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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 March 31, 2021

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

For the transition period from to .

Commission File Number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

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

210 Main Street West
Baudette, Minnesota 56623
(Address of principal executive offices)

(218) 634-3500
(Registrant's telephone number including area code)

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

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

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, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☒
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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

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

As of April 30, 2021 there were 12,729,072 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended March 31, 2021

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Exchange Act. Such statements include, but are not limited to, the announcement and pendency of the acquisition of Novitium Pharma LLC ("Novitium"), statements about future operations, strategies and growth potential, the revenue potential (licensing, royalty and sales) of products we sell, development timelines, expected timeframe for submission of new drug applications or supplemental new drug applications to the U.S. Food and Drug Administration (the "FDA"), pipeline or potential markets for our products, expected pre-launch charges for Cortrophin, impact of 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 those discussed in the "Risk Factors" section in Part I, Item 1A.of our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, and the following factors:

- *the ability of the parties to complete the announced acquisition of Novitium or any delay in the completion of the acquisition;*
- *risks that we may face with respect to importing raw materials;*
- *delays or failure in obtaining approvals by 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 outbreaks 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, 2020, 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®, OXISTAT® Lotion, Pandel® Cream, Reglan®, Vancocin®, and VEREGEN® Ointment 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.

Part I — FINANCIAL INFORMATION

Item 1. Financial Statements

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

	March 31, 2021	*December 31, 2020*
Assets		
Current Assets		
Cash and cash equivalents	$ 25,073	$ 7,864
Accounts receivable, net of $80,722 and $100,328 of adjustments for chargebacks and other allowances at March 31, 2021 and December 31, 2020, respectively	91,876	95,793
Inventories, net	59,927	60,803
Prepaid expenses and other current assets	5,922	5,861
Total Current Assets	182,798	170,321
Property and equipment	59,541	58,797
Accumulated depreciation	(18,774)	(17,528)
Property and equipment, net	40,767	41,269
Restricted cash	5,000	5,003
Deferred tax assets, net of deferred tax liabilities and valuation allowance	52,006	51,704
Intangible assets, net	178,859	188,511
Goodwill	3,580	3,580
Other non-current assets	833	802
Total Assets	$ 463,843	$ 461,190
Liabilities and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 14,438	$ 13,243
Accounts payable	13,769	11,261
Accrued expenses and other	2,381	2,456
Accrued royalties	5,310	6,407
Accrued compensation and related expenses	5,533	6,231
Current income taxes payable, net	3,659	3,906
Accrued government rebates	8,672	7,826
Returned goods reserve	28,944	27,155
Deferred revenue	62	80
Total Current Liabilities	82,768	78,565
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	168,985	172,443
Derivatives and other non-current liabilities	8,378	14,482
Total Liabilities	$ 260,131	$ 265,490
Commitments and Contingencies (Note 11)		
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 12,829,750 shares issued and 12,743,715 outstanding at March 31, 2021; 12,429,916 shares issued and 12,354,398 shares outstanding at December 31, 2020	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	—	—
Treasury stock, 86,035 shares of common stock, at cost, at March 31, 2021 and 75,518 shares of common stock, at cost, at December 31, 2020	(2,594)	(2,246)
Additional paid-in capital	216,223	214,354
Accumulated deficit	(4,886)	(4,972)
Accumulated other comprehensive loss, net of tax	(5,032)	(11,437)
Total Stockholders' Equity	203,712	195,700
Total Liabilities and Stockholders' Equity	$ 463,843	$ 461,190

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

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

	Three Months Ended March 31,	
	2021	***2020***
Net Revenues	$ 54,521	$ 49,774
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	19,985	21,804
Research and development	2,968	6,344
Selling, general, and administrative	17,587	13,683
Depreciation and amortization	10,898	11,183
Cortrophin pre-launch charges	38	4,602
Total Operating Expenses	51,476	57,616
Operating Income/(Loss)	3,045	(7,842)
Other Expense, net		
Interest expense, net	(2,454)	(2,032)
Other (expense)/income, net	(515)	10
Income/(Loss) Before Benefit for Income Taxes	76	(9,864)
Benefit for income taxes	10	2,853
Net Income/(Loss)	$ 86	$ (7,011)
Basic and Diluted Earnings/(Loss) Per Share:		
Basic Earnings/(Loss) Per Share	$ 0.01	$ (0.59)
Diluted Earnings/(Loss) Per Share	$ 0.01	$ (0.59)
Basic Weighted-Average Shares Outstanding	12,004	11,902
Diluted Weighted-Average Shares Outstanding	12,017	11,902

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

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

	Three Months Ended March 31,	
	2021	***2020***
Net income/(loss)	$ 86	$ (7,011)
Other comprehensive income/(loss), net of tax:		
Gains/(losses) on interest rate swap	6,405	(6,818)
Total other comprehensive income/(loss), net of tax	6,405	(6,818)
Total comprehensive income/(loss), net of tax	$ 6,491	$ (13,829)

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Three Months Ended March 31, 2021 and 2020
(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)/Gain, Net of Tax	Retained Earnings/ (Accumulated Deficit)	Total
Balance, December 31, 2019	$ 1	12,105	$ —	$ 200,800	15	$ (723)	$ (4,871)	$ 17,584	$ 212,791
Cumulative Effect of Change in Accounting Principle	—	—	—	—	—	—	—	(8)	(8)
Stock-based Compensation Expense	—	—	—	2,424	—	—	—	—	2,424
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	13	(488)	—	—	(488)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	7	—	281	—	—	—	—	281
Losses on Interest Rate Swap	—	—	—	—	—	—	(6,818)	—	(6,818)
Net Loss	—	—	—	—	—	—	—	(7,011)	(7,011)
Balance, March 31, 2020	$ 1	12,112	$ —	$ 203,505	28	$ (1,211)	$ (11,689)	$ 10,565	$ 201,171
Balance, December 31, 2020	$ 1	12,430	$ —	$ 214,354	76	$ (2,246)	$ (11,437)	$ (4,972)	$ 195,700
Stock-based Compensation Expense	—	—	—	1,869	—	—	—	—	1,869
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	10	(348)	—	—	(348)
Issuance of Restricted Stock Awards	—	438	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	(38)	—	—	—	—	—	—	—
Gains on Interest Rate Swap	—	—	—	—	—	—	6,405	—	6,405
Net Income	—	—	—	—	—	—	—	86	86
Balance, March 31, 2021	$ 1	12,830	$ —	$ 216,223	86	$ (2,594)	$ (5,032)	$ (4,886)	$ 203,712

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)

	Three Months Ended March 31,	
	2021	***2020***
Cash Flows From Operating Activities		
Net income/(loss)	$ 86	$ (7,011)
Adjustments to reconcile net income/(loss) to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	1,869	2,424
Deferred taxes	(279)	(19,243)
Depreciation and amortization	10,898	11,183
Acquired in-process research and development ("IPR&D")	—	3,753
Non-cash interest	572	182
Changes in operating assets and liabilities, net of acquisitions:		
Accounts receivable, net	3,917	(10,250)
Inventories, net	876	3,693
Prepaid expenses and other current assets	379	1,028
Accounts payable	2,462	(1,332)
Accrued royalties	(1,097)	1,201
Current income taxes payable, net	(247)	16,299
Accrued government rebates	846	(871)
Returned goods reserve	1,792	1,019
Accrued expenses, accrued compensation, and other	(1,406)	(365)
Net Cash and Cash Equivalents Provided by Operating Activities	20,668	1,710
Cash Flows From Investing Activities		
Acquisition of product rights, IPR&D, and other related assets	(39)	(56,007)
Acquisition of property and equipment, net	(698)	(1,539)
Net Cash and Cash Equivalents Used in Investing Activities	(737)	(57,546)
Cash Flows From Financing Activities		
Payments on Term Loan and Delayed Draw Term Loan agreements	(2,377)	(902)
Borrowings under Revolver agreement	—	15,000
Proceeds from stock option exercises and ESPP purchases	—	281
Treasury stock purchases for restricted stock vests	(348)	(488)
Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities	(2,725)	13,891
Net Change in Cash and Cash Equivalents	17,206	(41,945)
Cash and cash equivalents, beginning of period	12,867	67,361
Cash and cash equivalents, end of period	$ 30,073	$ 25,416
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	$ 7,864	$ 62,332
Restricted cash	5,003	5,029
Cash, cash equivalents, and restricted cash, beginning of period	$ 12,867	$ 67,361
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	$ 25,073	$ 20,414
Restricted cash	5,000	5,002
Cash, cash equivalents, and restricted cash, end of period	$ 30,073	$ 25,416
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 1,983	$ 1,848
Cash paid for income taxes	$ 112	$ 95
Supplemental non-cash investing and financing activities:		
Debt issuance costs in accrued expenses	$ 115	$ —
Acquisition of product rights, IPR&D, and other related assets included in returned goods reserve and accrued liabilities	$ 388	$ 1,940
Property and equipment purchased and included in accounts payable	$ 218	$ 138

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, oncology products (anti-cancer), 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.

