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, 2023

☐ **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 May 1, 2023 there were 17,963,188 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, 2023

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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 Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such statements include, but are not limited to, 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, abbreviated 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, selling and marketing strategies and associated costs to support the sales of Purified Cortrophin® Gel (Repository Corticotropin Injection USP) ("Cortrophin Gel"), 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, 2022 and the following factors:

- risks that we may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason;
- delays or failure in obtaining and maintaining 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;
- whether we experience disruptions to our operations resulting from the closure of our Oakville, Ontario manufacturing plant, including the transition of certain products manufactured there to our other facilities which has been completed, or have difficulties finding a buyer for the plant and property; and

- general business and economic conditions, such as inflationary pressures, geopolitical conditions including the conflict between Russia and the Ukraine, 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, 2022, 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.

The Company may use its investor relations website as a distribution channel of material company information. Financial and other important information regarding the Company is routinely posted on and accessible through the Company's investor relations website. We encourage investors and others interested in our Company to review the information we post on our investor relations website in addition to filings with the SEC, press releases, public conference calls and webcasts. Information contained on the Company's website is not included as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

NOTE REGARDING TRADEMARKS

Apexicon®, Cortenema®, Purified Cortrophin® Gel, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, Vancocin®, and Veregen® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries. Cortrophin-Zinc™ is a trademark owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries pending registration. 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. Oxistat® is the property of Fougera Pharmaceuticals Inc. and licensed to ANI Pharmaceuticals, Inc. for U.S. sales of Oxistat® Lotion. Pandel® is property of Taisho Pharmaceutical Co, Ltd. and licensed to ANI Pharmaceuticals for U.S. sales of Pandel® creme.

Part I — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

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

	March 31, 2023	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	$ 67,757	$ 48,228
Current restricted cash	—	5,006
Accounts receivable, net of $112,950 and $161,052 of adjustments for chargebacks and other allowances at March 31, 2023 and December 31, 2022, respectively	174,713	165,438
Inventories	103,654	105,355
Prepaid income taxes	3,735	3,827
Assets held for sale	8,020	8,020
Prepaid expenses and other current assets	6,874	8,387
Total Current Assets	364,753	344,261
Non-current Assets		
Property and equipment	70,553	75,958
Accumulated depreciation	(27,278)	(32,712)
Property and equipment, net	43,275	43,246
Deferred tax assets, net of deferred tax liabilities and valuation allowance	80,956	81,363
Intangible assets, net	238,791	251,635
Goodwill	28,221	28,221
Derivatives and other non-current assets	9,228	11,361
Total Assets	$ 765,224	$ 760,087
Liabilities, Mezzanine Equity, and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	32,687	29,305
Accrued royalties	8,957	9,307
Accrued compensation and related expenses	13,051	10,312
Accrued government rebates	8,607	10,872
Returned goods reserve	34,108	33,399
Current contingent consideration	22,761	—
Accrued expenses and other	4,804	5,394
Total Current Liabilities	125,825	99,439
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	285,457	285,669
Non-current contingent consideration	13,258	35,058
Other non-current liabilities	1,202	1,381
Total Liabilities	$ 425,742	$ 421,547
Commitments and Contingencies (Note 12)		
Mezzanine Equity		
Convertible Preferred Stock, Series A, $0.0001 par value, 1,666,667 shares authorized; 25,000 shares issued and outstanding at March 31, 2023 and December 31, 2022	24,850	24,850
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 18,225,921 shares issued and 17,992,397 outstanding at March 31, 2023; 17,643,497 shares issued and 17,494,466 shares outstanding at December 31, 2022	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	—	—
Treasury stock, 233,524 shares of common stock, at cost, at March 31, 2023 and 149,031 shares of common stock, at cost, at December 31, 2022	(8,643)	(5,094)
Additional paid-in capital	408,395	403,901
Accumulated deficit	(96,252)	(97,286)
Accumulated other comprehensive income, net of tax	11,131	12,168
Total Stockholders' Equity	314,632	313,690
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 765,224	$ 760,087

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, 2023	2022
Net Revenues	$ 106,786	$ 64,477
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	37,708	34,271
Research and development	5,924	5,274
Selling, general, and administrative	36,468	28,817
Depreciation and amortization	14,700	14,557
Contingent consideration fair value adjustment	961	753
Restructuring activities	1,130	—
Total Operating Expenses	96,891	83,672
Operating Income (Loss)	9,895	(19,195)
Other Expense, net		
Interest expense, net	(7,696)	(6,613)
Other expense, net	(34)	(89)
Income (Loss) Before Income Tax (Provision) Benefit	2,165	(25,897)
Income tax (provision) benefit	(726)	5,767
Net Income (Loss)	$ 1,439	$ (20,130)
Dividends on Series A Convertible Preferred Stock	(406)	(405)
Net Income (Loss) Available to Common Shareholders	$ 1,033	$ (20,535)
Basic and Diluted Income (Loss) Per Share:		
Basic Income (Loss) Per Share	$ 0.06	$ (1.27)
Diluted Income (Loss) Per Share	$ 0.06	$ (1.27)
Basic Weighted-Average Shares Outstanding	16,392	16,137
Diluted Weighted-Average Shares Outstanding	16,531	16,137

