, and in the event of such Participant's death, payment of any amounts due under the Plan will be made to, and exercise of any Options or Stock Appreciation Rights (to the extent permitted pursuant to Section 12 of the Plan) may be made by, such beneficiary. If a deceased Participant has failed to designate a beneficiary, or if a beneficiary designated by the Participant fails to survive the Participant, payment of any amounts due under the Plan will be made to, and exercise of any Options or Stock Appreciation Rights (to the extent permitted pursuant to Section 12 of the Plan) may be made by, the Participant's legal representatives, heirs and legatees. If a deceased Participant has designated a beneficiary and such beneficiary survives the Participant but dies before complete payment of all amounts due under the Plan or exercise of all exercisable Options or Stock Appreciation Rights, then such payments will be made to, and the exercise of such Options or Stock Appreciation Rights may be made by, the legal representatives, heirs and legatees of the beneficiary.

(c) Upon a Participant's request, the Committee may, in its sole discretion, permit a transfer of all or a portion of a Non-Statutory Stock Option, other than for value, to such Participant's child, stepchild, grandchild, parent, stepparent, grandparent, spouse, former spouse, sibling, niece, nephew, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, any person sharing such Participant's household (other than a

tenant or employee), a trust in which any of the foregoing have more than fifty percent of the beneficial interests, a foundation in which any of the foregoing (or the Participant) control the management of assets, and any other entity in which these persons (or the Participant) own more than fifty percent of the voting interests. Any permitted transferee will remain subject to all the terms and conditions applicable to the Participant prior to the transfer. A permitted transfer may be conditioned upon such requirements as the Committee may, in its sole discretion, determine, including, but not limited to execution and/or delivery of appropriate acknowledgements, opinion of counsel, or other documents by the transferee.

- 15.4 Non-Exclusivity of the Plan. Nothing contained in the Plan is intended to modify or rescind any previously approved compensation plans or programs of the Company or create any limitations on the power or authority of the Board to adopt such additional or other compensation arrangements as the Board may deem necessary or desirable.

16. Securities Law and Other Restrictions.

Notwithstanding any other provision of the Plan or any agreements entered into pursuant to the Plan, the Company will not be required to issue any shares of Common Stock under this Plan, and a Participant may not sell, assign, transfer or otherwise dispose of shares of Common Stock issued pursuant to Incentive Awards granted under the Plan, unless (a) there is in effect with respect to such shares a registration statement under the Securities Act and any applicable securities laws of a state or foreign jurisdiction or an exemption from such registration under the Securities Act and applicable state or foreign securities laws, and (b) there has been obtained any other consent, approval or permit from any other U.S. or foreign regulatory body which the Committee, in its sole discretion, deems necessary or advisable. The Company may condition such issuance, sale or transfer upon the receipt of any representations or agreements from the parties involved, and the placement of any legends on certificates representing shares of Common Stock, as may be deemed necessary or advisable by the Company in order to comply with such securities law or other restrictions.

17. Compliance with Section 409A.

It is intended that the Plan and all Incentive Awards hereunder be administered in a manner that will comply with the requirements of Section 409A of the Code, or the requirements of an exception to Section 409A of the Code. The Committee is authorized to adopt rules or regulations deemed necessary or appropriate to qualify for an exception from or to comply with the requirements of Section 409A of the Code (including any transition or grandfather rules relating thereto). Notwithstanding anything in this Section 17 to the contrary, with respect to any Incentive Award subject to Section 409A of the Code, no amendment to or payment under such Incentive Award will be made unless and only to the extent permitted under Section 409A of the Code.

18. Plan Amendment, Modification and Termination.

The Board may suspend or terminate the Plan or any portion thereof at any time. In addition to the authority of the Committee to amend the Plan under Section 3.2(e) of the Plan, the Board may amend the Plan from time to time in such respects as the Board may deem advisable in order that Incentive Awards under the Plan will conform to any change in applicable laws or regulations or in any other respect the Board may deem to be in the best interests of the Company; provided, however, that no such amendments to the Plan will be effective without approval of the Company's stockholders if: (i) stockholder approval of the amendment is then required pursuant to Section 422 of the Code or the rules of The NASDAQ Stock Market (or other applicable exchange or market on which the Company's Common Stock may be traded or quoted); or (ii) such amendment seeks to increase the number of shares authorized for issuance hereunder (other than by virtue of an adjustment under Section 4.3 of the Plan) or to modify Section 3.2(d) of the Plan. No termination, suspension or amendment of the Plan may adversely affect any outstanding Incentive Award without the consent of the affected Participant; provided, however, that this sentence will not impair the right of the Committee to take whatever action it deems appropriate under Sections 3.2(c), 4.3 and 14 of the Plan.

19. Effective Date and Duration of the Plan.

The Plan will be effective as of the Effective Date and will terminate one day prior to the tenth (10th) anniversary of the Effective Date, if not terminated prior to such time by Board action. No Incentive Award will be granted after

termination of the Plan. Incentive Awards outstanding upon termination of the Plan may continue to be exercised, earned or become free of restrictions, according to their terms.

20. Miscellaneous.
- 20.1 Dividend Equivalents. Any Participant selected by the Committee may be granted dividend equivalents based on the dividends declared on shares of Common Stock that are subject to any Incentive Award, to be credited as of dividend payment dates, during the period between the date the Incentive Award is granted and the date the Incentive Award is exercised, vests or expires, as determined by the Committee. Such dividend equivalents will be converted to cash or additional shares of Common Stock by such formula and at such time and subject to such limitations as may be determined by the Committee. Notwithstanding the foregoing, the Committee may not grant dividend equivalents based on the dividends declared on shares of Common Stock that are subject to an Option or Stock Appreciation Right and further, no dividend or dividend equivalents will be paid out with respect to any unvested Incentive Awards.
- 20.2 Fractional Shares. No fractional shares of Common Stock will be issued or delivered under the Plan or any Award. The Committee will determine whether cash, other Awards or other property will be issued or paid.
- 20.3 Governing Law. Except to the extent expressly provided herein or in connection with other matters of corporate governance and authority (all of which shall be governed by the laws of the Company's jurisdiction of incorporation), the validity, construction, interpretation, administration and effect of the Plan and any rules, regulations and actions relating to the Plan will be governed by and construed exclusively in accordance with the laws of the State of Delaware, notwithstanding the conflicts of laws principles of any jurisdictions.
- 20.4 Successors and Assigns. The Plan will be binding upon and inure to the benefit of the successors and permitted assigns of the Company and the Participants.
- 20.5 Construction. Wherever possible, each provision of the Plan and any agreement evidencing an Incentive Award granted under the Plan will be interpreted so that it is valid under the applicable law. If any provision of the Plan or any agreement evidencing an Incentive Award granted under the Plan is to any extent invalid under the applicable law, that provision will still be effective to the extent it remains valid. The remainder of the Plan and the Incentive Award agreement also will continue to be valid, and the entire Plan and Incentive Award agreement will continue to be valid in other jurisdiction.



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

I, Patrick D. Walsh, 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: August 6, 2020

/s/ Patrick D. Walsh  
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Patrick D. Walsh  
Interim President and  
Chief Executive Officer  
(principal executive officer)

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**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: August 6, 2020

/s/ Stephen P. Carey

Stephen P. Carey

Vice President, Finance and Chief Financial Officer

(principal financial officer)

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**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 June 30, 2020 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

Dated: August 6, 2020

/s/ Patrick D. Walsh

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Patrick D. Walsh  
Interim President and Chief Executive Officer  
(principal executive officer)

Dated: August 6, 2020

/s/ Stephen P. Carey

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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.

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