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, 2020, has been derived from audited financial statements as 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, 2020.

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. Our gain or loss on transactions denominated in foreign currencies was immaterial for the three months ended March 31, 2021 and 2020. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In the accompanying unaudited interim condensed consolidated financial statements, estimates are

used for, but not limited to, stock-based compensation, 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 or benefit, 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 continue have on our future business, financial condition, and results of operations due to numerous uncertainties. These uncertainties include the occurrence of recurring outbreaks and their severity and the duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. We remain unable to predict the future impact on our estimates and assumptions. There was not a material impact to these estimates or assumptions in our consolidated financial statements as of and for the three months ended March 31, 2021 and 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.

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 majority of the assets of the Company are located in the United States.

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

(in thousands) Location of Operations	Three Months Ended March 31, 2021	 2020
United States	$ 53,327	$ 48,231
Canada	1,194	1,543
Total Revenue	$ 54,521	$ 49,774

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

(in thousands)	March 31, 2021	December 31, 2020
United States	$ 26,612	$ 26,960
Canada	14,155	14,309
Total property and equipment, net	$ 40,767	$ 41,269

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

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.

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

Recently Adopted Accounting Pronouncements

In August 2020, the Financial Accounting Standards Board ("FASB") issued guidance simplifying the accounting for certain financial instruments with characteristics of liabilities and equity, including certain convertible instruments and contracts on an entity's own equity. The new standard will remove the separation models required for convertible debt with cash conversion features and convertible instruments with beneficial conversion features. It will also remove certain settlement conditions that are currently required for equity contracts to qualify for the derivative scope exception and will simplify the diluted earnings per share calculation for convertible instruments. The guidance will be effective January 1, 2022. We adopted this guidance as of January 1, 2021. The adoption of this guidance did not have a material impact on our consolidated financial statements but could have an impact on our consolidated financial statements in future periods if the pending acquisition discussed in Note 3, *Pending Business Combination*, closes under proposed terms.

In November 2019, the 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 for 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. Most of the provisions of this guidance were to be adopted on a prospective basis. Items 2) and 3) of the "removal" provisions were to be adopted on either a full or modified retrospective basis and item 4) of the "simplifying" provisions was to be adopted on a full retrospective basis. The guidance was effective for reporting periods beginning after December 15, 2020, including interim periods within that fiscal year. We adopted this guidance as of January 1, 2021. The adoption of this guidance did not have a material impact on our consolidated financial statements.

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:

	Three Months Ended	
Products and Services	**March 31,**	**March 31,**
(in thousands)	**2021**	**2020**
Sales of generic pharmaceutical products	$ 32,988	$ 37,495
Sales of branded pharmaceutical products	7,517	9,157
Sales of contract manufactured products	2,573	1,974
Royalties from licensing agreements	11,210	290
Product development services	158	577
Other	75	281
Total net revenues	$ 54,521	$ 49,774

	Three Months Ended	
Timing of Revenue Recognition	**March 31,**	**March 31,**
(in thousands)	**2021**	**2020**
Performance obligations transferred at a point in time	$ 54,363	$ 49,197
Performance obligations transferred over time	158	577
Total	$ 54,521	$ 49,774

In the three months ended March 31, 2021 and 2020, we did not incur, and therefore did not defer, any material incremental costs to fulfill contracts. We recognized an increase of $10.7 million to net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2021, consisting primarily of a final royalty revenue related to the Kite license agreement pursuant to the Tripartite Agreement as described herein in *Royalties from Licensing Agreements.* We recognized a decrease of $2.4 million of net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2020, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales, partially offset by royalties from licensing agreements. We provide technical transfer services to customers, for which services are transferred over time. As of March 31, 2021 and December 31, 2020, we did not have any contract assets related to revenue recognized based on percentage of completion but not yet billed. We had $0.1 million of deferred revenue at March 31, 2021 and December 31, 2020. For the three months ended March 31, 2021, we recognized less than $0.1 million of revenue that was included in deferred revenue as of December 31, 2020. For the three months ended March 31, 2020, we recognized $0.1 million of revenue that was included in deferred revenue as of December 31, 2019.

Revenue from Sales of Generic and Branded Pharmaceutical Products

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

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

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 Part II, 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, 2020.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the three months ended March 31, 2021 and 2020, respectively:

	Accruals for Chargebacks, Returns, and Other Allowances				
(in thousands)	**Chargebacks**	**Government Rebates**	**Returns**	**Administrative Fees and Other Rebates**	**Prompt Payment Discounts**
Balance at December 31, 2019 (1)	$ 49,882	$ 8,901	$ 16,595	$ 8,281	$ 2,549
Accruals/Adjustments	95,393	3,567	5,937	8,922	3,361
Credits Taken Against Reserve	(51,575)	(4,438)	(4,918)	(8,817)	(2,219)
Balance at March 31, 2020 (1)	$ 93,700	$ 8,030	$ 17,614	$ 8,386	$ 3,691
Balance at December 31, 2020 (1)	$ 88,746	$ 7,826	$ 27,155	$ 8,906	$ 3,839
Accruals/Adjustments	96,701	4,656	4,811	7,634	3,196
Credits Taken Against Reserve	(114,114)	(3,810)	(3,022)	(9,184)	(3,959)
Balance at March 31, 2021 (1)	$ 71,333	$ 8,672	$ 28,944	$ 7,356	$ 3,076

(1) Chargebacks are included as an offset to accounts receivable in the unaudited condensed consolidated balance sheets. Administrative Fees and Other Rebates and Prompt Payment Discounts are included as an offset to accounts receivable or as 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 March 31, 2021, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $6.3 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 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. The agreements governing this royalty were subject to multiple actions in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, the Company and Cabaret. In the first quarter of 2021, we became aware that the litigation between Cabaret and Kite was dismissed. In April 2021, Cabaret and the Company settled all amounts due for amounts actually received by Cabaret or Eshhar for the licensing or use of the patent rights governed by the Kite license agreement. As a result, we recorded $11.2 million as royalties from licensing agreements in our net revenues for the period ended March 31, 2021. In addition, we agreed to reimburse Cabaret $0.4 million, which has been recorded as other expense, net in the accompanying unaudited interim condensed consolidated statement of operations, related to certain legal expenditures incurred. Based upon the events that led to the dismissal of the litigation between Cabaret and Kite, the Company does not expect to receive any future royalty income related to the Kite license agreement. In conjunction with payment of amounts due to us, all outstanding litigation between the Company and Cabaret were dismissed.

In addition, the Israeli Tax Authority (the "ITA") 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 this matter may impact the amount of cash due to us from various tax escrow accounts that have been established.

Product Development Services Revenue

We provide product development services to customers, which are performed over time. These services primarily relate to the technical transfer of product development to our facility in Oakville, Ontario. The duration of these technical transfer projects can be up to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a percentage of completion basis, which results in contract assets on our balance sheet. As of March 31, 2021, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open product development services contracts was $0.8 million. We expect to satisfy these performance obligations within the next 18 months.

Credit Concentration

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

During the three months ended March 31, 2021 and 2020 we had three customers that accounted for 10% or more of net revenues. As of March 31, 2021, accounts receivable from these customers totaled 73% of accounts receivable,

net. Additionally, 21% of our net revenue during the three months ended March 31, 2021 relates to royalty revenue from one customer pursuant to the Tripartite Agreement.

The three customers represent the total percentage of net revenues as follows:

	Three Months Ended	
	March 31, 2021	March 31, 2020
Customer 1	28 %	31 %
Customer 2	24 %	23 %
Customer 3	16 %	18 %

3. PENDING BUSINESS COMBINATION

On March 8, 2021, we entered into a definitive agreement to acquire Novitium Pharma LLC ("Novitium"), a privately held New Jersey-based pharmaceutical company with development, manufacturing, and commercial capabilities (the "Acquisition"). The closing of the acquisition will occur (a) within five business days after all of the conditions to the closing set forth in the merger agreement are satisfied or waived or (b) at such other time, date and place as may be agreed by us and Novitium, subject to the completion of a minimum period. The closing is subject to the satisfaction of customary closing conditions and necessary regulatory approvals.

Consideration will consist of a combination of (i) an estimated cash amount of $89.5 million, subject to various adjustments and expected to be financed by a $25.0 million private placement of preferred stock (the "PIPE Investment") and by new debt financing, both described below, (ii) an aggregate of 2,466,667 shares of ANI common stock, and (iii) up to $46.5 million in contingent future earn-out payments.