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, 2023	2022
Net Income (Loss)	$ 1,439	$ (20,130)
Other comprehensive (loss) income, net of tax:		
Foreign currency translation adjustment	107	—
(Loss) gain on interest rate swap	(1,143)	5,767
Total other comprehensive (loss) income, net of tax	(1,036)	5,767
Total comprehensive income (loss), net of tax	$ 403	$ (14,363)

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Mezzanine Equity and Stockholders' Equity
For the Three Months Ended March 31, 2023 and 2022
(in thousands)
(unaudited)

	Mezzanine Equity Series A Convertible Preferred Stock	Mezzanine Equity Series A Convertible Preferred Stock Shares	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	Accumulated Deficit	Total Mezzanine Equity and Stockholders' Equity
Balance, December 31, 2021	$ 24,850	25	$ 1	16,913	$ —	$ 387,844	83	$ (3,135)	$ (3,055)	$ (47,765)	$ 358,740
Stock-based Compensation Expense	—	—	—	—	—	3,237	—	—	—	—	3,237
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	40	(1,118)	—	—	(1,118)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	—	—	3	—	—	—	—	3
Issuance of Restricted Stock Awards	—	—	—	461	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(405)	(405)
Other Comprehensive Income	—	—	—	—	—	—	—	—	5,767	—	5,767
Net Loss	—	—	—	—	—	—	—	—	—	(20,130)	(20,130)
Balance, March 31, 2022	$ 24,850	25	$ 1	17,374	$ —	$ 391,084	123	$ (4,253)	$ 2,712	$ (68,300)	$ 346,094
Balance, December 31, 2022	$ 24,850	25	$ 1	17,644	$ —	$ 403,900	149	$ (5,094)	$ 12,167	$ (97,285)	$ 338,539
Stock-based Compensation Expense	—	—	—	—	—	4,338	—	—	—	—	4,338
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	85	(3,549)	—	—	(3,549)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	5	—	157	—	—	—	—	157
Issuance of Restricted Stock Awards	—	—	—	520	—	—	—	—	—	—	—
Issuance of Performance Stock Units	—	—	—	85	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(28)	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(406)	(406)
Other Comprehensive Loss	—	—	—	—	—	—	—	—	(1,036)	—	(1,036)
Net Income	—	—	—	—	—	—	—	—	—	1,439	1,439
Balance, March 31, 2023	$ 24,850	25	$ 1	18,226	$ —	$ 408,395	234	$ (8,643)	$ 11,131	$ (96,252)	$ 339,482

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, 2023	2022
Cash Flows From Operating Activities		
Net income (loss)	$ 1,439	$ (20,130)
Adjustments to reconcile net income (loss) to net cash and cash equivalents (used in) provided by operating activities:		
Stock-based compensation	4,338	3,237
Deferred taxes	773	(7,464)
Depreciation and amortization	14,700	14,557
Non-cash interest	987	982
Contingent consideration fair value adjustment	961	753
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable, net	(9,275)	(3,099)
Inventories	1,701	(1,462)
Prepaid expenses and other current assets	1,513	(137)
Accounts payable	3,105	(1,009)
Accrued royalties	(350)	(1,227)
Current income taxes payable, net	92	1,685
Accrued government rebates	(2,265)	(935)
Returned goods reserve	713	(248)
Accrued expenses, accrued compensation, and other	2,992	(4,445)
Net Cash and Cash Equivalents Provided by (Used in) Operating Activities	21,424	(18,942)
Cash Flows From Investing Activities		
Acquisition of product rights, IPR&D, and other related assets	(4)	(229)
Acquisition of property and equipment, net	(2,349)	(1,949)
Net Cash and Cash Equivalents Used in Investing Activities	(2,353)	(2,178)
Cash Flows From Financing Activities		
Payments on borrowings under credit agreements	(750)	(750)
Series A convertible preferred stock dividends paid	(406)	(405)
Proceeds from stock option exercises and ESPP purchases	157	3
Treasury stock purchases for restricted stock vests	(3,549)	(1,118)
Net Cash and Cash Equivalents Used in Financing Activities	(4,548)	(2,270)
Net Change in Cash, Cash Equivalents, and Restricted Cash	14,523	(23,390)
Cash, cash equivalents, and restricted cash, beginning of period	53,234	105,301
Cash, cash equivalents, and restricted cash, end of period	$ 67,757	$ 81,911
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	$ 48,228	$ 100,300
Restricted cash	5,006	5,001
Cash, cash equivalents, and restricted cash, beginning of period	$ 53,234	$ 105,301
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	$ 67,757	$ 76,911
Restricted cash	—	5,000
Cash, cash equivalents, and restricted cash, end of period	$ 67,757	$ 81,911
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 4,293	$ 5,637
Cash paid for income taxes	$ 2,741	$ —
Supplemental non-cash investing and financing activities:		
Property and equipment purchased and included in accounts payable	$ 729	$ 253