We will finance the transaction with a new $340.0 million Senior Secured Credit Facility (the "New Facility"), consisting of a $300.0 million term loan and a $40.0 million revolving credit facility, the issuance of 2,466,667 shares of ANI common stock (approximately $74.0 million in value based on a $30.0 stock price), and a $25.0 million PIPE Investment by Ampersand 2020 Limited Partnership ("Ampersand"), an affiliate of Ampersand Capital Partners. At closing, we intend to use the proceeds from the New Facility to fund a portion of the Acquisition and repay all of the outstanding debt under the existing senior secured credit facility. The New Facility will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI's existing senior credit facilities.

Concurrently with the execution of the definitive agreement, on March 8, 2021, we entered into an Equity Commitment and Investment Agreement with Ampersand (the "PIPE Investor"), pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock, for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million PIPE Investment.

Patrick D. Walsh, Chairman of ANI's board of directors, is an operating partner for Ampersand Capital Partners.

The PIPE Investment and issuance of shares of ANI common stock are subject to approval by ANI shareholders.

During the three months ended March 31, 2021, we incurred approximately $2.9 million in transaction costs related to this pending Acquisition, all of which were expensed.

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4. INDEBTEDNESS

Credit Facility

Our five-year Senior Secured Credit Facility (the "Credit Facility") is comprised of a $72.2 million term loan (the "Term Loan"), a $118.0 million delayed draw term loan ("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 a repayment schedule, pursuant to which $6.8 million of the loan will be paid in quarterly installments during the 12 months ended March 31, 2022. As of March 31, 2021, $6.8 million of the Term Loan is recorded as current borrowings in the consolidated balance sheets. The DDTL includes a repayment schedule, pursuant to which $8.1 million will be paid in quarterly installments during the 12 months ended March 31, 2022. As of March 31, 2021, $8.1 million of the DDTL is recorded as current borrowings in the consolidated balance sheets. As of March 31, 2021, there is $7.5 million outstanding and payable on our Revolver, all of which is recorded as a long-term borrowing on the consolidated balance sheets. As of March 31, 2021, $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 1-month 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 March 31, 2021, our interest rate on outstanding borrowings was 1-month LIBOR plus 2.25% and our commitment fee rate was 0.4%.

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 is subject to customary financial and nonfinancial covenants.

The carrying value of the current and non-current components of the Term Loan and DDTL as of March 31, 2021 and December 31, 2020 are:

	Current	
(in thousands)	**March 31, 2021**	**December 31, 2020**
Current borrowing on debt	$ 14,880	$ 13,691
Deferred financing costs	(442)	(448)
Current debt, net of deferred financing costs	$ 14,438	$ 13,243

	Non-Current	
(in thousands)	**March 31, 2021**	**December 31, 2020**
Non-current borrowing on debt	$ 162,189	$ 165,755
Deferred financing costs	(704)	(812)
Non-current debt, net of deferred financing costs and current component	$ 161,485	$ 164,943

As of March 31, 2021, we had a $65.0 million balance on the Term Loan, $112.1 million balance on the DDTL, and $7.5 million balance on the Revolver. Of the $0.7 million of deferred debt issuance costs allocated to the Revolver, $0.4 million is included in other non-current assets in the accompanying unaudited interim condensed consolidated balance sheets and $0.3 million is included in prepaid expenses and other current assets in the accompanying unaudited interim condensed consolidated balance sheets.

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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
2021	$ 5,414	$ 5,900	$ —
2022	5,414	8,850	—
2023	54,141	97,350	7,500
Total	$ 64,969	$ 112,100	$ 7,500

The following table sets forth the components of total interest expense related to the Term Loan, DDTL, and Revolver recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three months ended March 31, 2021 and 2020:

	Three Months Ended	
(in thousands)	March 31, 2021	March 31, 2020
Contractual coupon	$ 2,304	$ 1,893
Amortization of finance fees	177	182
Capitalized interest	(26)	(25)
	$ 2,455	$ 2,050

5. 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 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 and are recognizing the net loss in accumulated other comprehensive loss at the time of the termination 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 March 31, 2021, the notional amount of the interest rate swap was $177.1 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 March

31, 2021, the fair value of the interest rate swap liability was valued at $8.2 million and was recorded in derivatives and other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets. As of March 31, 2021, $6.4 million was recorded in accumulated other comprehensive loss, net of tax in the accompanying unaudited interim condensed consolidated balance sheets.

During the three months ended March 31, 2021, the change in the fair value of the interest rate swap of $5.5 million, net of tax, was recorded in accumulated other comprehensive income, net of tax in our unaudited interim condensed consolidated statements of comprehensive income/(loss). Differences between the hedged 1-month 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 1-month LIBOR rate. In the three months ended March 31, 2021, $1.2 million of interest expense was recognized in relation to the interest rate swaps, respectively.

6. 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.

Earnings (loss) per share for the three months ended March 31, 2021 and 2020 are calculated for basic and diluted earnings (loss) per share as follows:

(in thousands, except per share amounts)	Basic		Diluted	
	Three Months Ended March 31,		Three Months Ended March 31,	
	2021	2020	2021	2020
Net income/(loss)	$ 86	$ (7,011)	$ 86	$ (7,011)
Net income allocated to restricted stock	(5)	—	(5)	—
Net income/(loss) allocated to common shares	$ 81	$ (7,011)	$ 81	$ (7,011)
Basic Weighted-Average Shares Outstanding	12,004	11,902	12,004	11,902
Dilutive effect of stock options and ESPP			13	—
Diluted Weighted-Average Shares Outstanding			12,017	11,902
Earnings/(loss) per share	$ 0.01	$ (0.59)	$ 0.01	$ (0.59)

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, was 1.7 million and 1.8 million for the three months ended March 31, 2021 and 2020, respectively. For the three months ended March 31, 2021, anti-dilutive shares consist of out-of-the-money Class C Special stock, out-of-

the-money common stock options, and common stock options that are anti-dilutive when calculating the impact of the potential dilutive common shares using the treasury stock method. For the three months ended March 31, 2020, all potentially dilutive shares were anti-dilutive and excluded from the calculation of diluted loss per share because we recognized a net loss.

7. INVENTORIES

Inventories consist of the following as of:

(in thousands)	March 31, 2021	December 31, 2020
Raw materials	$ 39,746	$ 41,591
Packaging materials	3,066	3,194
Work-in-progress	782	886
Finished goods	21,791	20,363
	65,385	66,034
Reserve for excess/obsolete inventories	(5,458)	(5,231)
Inventories, net	$ 59,927	$ 60,803

Vendor Concentration

We source the raw materials for our products, including active pharmaceutical ingredients (“API”), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. As a result, we are dependent upon our current vendors to reliably supply the API required for on-going product manufacturing. During the three months ended March 31, 2021, we purchased approximately 11% of our inventory from one supplier. As of March 31, 2021, our accounts payable to this supplier was immaterial. During the three months ended March 31, 2020, we purchased approximately 13% of our inventory from one supplier.

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 Pharma Services Inc., we recorded additional goodwill of $1.7 million in 2018. We assess the recoverability of the carrying value of goodwill as of October 31st of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value during the three months ended March 31, 2021. No impairment losses were recognized during the three months ended March 31, 2021 and 2020.

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Definite-lived Intangible Assets

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

(in thousands)	March 31, 2021 Gross Carrying Amount	March 31, 2021 Accumulated Amortization	December 31, 2020 Gross Carrying Amount	December 31, 2020 Accumulated Amortization	Weighted Average Amortization Period
Acquired ANDA intangible assets	$ 106,415	$ (45,473)	$ 106,415	$ (42,367)	8.8 years
NDAs and product rights	230,974	(118,766)	230,974	(112,483)	10.0 years
Marketing and distribution rights	17,157	(11,626)	17,157	(11,386)	5.7 years
Non-compete agreement	624	(446)	624	(423)	7.0 years
	$ 355,170	$ (176,311)	$ 355,170	$ (166,659)	9.4 years

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 $9.7 million and $10.0 million for the three months ended March 31, 2021 and 2020, 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 months ended March 31, 2021 and 2020 and therefore no impairment loss was recognized in the three months ended March 31, 2021 and 2020.

Expected future amortization expense is as follows:

(in thousands)	
2021	$ 28,954
2022	35,199
2023	34,451
2024	31,474
2025	28,127
2026 and thereafter	20,654
Total	$ 178,859

9. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of March 31, 2021, we had 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.

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

(in thousands)	Three Months Ended March 31,	
	2021	2020
Cost of sales	$ 4	$ 4
Research and development	5	7
Selling, general, and administrative	23	18
	$ 32	$ 29

Stock Incentive Plan

All equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"). As of March 31, 2021, 0.6 million shares of our common stock were available for issuance under the 2008 Plan.