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

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. Our team is focused on delivering growth by building a successful Cortrophin Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our manufacturing capabilities. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, and one is located in East Windsor, New Jersey, 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. On June 2, 2022, we announced that we intended to cease operations at our Oakville, Ontario, Canada manufacturing plant by the end of the first quarter 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. As of March 31, 2023, we have completed the transition of the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites. We are seeking to find potential buyers for the Oakville site.

Our operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, and possible fluctuations in financial results. The accompanying unaudited interim condensed consolidated financial statements have been prepared assuming that we will continue as a going concern, which contemplates continuity of operations, realization of assets, and satisfaction of liabilities in the ordinary course of business. The propriety of using the going-concern basis is dependent upon, among other things, the achievement of future profitable operations, the ability to generate sufficient cash from operations, and potential other funding sources, including cash on hand, to meet our obligations as they become due. We believe the going-concern basis is appropriate for the accompanying unaudited interim condensed consolidated financial statements based on our current operating plan and business strategy for the 12 months following the issuance of this report.

On November 19, 2021, the Company, as borrower, entered into a credit agreement (the "Credit Agreement") with Truist Bank and other lenders, which provides for credit facilities consisting of (i) a senior secured term loan facility in an aggregate principal amount of $300.0 million (the "Term Facility") and (ii) a senior secured revolving credit facility in an aggregate commitment amount of $40.0 million, which may be used for revolving credit loans, swingline loans and letters of credit (the "Revolving Facility," and together with the Term Facility, the "Credit Facility"). We believe that our financial resources, consisting of current working capital, anticipated future operating revenue and corresponding collections from customers, and our Credit Facility, under which $40.0 million remains available for borrowing as of March 31, 2023, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations, comprehensive income (loss), and cash flows. The consolidated balance sheet at December 31, 2022 has been derived from audited financial statements as of that date. The unaudited interim condensed consolidated statements 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 U.S. Securities and Exchange Commission (the "SEC"). 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, 2022 (the "2022 Form 10-K").

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 ceased operations at a subsidiary in Oakville, Ontario, Canada as of March 31, 2023. We currently have a subsidiary located in India. The Canada-based subsidiary conducted its transactions in U.S. dollars and Canadian dollars, but its functional currency was the U.S. dollar. The Indian-based subsidiary generally conducts its transactions in Indian rupees, which is also its functional currency. The results of any non-U.S. dollar transactions and balances 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 and the translation impact of local currencies to U.S. dollars was immaterial for the three months ended March 31, 2023 and 2022. 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 condensed consolidated financial statements, estimates are used for, but not limited to, variable consideration determined based on accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, income tax provision or benefit, deferred taxes and valuation allowance, stock-based compensation, revenue recognition, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, including contingent consideration in acquisitions, fair value of long-lived assets, determination of right-of-use assets and lease liabilities, allowance for credit losses, 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.

Restructuring Activities

We define restructuring activities to include costs directly associated with exit or disposal activities. Such costs include cash employee contractual severance and other termination benefits, one-time employee termination severance and benefits, contract termination charges, impairment and acceleration of depreciation associated with long-lived assets, and other exit or disposal costs. In general, we record involuntary employee- related exit and disposal costs when there is a substantive plan for employee severance and related payments are probable and estimable. For one-time termination benefits, including those with a service requirement, expense is recorded when the employees are entitled to receive such benefits and the amount can be reasonably estimated. Expense related to one-time termination benefits with a service requirement is recorded over time, as the service is completed. Contract termination fees and penalties, and other exit and disposal costs are generally recorded as incurred. Restructuring activities are recognized as an operating expense in our consolidated statements of operations.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In December 2022, the Financial Accounting Standards Board issued ASU 2022-06, which extended the sunset date of the reference rate reform in ASU 848 from December 31, 2022, to December 31, 2024. We have not adopted the guidance and are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

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

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, rare disease, and established brand pharmaceutical products, royalties, and other pharmaceutical services. 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 (in thousands)	**March 31, 2023**	**March 31, 2022**
Sales of generic pharmaceutical products	$ 63,713	$ 49,107
Sales of established brand pharmaceutical products, royalties, and other pharmaceutical services	26,743	14,078
Sales of rare disease pharmaceutical products	16,330	1,292
Total net revenues	$ 106,786	$ 64,477

	Three Months Ended	
Timing of Revenue Recognition (in thousands)	**March 31, 2023**	**March 31, 2022**
Performance obligations transferred at a point in time	$ 106,411	$ 63,911
Performance obligations transferred over time	375	566
Total	$ 106,786	$ 64,477