From time to time, we may grant stock options to employees through an inducement grant outside of our 2008 Plan to induce prospective employees to accept employment with us (the "Inducement Grants"). The options are granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant date and are generally exercisable in four equal annual installments beginning on the first anniversary of the respective grant date. The grants are made pursuant to inducement grants outside of our shareholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

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

(in thousands)	Three Months Ended March 31,	
	2021	2020
Cost of sales	$ —	$ 26
Research and development	114	187
Selling, general, and administrative	1,723	2,182
	$ 1,837	$ 2,395

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A summary of stock option and restricted stock activity under the 2008 Plan and Inducement Grants during the three months ended March 31, 2021 and 2020 is presented below:

(in thousands)	Options	Inducement Grants	RSAs
Outstanding at December 31, 2019	757	—	192
Granted	8	—	—
Options Exercised/RSAs Vested	(7)	—	(49) (1)
Forfeited	(3)	—	—
Expired	—	—	—
Outstanding at March 31, 2020	755	—	143
Outstanding at December 31, 2020	756	180	352
Granted	42	61	438
Options Exercised/RSAs Vested	—	—	(34) (2)
Forfeited	(10)	—	(38)
Expired	—	—	—
Outstanding at March 31, 2021	788	241	718

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

(2) Includes 10 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 $348 thousand total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

10. INCOME TAXES

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

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of March 31, 2021, we have provided a valuation allowance against consolidated net deferred tax assets of $0.3 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any such amounts accrued as of March 31, 2021 and December 31, 2020. 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.

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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. Prior to the adoption of new accounting guidance that we adopted on a prospective basis on January 1, 2021, during periods when we incurred net losses before income taxes, our annual estimated effective tax rate was at times adjusted based on the “loss limitation” requirements applicable to interim tax provisions, resulting in a limited income tax benefit recognized in that period. Under these provisions, our income tax benefit for the three months ended March 31, 2020 was limited. The “loss limitation” requirements were removed by the new accounting guidance and, therefore, we were not required to assess any such limitation for the three months ended March 31, 2021. 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 March 31, 2021, we recognized an income tax benefit of less than $0.1 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 27.7% to pre-tax consolidated income of $0.1 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 March 31, 2021.

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

11. COMMITMENTS AND CONTINGENCIES

Operating Leases

All our existing leases as of March 31, 2021 are classified as operating leases. As of March 31, 2021, we have 13 material operating leases for facilities and office equipment with remaining terms expiring from 2021 through 2026 and a weighted average remaining lease term of 1.8 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%.

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Rent expense for the three months ended March 31, 2021 and 2020 consisted of the following:

(in thousands)	Three Months Ended March 31, 2021	2020
Operating lease costs	$ 49	$ 52
Variable lease costs	7	15
Total lease costs	$ 56	$ 67

A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2021	$ 110
2022	127
2023	82
2024	56
2025 and thereafter	43
Total	$ 418
Discount	(36)
Lease liability	382
Current lease liability	(132)
Non-current lease liability	$ 250

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies, such as the Drug Enforcement Administration ("DEA"), the U.S. Food and Drug Administration ("FDA"), the Centers for Medicare and Medicaid Services ("CMS"), and Health Canada. The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The DEA and Health Canada maintain oversight over our products that are considered controlled substances.

Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone ("EEMT") and Opium Tincture, are marketed without approved NDAs or Abbreviated New Drug Applications ("ANDAs"). During the three months ended March 31, 2021 and 2020, net revenues for these products totaled $3.8 million and $4.4 million, respectively.

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 the group of unapproved products for the three months ended March 31, 2021 and 2020 were $0.8 million and $1.0 million, respectively.

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 director and officer 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 us.

Legal fees for litigation-related matters are expensed as incurred and included in the consolidated statements of operations under the selling, general, and administrative expense line item.

Commercial Litigation

In November of 2017, we were served with a complaint filed by Arbor Pharmaceuticals, LLC, in the United States District Court for the 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 is currently expected to be in August 2021. In light of the significant disagreement over the facts and legal theories in this case which will be determined at trial, we are unable to predict or reasonably estimate the potential loss or effect on our operations at this time. We have not established any reserves related to this action and it is not covered by insurance. We believe the action is without merit and continue to defend this lawsuit vigorously. Any adverse outcome in this case could have a material adverse impact on our financial condition, results of operations or cash flows.

On December 3, 2020, class action complaints were filed against the Company on behalf of putative classes of direct and indirect purchasers of the drug Bystolic. On December 23, 2020, six individual purchasers of Bystolic, CVS, Rite Aid, Walgreen, Kroger, Albertsons, and H-E-B, filed complaints against the Company. On March 15, 2021, the plaintiffs in these actions filed amended complaints. All amended complaints are substantively identical. The plaintiffs in these actions allege that, beginning in 2012, Forest Laboratories, the manufacturer of Bystolic, entered into anticompetitive agreements when settling patent litigation related to Bystolic with seven potential manufacturers of a generic version of Bystolic: Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, Watson, and various of their corporate parents, successors, subsidiaries, and affiliates. ANI itself was not a party to patent litigation with Forest concerning Bystolic and did not settle patent litigation with Forest. The plaintiffs named

the Company as a defendant based on the Company's January 8, 2020 Asset Purchase Agreement with Amerigen. The complaints allege that the 2013 patent litigation settlement agreement between Forest and Amerigen violates federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs allege they paid higher prices as a result of delayed generic competition. Plaintiffs seek damages, trebled or otherwise multiplied under applicable law, injunctive relief, litigation costs and attorneys' fees. The complaints do not specify the amount of damages sought from the Company or other defendants and the Company at this early stage of the litigation cannot reasonably estimate the potential damages that the plaintiffs will seek. The cases have been consolidated in the United States District Court for the Southern District of New York as In re Bystolic Antitrust Litigation, Case No. 20-cv-005735 (LJL). On April 23, 2021, the Company and other defendants filed motions to dismiss the amended complaints, which are pending. The Company disputes any liability in these matters.

On March 24, 2021, Azurity Pharmaceuticals, Inc. ("Azurity") filed a complaint in the United States District Court for the District of Minnesota against ANI Pharmaceuticals, Inc., asserting that ANI's vancomycin hydrochloride oral solution drug product infringes U.S. Patent No. 10,688,046. The complaint seeks injunctive relief, damages, including lost profits and/or royalty, treble damages, and attorneys' fee and costs. Azurity has not yet served its complaint, and accordingly ANI has not yet filed an answer and intends to dispute any liability.

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 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. On December 15, 2020, the case was removed to federal court and transferred to the In re Zantac multidistrict litigation ("MDL") pending in the United States District Court for the Southern District of Florida. New Mexico moved for remand to state court. The MDL court granted the remand motion on February 25, 2021. On April 16, 2021, New Mexico filed an amended complaint in the New Mexico First Judicial District Court in Santa Fe County. It did not name ANI in the amended complaint, effectively voluntarily dismissing ANI from the action. In December 2020, the City of Baltimore served ANI with a complaint against manufacturers and sellers of ranitidine products. The City of Baltimore complaint tracks the allegations of the New Mexico complaint. The Baltimore action was removed to federal court and transferred to the In re Zantac MDL on February 1, 2021. The City of Baltimore moved for remand, which was granted on April 1, 2021. The parties stipulated to allow the City of Baltimore to file an amended complaint in the Circuit Court of Maryland for Baltimore City in "due course," without a specific filing deadline. We dispute any liability in these matters.

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 United States District Court for 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 ("MPIC") in that MDL that was filed on June 22, 2020 also named the Company as a defendant. The Company was dismissed from the Koepsel case on August 21, 2020 and was dismissed from the MPIC on September 8, 2020. On December 31, 2020, after ANI was dismissed, the district court dismissed the MPIC claims against generic manufacturer defendants partially with prejudice and partially with leave to replead. The failure to warn and design defect claims were dismissed with prejudice on preemption grounds. An Amended Master Personal Injury Complaint was filed on February 8, 2021, which does not name ANI. The Company has been named in other individual personal injury complaints filed in MDL 20 MD 2924 in which plaintiffs allege that they developed cancer after taking prescription and over the counter medication containing ranitidine. To date, the Company has been served with complaints in five of those additional cases: Cooper v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81130-RLR (served September 30, 2020), Lineberry v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81079-RLR (served August 20, 2020), Lovette v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81040-RLR (served August 26, 2020), Hightower v. Pfizer, et al, MDL No. 20-MD-2924, Case No. 9-20-cv-82214-RLR (served December 16, 2020) and Bird v. Boehringer Ingelheim Pharmaceuticals, et al., MDL No. 20-MD-2924, Case No. 9-20-cv-80837-RLR (served December 30, 2020). We have informed counsel for the plaintiffs that we did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited two-month period of time, from July 2019 to September 2019. Our product was voluntarily recalled in January 2020. Each of the plaintiffs in the five pending cases alleges a cancer diagnosis prior to the time that ANI sold ranitidine, and we have informally sought dismissal from these cases on that basis. ANI was voluntarily dismissed from the Cooper, Lineberry and Lovette actions on November 20, 2020. ANI was voluntarily dismissed from the Bird action on March 15, 2021 and from the Hightower action on March 29, 2021. We dispute any liability in these MDL matters.