In the three months ended March 31, 2023 and 2022, we did not incur, and therefore did not defer, any material incremental costs to obtain or fulfill contracts. We recognized an increase of $5.1 million to net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2023, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We recognized a decrease of $1.3 million to net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2022, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We provide technical transfer services to customers, for which services are transferred over time. As of March 31, 2023 and December 31, 2022, we did not have any contract assets related to revenue recognized based on percentage of completion but not yet billed. Our deferred revenue balance as of March 31, 2023, December 31, 2022, and December 31, 2021 was immaterial. For the three months ended March 31, 2023, we did not recognize deferred revenue. For the three months ended March 31, 2022, we recognized less than $0.1 million of revenue that was included in deferred revenue as of December 31, 2021. Deferred revenue is included in accrued expenses and other in the unaudited interim condensed consolidated balance sheets.

Variable consideration

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.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the three months ended March 31, 2023 and 2022, 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, 2021	$ 94,066	$ 5,492	$ 35,831	$ 13,100	$ 4,642
Accruals/Adjustments	152,566	2,810	6,942	9,785	5,060
Credits Taken Against Reserve	(142,991)	(3,745)	(7,219)	(10,915)	(4,539)
Balance at March 31, 2022 (1)	$ 103,641	$ 4,557	$ 35,554	$ 11,970	$ 5,163
Balance at December 31, 2022	$ 148,562	$ 10,872	$ 33,399	$ 9,442	$ 6,488
Accruals/Adjustments	146,113	4,461	4,640	12,026	5,483
Credits Taken Against Reserve	(193,859)	(6,726)	(3,931)	(12,018)	(6,538)
Balance at March 31, 2023 (1)	$ 100,816	$ 8,607	$ 34,108	$ 9,450	$ 5,433

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

Credit Concentration

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

During the three months ended March 31, 2023 and 2022, we had three customers that accounted for 10% or more of net revenues. As of March 31, 2023, accounts receivable from these customers totaled 83% of accounts receivable, net.

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

	Three Months Ended	
	March 31, 2023	March 31, 2022
Customer 1	33 %	31 %
Customer 2	15 %	19 %
Customer 3	14 %	14 %

3. RESTRUCTURING

On June 2, 2022, we announced that we intended to cease operations at our Oakville, Ontario, Canada manufacturing plant by the first quarter of 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium in November 2021. We have completed the transition of the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites. We are seeking to find potential buyers for the Oakville site, though there can be no assurance as to when or if that will occur or the amount of any net proceeds that may be received.

For the three months ended March 31, 2023, restructuring activities resulted in expenses of $1.1 million. This included $0.2 million of severance and other employee benefit costs and $0.7 million of accelerated depreciation costs and $0.2 million for other miscellaneous costs. As of March 31, 2023, $1.2 million of the severance and other employee benefits are unpaid and accrued. These costs are recorded as restructuring activities, an operating item, in the accompanying unaudited interim condensed consolidated statements of operations and are part of the Generics, Established Brands, and Other segment. Certain of the severance and other employee benefit costs contain a service requirement, and as such, were accrued over time as they were earned.

In conjunction with the exit of our Canadian facility, we have determined that the land and building at our Oakville, Ontario, Canada plant will be sold together and meet the criteria to be classified as held for sale as of March 31, 2023. The land and building have a net carrying value of $8.0 million, which is presented as assets held for sale on the accompanying unaudited interim condensed consolidated balance sheets. These assets are part of the Generics, Established Brands, and Other segment.

4. INDEBTEDNESS

Credit Facility

On November 19, 2021, the Company completed its previously announced acquisition (the “Acquisition”) of Novitium pursuant to the terms of the Agreement and Plan of Merger, dated as of March 8, 2021 (the “Merger Agreement”), by and among the Company, Novitium, Nile Merger Sub LLC, a Delaware limited liability company, and certain other parties, with Novitium becoming a wholly owned subsidiary of ANI.

On November 19, 2021, the Company, as borrower, entered into a credit agreement (the “Credit Agreement”) with Truist Bank and other lenders, which provides for credit facilities consisting of (i) a senior secured term loan facility in an aggregate principal amount of $300.0 million (the “Term Facility”) and (ii) a senior secured revolving credit facility in an aggregate commitment amount of $40.0 million, which may be used for revolving credit loans, swingline loans and letters of credit (the “Revolving Facility,” and together with the Term Facility, the “Credit Facility”).

The Term Facility proceeds were used to finance the cash portion of the consideration under the Merger Agreement, repay our existing credit facility, and pay fees, costs and expenses incurred in connection with the merger. Proceeds from the Revolving Facility are expected to be used, subject to certain limitations, for working capital and other general corporate purposes.