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 March 31, 2021.

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

Our contingent value rights ("CVRs"), which were granted coincident with our merger with BioSante and expire in June 2023, are considered contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of our projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs was immaterial as of March 31, 2021 and December 31, 2020. We also determined that the changes in such fair value were immaterial in the three months ended March 31, 2021 and 2020.

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 5). The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 5, the fair value of the interest rate swap was a $8.1 million liability at March 31, 2021.

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of March 31, 2021 and December 31, 2020, by level within the fair value hierarchy:

(in thousands) Description	Fair Value at March 31, 2021	Level 1	Level 2	Level 3
Liabilities				
Interest rate swaps	$ 8,122	$ —	$ 8,122	$ —
CVRs	$ —	$ —	$ —	$ —

Description	Fair Value at December 31, 2020	Level 1	Level 2	Level 3
Liabilities				
Interest rate swaps	$ 14,109	$ —	$ 14,109	$ —
CVRs	$ —	$ —	$ —	$ —

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

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

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

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

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

We measure our long-lived assets, including property, plant, and equipment, ROU assets, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three months ended March 31, 2021 and 2020.

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Acquired Non-Financial Assets Measured at Fair Value

In July 2020, we acquired an ANDA and certain related inventories from a private company for total consideration of $4.3 million. We also incurred and paid $0.1 million in transaction costs directly related to the acquisition. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $3.0 million as an acquired ANDA intangible asset and $1.4 million in inventory at fair value. 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. The ANDA is being 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 March 31, 2021 and therefore no impairment loss was recognized for the three months ended March 31, 2021.

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. Payments were made using cash on hand and through borrowings of $15.0 million under our Revolver. 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 are being 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 had significant remaining work required in order to be commercialized and the products did 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 will be accrued when they are both estimable and probable. The intangible assets will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to March 31, 2021 and therefore no impairment loss was recognized for the three months ended March 31, 2021.

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 were 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 continue in 2021 as we build raw materials, API and finished goods for the expected launch of this product. In the three months ended March 31, 2021 we incurred

immaterial charges for the purchase of materials. During the three months ended March 31, 2020, we incurred $4.6 million in charges for the purchase of materials. 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. SUBSEQUENT EVENT

On April 1, 2021, we acquired the NDAs for OXISTAT® Lotion, VEREGEN® Ointment, and Pandel® Cream and the ANDA for ApexiCon® E Cream from Sandoz Inc. for a purchase price of $18.5 million plus approximately $2.2 million for the purchase of API and finished goods inventory. Pandel® Cream will be transitioned later upon receiving the requisite approvals. The acquisition was funded by a $24.0 million borrowing under our Revolver, which was drawn on April 1, 2021.

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 Quarterly Report Form 10-Q quarterly, 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, 2020 (the "2020 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 2020 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 2020 Annual Report and this Quarterly Report on Form 10-Q.

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, oncology products (anti-cancer), 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.

Strategy

Our objective is to build a sustainable and growing biopharmaceutical company serving patients in need and creating long-term value for our investors. Our growth strategy is driven by the following key pillars:

Building a successful Cortrophin Gel franchise

We acquired the NDAs for Cortrophin gel and Cortrophin-Zinc in January 2016 and executed long-term supply agreements with a supplier of our primary raw material for corticotrophin active pharmaceutical ingredient ("API"), a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin gel fill/finish contract manufacturer. In April 2020, the FDA issued a Refusal to File ("RTF") letter for our Supplemental New Drug Application ("sNDA") for Cortrophin Gel. Currently, our efforts are focused on the preparation of a complete resubmission of sNDA. We have retained a prominent regulatory consulting firm to support our efforts and augment the capabilities of our restructured internal Cortrophin development team. Together, we have performed a comprehensive review of the original sNDA filing and prepared an internal gap assessment and execution plan to address these gaps. Throughout, we have remained engaged with the FDA and plan to re-submit our supplemental NDA in the second quarter of 2021.

We have invested in leadership and expertise in the areas of commercialization of rare disease therapies to develop a launch strategy and commercial plan for this product.

Strengthening our generics business with enhanced research and development capability and increased focus on niche opportunities

We have grown our generics business through a combination of market share gains on existing products and new product launches. We have also successfully acquired numerous ANDAs through asset acquisitions, including, most recently, the U.S. portfolio of 23 generic products, including 10 commercial products at the time of the acquisition, from Amerigen Pharmaceuticals, Ltd. We also focus on niche lower competition opportunities such as injectables and

Paragraph IV filings. Additionally, we will seek opportunities to enhance our research and development capabilities through strategic partnerships and acquisitions of businesses.

Maximizing the value from our established brands through innovative "go-to-market" ("GTM") strategies and continued programmatic acquisitions

We have acquired the NDAs for and market Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, InnoPran XL, OXISTAT Lotion, VEREGEN Ointment, and Pandel Cream. We are innovating in our GTM strategy through creative partnerships. In addition, we will continue to explore opportunities in acquiring new brands to grow our established brands portfolio.

Expansion of contract development and manufacturing organization ("CDMO") business by leveraging our unique manufacturing capabilities

We built a CDMO business through our sites in Baudette and grew it through the acquisition of WellSpring Pharma Services Inc. ("ANI Canada"). Our North America based manufacturing and unique capabilities in high-potency, hormonal, steroid, and oncolytic products can be leveraged to expand our CDMO business.

The pillars of our strategy will be enabled by an empowered, collaborative, and purposeful team with high performance-orientation.

Product Development Considerations

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

Pending Business Acquisition

On March 8, 2021, we entered into a definitive agreement to acquire Novitium Pharma LLC ("Novitium"), a privately held New Jersey-based pharmaceutical company with development, manufacturing, and commercial capabilities. The closing of the acquisition will occur (a) within five business days after all of the conditions to the closing set forth in the merger agreement are satisfied or waived or (b) at such other time, date and place as may be agreed by us and Novitium, subject to the completion of a minimum period. The closing is subject to the satisfaction of customary closing conditions and necessary regulatory approvals and we expect it to close in the second half of 2021.

Consideration will consist of a combination of (i) an estimated cash amount of $89.5 million, subject to various adjustments and expected to be financed by a $25.0 million private placement of preferred stock (the "PIPE Investment") and new debt financing, both described below, (ii) an aggregate of 2,466,667 shares of ANI common stock, and (iii) up to $46.5 million in contingent future earn-out payments.

We will finance the transaction with a new $340.0 million Senior Secured Credit Facility (the "New Facility"), consisting of a $300.0 million term loan and a $40.0 million revolving credit facility, the issuance of 2,466,667 shares of ANI common stock (approximately $74.0 million in value based on a $30 stock price), and a $25.0 million PIPE Investment by Ampersand 2020 Limited Partnership ("Ampersand"), an affiliate of Ampersand Capital Partners. The New Facility will be secured by substantially all the assets of ANI and its subsidiaries and used for the cash portion of the acquisition and to refinance ANI's existing senior credit facilities.

Concurrently with the execution of the definitive agreement, on March 8, 2021, we entered into an Equity Commitment and Investment Agreement with Ampersand (the "PIPE Investor"), pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock, for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million PIPE Investment.

The PIPE Investment and issuance of shares of ANI common stock are subject to approval by ANI shareholders.

For more information about the pending Novitium acquisition transaction, please see our Form 8-K filed on March 9, 2021.

NDA Acquisition

On April 1, 2021, we acquired the NDAs for OXISTAT® Lotion, VEREGEN® Ointment, and Pandel® Cream and the ANDA for ApexiCon® E Cream from Sandoz Inc. Pandel® Cream will be transitioned later upon receiving the requisite approvals. The acquisition was funded through borrowings under our pre-existing Revolver.

Cortrophin Gel Re-commercialization Update

In April 2020, the U.S. 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 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 in the second quarter of 2021.

In addition, 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 continue in 2021 as we build raw materials, API and finished goods for the expected launch of this product.