The Term Facility matures in November 2027 and the Revolving Facility in November 2026. Each permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the LIBOR Rate (as defined in the Credit Agreement) in the case of LIBOR loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the LIBOR Rate (as defined in the Credit Agreement) in the case of loans under the Revolving Facility. The interest rate under the Term Facility was 9.14% at March 31, 2023. The Credit Facility has a subjective acceleration clause in case of a material adverse effect. The Term Facility includes a repayment schedule, pursuant to which $750 thousand of the loan will be paid in quarterly installments during the twelve months ended March 31, 2024. As of March 31, 2023, $3.0 million of the loan is recorded as current borrowings in the unaudited interim condensed consolidated balance sheets. As of March 31, 2023, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

We incurred $14.0 million in deferred debt issuance costs associated with the Credit Facility. Costs allocated to the Term Facility are classified as a direct reduction to the current and non-current portion of the borrowings, depending on their nature. Costs allocated to the Revolving Facility are classified as other current and other non-current assets, depending on their nature. We incur a commitment fee of 0.5% per annum on any unused portion of the Revolving Facility.

In connection with entry into the Credit Facility, on November 19, 2021, we terminated our existing Amended and Restated Credit Agreement, dated as of December 27, 2018 (the "Prior Credit Agreement"), among the Company, as borrower, and Citizens Bank with other lenders.

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 Facility as of March 31, 2023 and December 31, 2022 are:

	Current	
(in thousands)	March 31, 2023	December 31, 2022
Current borrowing on debt	$ 3,000	$ 3,000
Deferred financing costs	(2,150)	(2,150)
Current debt, net of deferred financing costs	$ 850	$ 850

	Non-Current	
(in thousands)	March 31, 2023	December 31, 2022
Non-current borrowing on debt	$ 293,250	$ 294,000
Deferred financing costs	(7,793)	(8,331)
Non-current debt, net of deferred financing costs and current component	$ 285,457	$ 285,669

As of March 31, 2023, we had a $296.3 million balance on the Term Facility. Of the $0.8 million of unamortized deferred debt issuance costs allocated to the Revolving Facility, $0.6 million is included in other non-current assets in the unaudited interim condensed consolidated balance sheets, and $0.2 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets.

The contractual maturity of our Term Facility is as follows for the period ending:

(in thousands)	Term Facility
2023 (remainder of the year)	$ 2,250
2024	3,000
2025	3,000
2026	3,000
2027	285,000
Total	$ 296,250

The following table sets forth the components of total interest expense related to the Term Facility during the three months ended March 31, 2023 and 2022, as recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three months ended March 31, 2023 and 2022:

	Three Months Ended	
(in thousands)	March 31, 2023	March 31, 2022
Contractual coupon	$ 7,350	$ 6,058
Amortization of finance fees	591	591
Capitalized interest	(21)	(30)
	$ 7,920	$ 6,619

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 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 term facilities related to our Prior Credit Agreement. The interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Agreement with Truist Bank, the interest rate swap with a notional value of $168.6 million at origin on November 21, 2021 was novated and Truist Bank is the new counterparty. The swap is used to manage changes in LIBOR-based interest rates underlying a portion of the borrowing under the Term Facility. The interest rate swap provides an effective fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of March 31, 2023, the notional amount of the interest rate swap was $147.5 million and decreases quarterly by approximately $4.0 million until December 2023, after which it remains static until maturity in December 2026. As of March 31, 2023, the fair value of the interest rate swap asset recorded in other non-current assets in the unaudited interim condensed consolidated balance sheets was $6.9 million. As of March 31, 2023, $11.1 million was recorded in accumulated other comprehensive income, net of tax in the unaudited interim condensed consolidated balance sheets.

During the three months ended March 31, 2023, the change in fair value of the interest rate swaps was a loss of $2.2 million. During the three months ended March 31, 2023, losses on the interest rate swap of $1.1 million were recorded in accumulated other comprehensive (loss) income, net of tax in our unaudited interim condensed consolidated statements of comprehensive (loss) income. Differences between the hedged LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Facility based on the LIBOR rate. In the three months ended March 31, 2023, $0.5 million of interest expense was recognized in relation to the interest rate swaps. Included in this amount for the three months ended March 31, 2023 and 2022 are reclassifications out of accumulated other comprehensive income (loss) of $0.7 million and $0.7 million and during the three months ended March 31, 2023 and 2022 are $0.7 million and $0.7 million in expense related to terminated and de-designated cash flow hedges.

6. EARNINGS (LOSS) PER SHARE

Basic earnings (loss) per share is computed by dividing net income (loss) available to common stockholders 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 stockholders 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"), common stock options, and performance stock units, using the more dilutive of the treasury stock or the two-class method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share.

Our unvested restricted shares and Series A convertible preferred stock 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 the common shares assumed converted from the preferred shares and excludes the impact of those shares from the denominator.

Earnings (loss) per share for the three months ended March 31, 2023 and 2022 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,	
	2023	2022	2023	2022
Net income (loss) available to common shareholders	$ 1,033	$ (20,535)	$ 1,033	$ (20,535)
Earnings allocated to participating securities	(113)	—	(113)	—
Net income (loss) available to common shareholders	$ 920	$ (20,535)	$ 920	$ (20,535)
Basic Weighted-Average Shares Outstanding	16,392	16,137	16,392	16,137
Dilutive effect of common stock options, ESPP, and performance stock units			139	—
Diluted Weighted-Average Shares Outstanding			16,531	16,137
Income (loss) per share	$ 0.06	$ (1.27)	$ 0.06	$ (1.27)

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, was 2.6 million and 2.5 million for the three months ended March 31, 2023 and 2022, respectively. For the three months ended March 31, 2022, 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, 2023	December 31, 2022
Raw materials	$ 69,533	$ 67,726
Packaging materials	7,782	7,720
Work-in-progress	1,540	1,889
Finished goods	24,799	28,020
Inventories	$ 103,654	$ 105,355

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, 2023, no single vendor represented more than 10% of inventory purchases. During the three months ended March 31, 2022, one vendor represented 16% of inventory purchases.

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. From our acquisition of Novitium in 2021, we recorded goodwill of $24.6 million. We have two operating segments, which are the same as our two reporting units, Generics, Established Brands, and Other reporting unit and the Rare Disease reporting unit. All of the goodwill is recorded in our Generics, Established Brands, and Other reporting unit.

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, 2023. No impairment losses were recognized during the three months ended March 31, 2023 and 2022.

Intangible Assets

The components of definite-lived intangible assets and indefinite-lived intangible assets other than goodwill are as follows:

	March 31, 2023		December 31, 2022		Remaining Weighted Average Amortization Period[(1)]
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	
Definite-Lived Intangible Assets:					
Acquired ANDAs intangible assets	$ 195,862	$ (81,630)	$ 195,862	$ (75,606)	5.6 years
NDAs and product rights	242,372	(167,856)	242,372	(162,188)	3.7 years
Marketing and distribution rights	17,157	(13,550)	17,157	(13,309)	3.8 years
Non-compete agreement	624	(624)	624	(602)	— years
Customer relationships	24,900	(5,039)	24,900	(4,150)	5.6 years
Total Definite-Lived Intangible Assets	480,915	(268,699)	480,915	(255,855)	4.9 years
Indefinite-Lived Intangible Assets:					

In process research and development	26,575	—	26,575	—	Indefinite
Total Intangible Assets, net	$ 507,490	$ (268,699)	$ 507,490	$ (255,855)	

(1) Weighted average amortization period as of March 31, 2023.

The definite-lived Abbreviated New Drug Applications ("ANDAs"), New Drug Applications ("NDAs") and product rights, marketing and distribution rights, customer relationships, and non-compete agreement are stated at cost, net of amortization, and generally amortized over their remaining estimated useful lives, ranging from seven to 10 years, based on the straight-line method. In the case of certain NDAs and product rights assets, we use an accelerated amortization method to better match the anticipated economic benefits expected to be provided. Our indefinite-lived intangible assets other than goodwill include in-process research and development ("IPR&D") projects. IPR&D intangible assets represent the fair value of technology acquired in a business combination for which the technology projects are incomplete but have substance. When an IPR&D project is completed (generally upon receipt of regulatory approval), the asset is then accounted for as a definite-lived intangible asset.

Amortization expense was $12.8 million and $12.5 million for the three months ended March 31, 2023 and 2022, respectively.

We test for impairment of definite-lived intangible assets and indefinite-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 in the three months ended March 31, 2023. No such triggering events were identified during the three months ended March 31, 2023 and 2022 and therefore no impairment loss was recognized in the three months ended March 31, 2023 and 2022.

Expected future amortization expense for definite-lived intangible assets is as follows:

(in thousands)	
2023 (remainder of the year)	$ 38,464
2024	48,331
2025	45,096
2026	31,778
2027	22,866
2028 and thereafter	25,681
Total	$ 212,216

9. MEZZANINE AND STOCKHOLDERS' EQUITY

Stockholders' Equity

Authorized shares

We are authorized to issue up to 33.3 million shares of common stock with a par value of $0.0001 per share, 0.8 million shares of class C special stock with a par value of $0.0001 per share, and 1.7 million shares of undesignated preferred stock with a par value of $0.0001 per share at March 31, 2023.

There were 18.2 million and 18.0 million shares of common stock issued and outstanding as of March 31, 2023, respectively, and 17.6 million and 17.5 million shares of common stock issued and outstanding as of December 31, 2022, respectively.

There were 11 thousand shares of class C special stock issued and outstanding as of March 31, 2023 and December 31, 2022. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock is exchangeable, at the option of the holder, for one share of our common stock, at an exchange price of $90.00 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of our assets if we were to liquidate,

dissolve, or wind-up the Company. The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption, or sinking fund rights.