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 March 31, 2021 per IQVIA/IMS data, total market generic prescriptions in the United States declined when compared to the three months ended December 31, 2020 and March 31, 2020. Over these same periods, total market brand prescriptions were steady or increased. The decline in generic prescriptions, which generally make up 70-80% of our net revenues, was in part attributable to the COVID-19 pandemic, as subsequent waves impacted patient and customer behavior. The decline in generic prescriptions due to the COVID-19 pandemic negatively impacted our generic net revenues during the three months ended March 31, 2021. We have not experienced a significant impact to our manufacturing operations; however, we continue to see minor disruptions to our supply chain from the COVID-19 pandemic during 2021. Our manufacturing facilities in Baudette, Minnesota and Oakville, Ontario have remained open throughout the pandemic and have operated in accordance with local, state and national safety guidelines. The pandemic has not impacted our access to capital and has not significantly impacted our 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 continue to 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 level of success of continued actions taken to contain the pandemic or mitigate its impact, including the availability of vaccines, 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 has negatively impacted 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:

	Three Months Ended March 31,	
(in thousands)	2021	2020
Net revenues	$ 54,521	$ 49,774
Operating expenses		
Cost of sales (exclusive of depreciation and amortization)	19,985	21,804
Research and development	2,968	6,344
Selling, general, and administrative	17,587	13,683
Depreciation and amortization	10,898	11,183
Cortrophin pre-launch charges	38	4,602
Operating income/(loss)	3,045	(7,842)
Interest expense, net	(2,454)	(2,032)
Other (expense)/income, net	(515)	10
Income/(loss) before benefit for income taxes	76	(9,864)
Benefit for income taxes	10	2,853
Net income/(loss)	$ 86	$ (7,011)

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

	Three Months Ended March 31,	
	2021	2020
Net revenues	100.0 %	100.0 %
Operating expenses		
Cost of sales (exclusive of depreciation and amortization)	36.7 %	43.8 %
Research and development	5.4 %	12.7 %
Selling, general, and administrative	32.3 %	27.5 %
Depreciation and amortization	20.0 %	22.5 %
Cortrophin pre-launch charges	0.1 %	9.2 %
Operating income/(loss)	5.5 %	(15.7)%
Interest expense, net	(4.5)%	(4.1)%
Other (expense)/income, net	(0.9)%	— %
Income/(loss) before benefit for income taxes	0.1 %	(19.8)%
Benefit for income taxes	— %	5.7 %
Net income/(loss)	0.1 %	(14.1)%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2021 AND 2020

Net Revenues

(in thousands)	Three Months Ended March 31, 2021	2020	Change	% Change
Generic pharmaceutical products	$ 32,988	$ 37,495	$ (4,507)	(12.0)%
Branded pharmaceutical products	7,517	9,157	(1,640)	(17.9)%
Contract manufacturing	2,573	1,974	599	30.3 %
Royalty and other	11,443	1,148	10,295	896.8 %
Total net revenues	$ 54,521	$ 49,774	$ 4,747	9.5 %

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

Net revenues for the three months ended March 31, 2021 were $54.5 million compared to $49.8 million for the same period in 2020, an increase of $4.7 million, or 9.5%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $33.0 million during the three months ended March 31, 2021, a decrease of 12.0% compared to $37.5 million for the same period in 2020. Based upon an analysis of IQVIA/IMS data, during the three months ended March 31, 2021, the total market for generic prescriptions in the United States declined approximately 9% when compared to the three months ended March 31, 2020. We believe that this overall decline in prescription activity is principally due to the COVID-19 pandemic, and it negatively impacted the market for many of our generic pharmaceutical products. The decrease in net revenues was also due in part to lower average selling prices among generic products over the comparable periods and a shift in mix towards generic products with lower average selling prices. From a product perspective, the net decrease was driven by declines in sales of Ezetimibe Simvastatin, Methazolamide, Miglustat, and Diphenoxylate, somewhat tempered by increased revenues from sales of Paliperidone ER and Erythromycin Ethylsuccinate (“EES”).

- Net revenues for branded pharmaceutical products were $7.5 million during the three months ended March 31, 2021, a decrease of 17.9% compared to $9.2 million for the same period in 2020. The primary reasons for the decrease were lower unit sales of Inderal XL and InnoPran XL. These decreases were tempered by increased sales of Casodex and Inderal LA. The decreases were primarily due to a shift in mix towards branded products with lower average selling prices, which were tempered by an increase in average selling prices for certain products during the three months ended March 31, 2021.

- Contract manufacturing revenues were $2.6 million during the three months ended March 31, 2021, an increase of 30.3% compared to $2.0 million for the same period in 2020, due to an increased volume of orders from contract manufacturing customers in the period.

- Royalty and other revenues were $11.4 million during the three months ended March 31, 2021, an increase of $10.3 million from $1.1 million for the same period in 2020, primarily due to the recognition of the final royalty related to the Kite Pharma, Inc. license agreement pursuant to the Tripartite Agreement.

Cost of Sales (Excluding Depreciation and Amortization)

	Three Months Ended March 31,			
(in thousands)	2021	2020	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 19,985	$ 21,804	$ (1,819)	(8.3)%

Cost of sales consists of direct labor, including manufacturing and packaging, active and inactive pharmaceutical ingredients, freight costs, packaging components, and royalties related to profit-sharing arrangements. Cost of sales does not include depreciation and amortization expense, which is reported as a separate component of operating expenses on our unaudited interim condensed consolidated statements of operations.

For the three months ended March 31, 2021, cost of sales decreased to $20.0 million from $21.8 million for the same period in 2020, a decrease of $1.8 million, or 8.3%, primarily as a result of the non-recurrence of $2.7 million in cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the three months ended March 31, 2020. The decrease was tempered by a $0.5 million increase related to an increase in sales of products subject to profit sharing arrangements. Cost of sales as a percentage of net revenues decreased to 36.7% during the three months ended March 31, 2021, from 38.4% during same period in 2020 (exclusive of $2.7 million cost of sales representing the excess of fair value over cost for inventory acquired in the Amerigen acquisition and subsequently sold during the comparable 2020 period), primarily as a result of royalty revenue of $11.2 million with no associated cost of sales during the three months ended March 31, 2021. This impact was significantly offset by the impact from increased sales of generic products subject to profit sharing arrangements, a decrease in average selling prices of generic products, and a shift in mix towards generic and brand products with lower average selling prices during the three months ended March 31, 2021.

During the three months ended March 31, 2021, we purchased approximately 11% of our inventory from one supplier. As of March 31, 2021, our amount payable to this supplier was immaterial. During the three months ended March 31, 2020, we purchased 13% of our inventory from one supplier.

Other Operating Expenses

	Three Months Ended March 31,			
(in thousands)	2021	2020	Change	% Change
Research and development	$ 2,968	$ 6,344	$ (3,376)	(53.2)%
Selling, general, and administrative	17,587	13,683	3,904	28.5 %
Depreciation and amortization	10,898	11,183	(285)	(2.5)%
Cortrophin pre-launch charges	38	4,602	(4,564)	(99.2)%
Total other operating expenses	$ 31,491	$ 35,812	$ (4,321)	(12.1)%

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 March 31, 2021, other operating expenses decreased to $31.5 million from $35.8 million for the same period in 2020, a decrease of $4.3 million, or 12.1%, primarily as a result of the following factors:

- Research and development expenses decreased from $6.3 million to $3.0 million, a decrease of 53.2%, primarily due to the non-recurrence of the $3.8 million in-process research and development expense from the Amerigen acquisition in the first quarter 2020.

- Selling, general, and administrative expenses increased from $13.7 million to $17.6 million, an increase of $3.9 million, or 28.5%, primarily due to $2.9 million of transaction expenses related to the pending Novitium acquisition incurred in the three months ended March 31, 2021, increased pharmacovigilance compliance costs in continued support of the expansion of our commercial portfolio, and increased legal, insurance, and other professional fees.

- Depreciation and amortization decreased from $11.2 million to $10.9 million, a decrease of 2.5%, primarily due to assets that became fully amortized in 2020.

- 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 Quarterly Report on Form 10-Q quarterly, we recognized Cortrophin pre-launch charges of $38 thousand in the three months ended March 31, 2021. We recognized Cortrophin pre-launch charges of $4.6 million in the three months ended March 31, 2020.

Other Expense, net

(in thousands)	Three Months Ended March 31, 2021	2020	Change	% Change
Interest expense, net	$ (2,454)	$ (2,032)	$ (422)	20.8 %
Other (expense)/income, net	(515)	10	(525)	NM [1]
Total other expense, net	$ (2,969)	$ (2,022)	$ (947)	46.8 %

[1] Not Meaningful

For the three months ended March 31, 2021, we recognized other expense of $3.0 million versus other expense of $2.0 million for the same period in 2020, an increase of $0.9 million. Interest expense, net for the three months ended March 31, 2021 and 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”). For the three months ended March 31, 2021 and 2020, there was $26 thousand and $25 thousand of interest capitalized into construction in progress, respectively.