Mezzanine Equity

PIPE Shares

Concurrently with the execution of the Merger Agreement, and as financing for a portion of the acquisition, on March 8, 2021, we entered into an Equity Commitment and Investment Agreement with Ampersand 2020 Limited Partnership (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 (the "PIPE Shares"), for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million. This agreement closed and the 25,000 PIPE Shares were sold and issued for $25.0 million on November 19, 2021. The PIPE Shares are classified as mezzanine equity because the shares are mandatorily redeemable for cash upon a change in control, an event that is not solely in our control.

The PIPE Shares accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and will also participate, on a pro-rata basis, in any dividends that may be declared with respect to our common stock. The PIPE Shares are convertible into our common shares at the conversion price of $41.47 (i) beginning two years after their issuance date, at the election of ANI (in which case the PIPE Investor must convert all of the PIPE Shares), if the volume-weighted average price of our common stock for any 20 trading days out of 30 consecutive trading days exceeds 170% of the conversion price, and (ii) at any time after issuance, at the election of the PIPE Investor. As of March 31, 2023, the PIPE shares are currently convertible into a maximum of 602,901 shares of our common stock.

In case of a liquidation event, the holder of the PIPE Shares will be entitled to receive, in preference to holders of our common stock, the greater of (i) the PIPE Shares' purchase price plus any accrued and unpaid dividends thereon and (ii) the amount the holder of the PIPE Shares would have received in the liquidation event if it had converted its PIPE Shares into our common stock. The PIPE Shares will have voting rights, voting as one series with our common stock, on as-converted basis, and will have separate voting rights on any (i) amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the "Certificate") that adversely amends and relates solely to the terms of the PIPE Shares and (ii) issuance of additional Series A convertible preferred stock. In case of a change of control of ANI, the PIPE Shares will be redeemed at the greater of (i) the PIPE Shares' purchase price plus any accrued and unpaid dividends thereon and (ii) the change of control transaction consideration that the holder of the PIPE Shares would have received if it had converted into our common stock.

There were 25,000 shares of Series A convertible preferred stock outstanding as of March 31, 2023.

10. 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, 2023, 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.

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,	
	2023	2022
Cost of sales	$ 12	$ 10
Research and development	7	7
Selling, general, and administrative	72	21

$	91	$	38

Stock Incentive Plan

Equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan (the "2022 Plan"), which was approved by our stockholders at the 2022 Annual Meeting of Stockholders (the "Annual Meeting") held on April 27, 2022. Prior to this approval, we had been granting equity-based incentive awards under our Sixth Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"), which was renamed and was amended and restated to become the 2022 Plan. This amendment and restatement, among other things, increased the number of shares reserved for issuance thereunder by 1,150,000 shares. As of March 31, 2023, 0.4 million shares of our common stock were available for issuance under the 2022 Plan.

Stock Options: Outstanding stock options granted to employees and consultants generally vest over a period of four years and have 10-year contractual terms. Outstanding stock options granted to non-employee directors generally vest over a period of one to four years and have 10-year contractual terms. Upon exercise of an option, we issue new shares of our common stock or issue shares from treasury stock.

From time to time, we may grant stock options to employees through an inducement grant outside of our 2022 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 stockholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

Restricted Stock Awards: Restricted stock awards ("RSAs") granted to employees generally vest over a period of four years. RSAs granted to non-officer directors generally vest over a period of one year.

Shares of our common stock delivered to employees and directors will be unrestricted upon vesting. During the vesting period, the recipient of the RSAs has full voting rights as a stockholder and would receive dividends, if declared, even though the restricted stock remains subject to transfer restrictions and will generally be forfeited upon termination of the officer prior to vesting. The fair value of each RSA is based on the market value of our stock on the date of grant.

Performance-Based Restricted Stock Units: Awards may also be issued in the form of Performance Stock Units ("PSUs"). PSUs represent the right to receive an amount of cash, a number of shares of our common stock or a combination of both, contingent upon the achievement of specified performance objectives during a specified performance period. PSUs granted to date have vested over a three-year performance period. On February 28, 2023, as part of our equity compensation program, we granted PSUs to certain executives. Of these PSUs, 50% were market performance-based restricted stock units ("MPRSUs"), vesting of which is contingent upon the Company meeting certain total shareholder return ("TSR") levels as compared to a select peer group over the over three years starting January 1, 2023. The MPRSUs are also subject to the recipient's continued employment or service through December 31, 2025. The MPRSUs cliff vest at the end of the three-year period and have a maximum potential to vest at 200% (85,099 shares) based on TSR performance. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized straight-line over the vesting term. The estimated grant date fair value per share of the MPRSUs was $68.65 and was calculated using a Monte Carlo simulation model. These MPRSUs are included at 100% of the estimate number of shares at the end of the three-year performance period and are reflected under "Granted" in the table below.