Benefit for Income Taxes

(in thousands)	Three Months Ended March 31, 2021	2020	Change	% Change
Benefit for income taxes	$ 10	$ 2,853	$ (2,843)	(99.6)%

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

For the three months ended March 31, 2021, we recognized an income tax benefit of less than $0.1 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 27.7% to pre-tax consolidated income of $0.1 million reported during the period, reduced by the net effects of certain discrete items occurring in 2021

which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended March 31, 2021.

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

LIQUIDITY AND CAPITAL RESOURCES

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

(in thousands)	March 31, 2021	December 31, 2020
Cash and cash equivalents	$ 25,073	$ 7,864
Accounts receivable, net	91,876	95,793
Inventories, net	59,927	60,803
Prepaid expenses and other current assets	5,922	5,861
Total current assets	$ 182,798	$ 170,321
Current debt, net of deferred financing costs	$ 14,438	$ 13,243
Accounts payable	13,769	11,261
Accrued expenses and other	2,381	2,456
Accrued royalties	5,310	6,407
Accrued compensation and related expenses	5,533	6,231
Current income taxes payable, net	3,659	3,906
Accrued government rebates	8,672	7,826
Returned goods reserve	28,944	27,155
Deferred revenue	62	80
Total current liabilities	$ 82,768	$ 78,565

On March 31, 2021, we had $25.1 million in unrestricted cash and cash equivalents. On December 31, 2020, we had $7.9 million in unrestricted cash and cash equivalents. We generated $20.7 million of cash from operations in the three months ended March 31, 2021.

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 March 31, 2021, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months.

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

	Three Months Ended March 31,	
(in thousands)	2021	2020
Operating Activities	$ 20,668	$ 1,710
Investing Activities	$ (737)	$ (57,546)
Financing Activities	$ (2,725)	$ 13,891

Net Cash Provided by Operations

Net cash provided by operating activities was $20.7 million for the three months ended March 31, 2021, compared to $1.7 million provided by operating activities during the same period in 2020, an increase of $19.0 million. The increase

was due to changes in working capital, including trade accounts receivable, and a reduction in net income/(loss) in the three months ended March 31, 2021 against the comparable 2020 period.

Net Cash Used in Investing Activities

Net cash used in investing activities for the three months ended March 31, 2021 was $0.7 million, principally due to $0.7 million of capital expenditures during the period. Net cash used in investing activities for the three months ended March 31, 2020 was $57.5 million, principally due to the January 2020 acquisition of 23 generic products and inventory and materials from Amerigen Pharmaceuticals, Ltd. for $55.5 million and $1.5 million of capital expenditures during the period.

Net Cash (Used In)/Provided by Financing Activities

Net cash used in financing activities was $2.7 million for the three months ended March 31, 2021, principally due to $2.3 million of maturity payments on the Term Loan and DDTL and $0.3 million of treasury stock purchased in relation to restricted stock vests. Net cash provided by financing activities was $13.9 million for the three months ended March 31, 2020, principally due to $15.0 million in borrowings on the Revolver and $0.3 million of proceeds from stock option exercises, partially offset by $0.9 million of payment on the Term Loan, and $0.5 million of treasury stock purchased in relation to restricted stock vests.

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 Part II, 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, 2020. 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 Part I, 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, 2020.

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 Quarterly Report on Form 10-Q and is incorporated herein by reference.

OFF-BALANCE SHEET ARRANGEMENTS

As of March 31, 2021, 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 March 31, 2021, 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. As of March 31, 2021, $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 1-month 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 March 31, 2021, we had a $184.6 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 March 31, 2021 by less than $1,000.

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 three months ended March 31, 2021.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure

controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of March 31, 2021. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2021 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 Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

Item 1A. Risk Factors

In addition to the other information set forth in this report, please carefully consider the factors described in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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 related to the pending Novitium acquisition 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.

Risks Relating to the Acquisition

If we fail to obtain stockholder approval as required by the Nasdaq Listing Rules for our proposed issuance of shares in connection with the pending acquisition of Novitium Pharma LLC ("Novitium"), we will be unable to consummate the Novitium acquisition.

Nasdaq Listing Rule 5635(a) requires stockholder approval when, in connection with an acquisition of stock or assets of another company, we issue a number of shares of our common stock that equals or exceeds 20% of the total number of shares of our common stock or voting power outstanding before the transaction. We are proposing to issue (a) 2,466,667 shares of common stock to certain members of Novitium in connection with the Novitium acquisition, and (b) 25,000 shares of Series A Convertible Preferred Stock to Ampersand 2020 Limited Partnership in connection with its related $25.0 million PIPE Investment, subject to stockholder approval under Nasdaq Listing Rule 5635(a) (the "Share Issuance Proposal").If we fail to obtain the necessary stockholder approvals, we will be unable to consummate the acquisition and the PIPE Investment.

Cash expenditures associated with the acquisition of Novitium may create significant liquidity and cash flow risks for us.

We expect to incur significant transaction costs and some integration costs in connection with the acquisition of Novitium. While we have assumed that this level of expense will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the acquisition and integration expenses. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. To the extent these acquisition and integration expenses are higher than anticipated, we may experience liquidity or cash flow issues.

We will incur substantial debt in order to satisfy our obligations in connection with the acquisition of Novitium.

In order to finance a portion of the purchase price of the Acquisition and expenses associated therewith, we will enter into the New Facility, consisting of a $300.0 million term loan and a $40.0 million revolving credit facility. The New Facility will also be used to refinance ANI's existing senior credit facilities and be secured by substantially all the assets of ANI and its subsidiaries. In order to service the debt we incur under this facility, we will require a significant amount of cash. Our ability to make scheduled payments of principal and interest depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional debt or equity financing on terms that may not be favorable to us or available to us at all. Our ability to refinance any such debt will depend on the capital markets and our financial condition at that time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default under our current or future indebtedness. Any event of default or inability to otherwise satisfy our obligations could have a material adverse effect on our future operating results and financial condition.

If our stockholders approve the Share Issuance Proposal, our stockholders will experience dilution as a result of the issuance of shares of our common stock in connection with the acquisition of Novitium and the issuance of our Series A Convertible Preferred Stock in the PIPE Investment.

As of April 15, 2021, we had 12,729,072 shares of common stock outstanding. The amount of dilution our stockholders may experience is dependent on the number of shares of our common stock actually issued or issuable in connection with the acquisition of Novitium and the related PIPE Investment. If the Share Issuance Proposal is approved by our stockholders, the maximum number of shares of our common stock that may be issued or issuable in connection with the acquisition of Novitium and the PIPE Investment is 3,203,478 shares, consisting of (a) 2,466,667 shares to be issued to Novitium Members, and (b) up to 736,811 shares issuable to Ampersand on conversion of the Series A Convertible Preferred Stock to be issued to Ampersand in the PIPE Investment, depending on the price of our common stock over a specified period of time. If our stockholders approve the Share Issuance Proposal, and we issue all 3,203,478 shares authorized to be issued pursuant to the Share Issuance Proposal, the total number of shares of our issued and outstanding common stock will increase by approximately 25% and such newly issued shares will represent approximately 25% of our outstanding voting power prior to the transactions. Accordingly, if we issue all 3,203,478 shares authorized by the Share Issuance Proposal, the percentage ownership and voting power held by our existing stockholders will be reduced and our stockholders will experience significant dilution.

The market price of our common stock may decline as a result of the acquisition of Novitium and the related PIPE Investment or the issuance of shares of our common stock in connection with the acquisition of Novitium or the PIPE Investment.

We are unable to predict the potential effects of issuing shares of our common stock in connection with the acquisition of Novitium and the PIPE Investment on the trading activity and market price of our common stock. If the Share Issuance Proposal is approved by our stockholders, and we issue all 3,203,478 shares authorized to be issued pursuant to the Share Issuance Proposal, the number of shares of our common stock available for public trading would increase substantially once the shares approved to be issued under the Share Issuance Proposal become available for public trading. Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales might occur, could have a material adverse effect on the price of our common stock.

Failure to complete the acquisition of Novitium could materially and adversely affect our results of operations and the market price of our common stock.

Our consummation of the acquisition of Novitium is subject to many contingences, including the approval of the Share Issuance Proposal by our stockholders. We cannot assure you that we will be able to successfully

consummate the pending acquisition as currently contemplated or at all. Risks related to the failure of the pending acquisition to be consummated include, but are not limited to, the following:

- we would not realize any of the potential benefits of the transaction, which could have a negative effect on our stock price;
- we may remain liable for significant transaction costs, including certain expense reimbursement obligations, if the merger agreement relating to the Novitium acquisition is terminated as a result of our inability to obtain approval of the Share Issuance Proposal prior to the termination date under the merger agreement;
- we may experience negative reactions from customers, clients, business partners, lenders, and employees;
- the trading price of our common stock may decline to the extent that the current market price for our stock reflects a market assumption that the Novitium acquisition will be completed; and
- the attention of our management may be diverted to the Acquisition rather than to our own operations and the pursuit of other opportunities that could have been beneficial to us.

The occurrence of any of these events individually or in combination could materially and adversely affect our results of operations and the market price of our common stock.

If the acquisition of Novitium is consummated, the combined company may not perform as we or the market expects, which could have an adverse effect on the price of our common stock.

Even if the Novitium acquisition is consummated, the combined company may not perform as we or the market expects. Risks associated with the combined company following the Acquisition include:

- integrating businesses is a difficult, expensive, and time-consuming process, and the failure to successfully integrate our businesses with the business of Novitium in the expected time frame would adversely affect our financial condition and results of operation;
- the acquisition of Novitium will materially increase the size of our operations, and if we are not able to effectively manage our expanded operations, our common stock price may be adversely affected;
- it is possible that our key employees or key employees of Novitium might decide not to remain with us after the Novitium acquisition is completed, and the loss of such personnel could have a material adverse effect on the financial condition, results of operations, and growth prospects of the combined company;
- the success of the combined company will also depend upon relationships with third parties and Novitium's or our pre-existing customers, which relationships may be affected by customer preferences or public attitudes about the Acquisition. Any adverse changes in these relationships could adversely affect the combined company's business, financial condition, and results of operations; and
- if government agencies or regulatory bodies impose requirements, limitations, costs, divestitures or restrictions on the consummation of the Acquisition, the combined company's ability to realize the anticipated benefits of the Acquisition may be impaired.

The obligations and liabilities of Novitium, some of which may be unanticipated or unknown, may be greater than we have anticipated, which may diminish the value of Novitium to us.

Novitium's obligations and liabilities, some of which may not have been disclosed to us or may not be reflected or reserved for in Novitium's historical financial statements, may be greater than we have anticipated. The obligations and liabilities of Novitium could have a material adverse effect on Novitium's business or Novitium's value to us or on our business, financial condition, or results of operations. Under the merger agreement relating to the Novitium acquisition, we have only limited indemnification with respect to obligations or liabilities of Novitium, whether known or unknown. In addition, even in cases where we are able to obtain indemnification, we may discover liabilities greater than the contractual limits or the financial resources of the indemnifying party. In the event that we are responsible for liabilities substantially in excess of any amounts recovered through rights to indemnification or alternative remedies that might be available to us, or any applicable insurance, we could suffer

severe consequences that would substantially reduce our earnings and cash flows or otherwise materially and adversely affect our business, financial condition, or results of operations.

If the acquisition of Novitium is consummated, the global nature of Novitium's operations (including those of its Indian subsidiary Novitium Labs Private Limited) will subject us to political and economic risks that could adversely affect our business, results of operations, or financial condition.

The risks presented by global operations include:

- limitations on ownership or participation in local enterprises;
- price controls, exchange controls, and limitations on repatriation of earnings;
- transportation delays and interruptions;
- the application of additional legal, regulatory and taxation regimes to our operations;
- political, social, and economic instability and disruptions in applicable regions;
- acts of terrorism;
- government embargoes or foreign trade restrictions;
- imposition of duties and tariffs and other trade barriers;
- import and export controls;
- labor unrest and current and changing regulatory environments;
- fluctuations in foreign current exchange and interest rates;
- difficulties in staffing and managing multi-national operations;
- limitations on our ability to enforce legal rights and remedies; and
- the severity and duration of the COVID-19 pandemic and its impacts where we operate globally.

If we are unable to successfully manage these and other risks associated with managing the expansion of our business to the jurisdictions in which Novitium operates, including India, the risks could have a material adverse effect on our business, results of operations, or financial condition.

If the acquisition of Novitium is consummated, our expanded international operations would increase our exposure to potential liability under anti-corruption, trade protection, tax, and other laws and regulations.

The Foreign Corrupt Practices Act and other anti-corruption laws and regulations ("Anti-Corruption Laws") prohibit corrupt payments by our employees, vendors, or agents. From time to time, we receive inquiries from authorities in the U.S. and elsewhere about our business activities outside of the U.S. and our compliance with Anti-Corruption Laws. While we devote substantial resources to our global compliance programs and have implemented policies, training, and internal controls designed to reduce the risk of corrupt payments, our employees, vendors or agents may violate our policies and if the pending acquisition of Novitium is consummated, our expanded international operations would significantly increase our exposure to potential liability. Our failure to comply with Anti-Corruption Laws could result in significant fines and penalties, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business, and damage to our reputation. Operations outside of the U.S. may be affected by changes in trade production laws, policies, and measures, and other regulatory requirements affecting trade and investment.

If the acquisition of Novitium is consummated, we would also become subject to Indian and other foreign tax regulations. Such regulations may not be clear, not consistently applied and subject to sudden change, particularly with regard to international transfer pricing. Our earnings could be reduced by the uncertain and changing nature of such tax regulations.

Fluctuations in foreign currency exchange and interest rates could adversely affect our results of operations.

Our business is generally conducted in U.S. dollars. However, the costs of operating in India will be subject to the effects of currency exchange fluctuations of the Indian rupee against the U.S. dollar. When the U.S. dollar weakens against the Indian rupee, our operating costs in such currency will increase. This currency risk can be minimized by matching the timing of working capital borrowing needs against operating cost requirements in India. However, fluctuations in the value of the Indian rupee will create greater uncertainty in our revenues and could have a significant adverse effect on our operating results.

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

Sales of Unregistered Securities

On February 15, 2021, the Company granted non-qualified stock options to purchase 27,006 shares of Company common stock to Ori Gutwerg, Senior Vice President, Generics, and 33,758 shares of Company common stock to Christopher Mutz, Chief Commercial Officer & Head of Rare Diseases, as inducements to enter into employment with the Company. The options will vest with respect to 25% of the shares underlying the options on each one-year anniversary of the executive's employment start date, subject to continued service to the Company through each relevant vesting date and will accelerate upon a change in control transaction or upon certain terminations of the executives' employment. The options have 10-year terms and exercise prices of $31.49 per share. The options were granted under Section 4(a)(2) of the Securities Act.

Issuer Purchases of Equity Securities

The following table provides information about common stock repurchased by us during the first quarter of fiscal 2021:

(in thousands, except per share data)

Period	Total Number of Shares Purchased[1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Program	Maximum Number (or approximate dollar value) of Shares (or units) that May Yet be Purchased Under the Plans or Programs
January 1 - January 31, 2021	—	$ —	—	$ —
February 1 - February 28, 2021	—	$ —	—	$ —
March 1 - March 31, 2021	3,851	$ —	—	$ —
Total	3,851	$ —	—	

[1] Shares purchased during the period were transferred to the Company from employees in satisfaction of minimum tax withholding obligations associated with the vesting of restricted stock awards during the period.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

INDEX TO EXHIBITS

Exhibit No.	Description
2.1	Agreement and Plan of Merger dated March 8, 2021 by and among ANI Pharmaceuticals, Inc., Nile Merger Sub LLC, Novitium Pharma LLC ("Novitium"), Esjay LLC, Chali Properties, LLC, Chad Gassert, Muthusamy Shanmugam and Thorappadi Vijayaraj, and Shareholder Representative Services LLC, as the representative of the Novitium members (incorporated by reference to Exhibit 2.1 to the Current Report on Form 8-K filed on March 9, 2021, file no. 001-31812).
10.1	Support Agreement, dated March 8, 2021 among ANI Pharmaceuticals, Inc., Nile Merger Sub LLC, Novitium Pharma LLC, Esjay Pharma, LLC, Chali Properties, LLC, Chad Gassert, Muthusamy Shanmugam and Thorappadi Vijayaraj, Novitium members party thereto and Shareholder Representative Services LLC, as representative of Novitium members (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 9, 2021, file no. 001-31812).
10.2	Equity Commitment and Investment Agreement dated March 8, 2021 by and between ANI Pharmaceuticals, Inc. and Ampersand 2020 Limited Partnership (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on March 9, 2021, file no. 001-31812).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2021 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: May 7, 2021

By: /s/ Nikhil Lalwani
Nikhil Lalwani
President and
Chief Executive Officer
(principal executive officer)

Date: May 7, 2021

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

Exhibit 31.1

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

I, Nikhil Lalwani, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ANI Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: May 7, 2021

/s/ Nikhil Lalwani
Nikhil Lalwani
President and
Chief Executive Officer
(principal executive officer)

Exhibit 31.2

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

I, Stephen P. Carey, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of ANI Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a–15(e) and 15d–15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a–15(f) and 15d–15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

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

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

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

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

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

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

Date: May 7, 2021

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended March 31, 2021 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

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

Dated: May 7, 2021

/s/ Nikhil Lalwani
Nikhil Lalwani
President and Chief Executive Officer
(principal executive officer)

Dated: May 7, 2021

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