The other 50% of the PSUs were performance based restricted stock units ("PRSUs"), vesting of which is contingent upon the Company meeting certain adjusted non-GAAP year-on-year EBITDA growth rates over the over three years starting January 1, 2023. The PRSUs are also subject to the recipient's continued employment or service through December 31, 2025. The PRSUs cliff vest at the end of the three-year period and have a maximum potential to vest at 200% (85,099 shares) based on adjusted non-GAAP year-on-year EBITDA growth rates. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares

on the date of grant and is recognized straight-line over the vesting term. We analyzed progress on the performance goals to assess the likelihood of achievement. The estimated grant date fair value per share of the PRSUs was $41.84 based on the closing price of the stock on the date of grant. These PRSUs are included at 100% of the estimated number of shares at the end of the three-year performance period and are reflected under "Granted" in the table below.

The following table summarizes stock-based compensation expense incurred under the 2022 Plan and Inducement Grants included in our accompanying unaudited interim condensed consolidated statements of operations:

(in thousands)	Three Months Ended March 31,	
	2023	2022
Cost of sales	$ 139	$ 135
Research and development	200	246
Selling, general, and administrative	3,908	2,818
	$ 4,247	$ 3,199

A summary of stock option, RSA, and PSU activity under the 2022 Plan and Inducement Grants during the three months ended March 31, 2023 and 2022 is presented below:

(in thousands)	Options	Inducement Grants	PSUs	RSAs
Outstanding at December 31, 2021	747	241	—	707
Granted	27	—	—	460
Options Exercised/RSAs Vested	—	—	—	(161) (1)
Forfeited	—	—	—	—
Expired	—	—	—	—
Outstanding at March 31, 2022	774	241	—	1,006
Outstanding at December 31, 2022	907	241	—	1,141
Granted	3	—	85	520
Options Exercised/RSAs Vested	(5)	—	—	(235) (2)
Forfeited	(16)	—	—	(28)
Expired	—	—	—	—
Outstanding at March 31, 2023	889	241	85	1,398

(1) Includes 40 thousand shares purchased from employees to cover employee income taxes related to income earned upon vesting of restricted stock. The shares purchased are held in treasury and the $1.1 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

(2) Includes 85 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 $3.5 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

11. INCOME TAXES

We use the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to

reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted.

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of March 31, 2023, we had provided a valuation allowance against consolidated net deferred tax assets of $0.4 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any such amounts accrued as of March 31, 2023 and December 31, 2022. We are subject to taxation in various U.S. jurisdictions, Canada, and India and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

For interim periods, we recognize an income tax provision (benefit) based on our estimated annual effective tax rate, calculated on a worldwide consolidated basis, expected for the entire year. 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, are recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discrete items result in variances to the effective tax rate from period to period. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. Our estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discrete items occur. Global Intangible Low-Taxed Income (“GILTI”), as defined in the Tax Cuts and Jobs Act of 2017, generated from our Canadian and Indian 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, 2023, we recognized an income tax provision of $0.7 million. The income tax provision resulted from applying an estimated annual worldwide effective tax provision rate of 34.9% to pre-tax consolidated income of $2.2 million reported during the period. There were no material discrete items occurring during the three months ended March 31, 2023.

For the three months ended March 31, 2022, we recognized an income tax benefit of $5.8 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 22.3% to pre-tax consolidated loss of $25.9 million reported during the period. There were no material discrete items occurring during the three months ended March 31, 2022.

We expect that recent tax law changes contained in Inflation Reduction Act and the Creating Helpful Incentives to Produce Semiconductors and Science Act of 2022 (“CHIPS Act”) will not have a material impact on the provision for income taxes.

12. COMMITMENTS AND CONTINGENCIES

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 Food and Drug Administration (“FDA”), the Centers for Medicare and Medicaid Services (“CMS”), the Central Drugs Standard Control Organization (“CDSCO”), The Narcotics Control Bureau (“NCB”), and India’s Ministry of Health and Family Welfare (“MoHFW”). The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our

products. The DEA, Health Canada, and NCB 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 ANDAs. During the three months ended March 31, 2023 and 2022, net revenues for these products totaled $3.7 million and $4.0 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, 2023 and 2022 were $0.6 million.

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. Due to the inherent unpredictability of legal matters, including litigation, governmental and regulatory matters, particularly where the damages sought are substantial or indeterminate or when the proceedings, investigations or inquiries are in the early stages, 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 in our 2022 Form 10-K, 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 many 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. 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 condensed 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 ("Arbor"), in the United States District Court for the District of Minnesota. The complaint alleged 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 sought a trial by jury and monetary damages (inclusive of actual and consequential damages, treble damages, disgorgement of ANI profits, and legal fees) of an unspecified amount. Discovery in this action closed on March 31, 2019 and trial was scheduled to commence on August 25, 2021. On August 3, 2021, the Company entered into a Settlement Agreement with Arbor to resolve all claims related to Civil Action 17-4910, Arbor Pharmaceuticals, LLC v. ANI Pharmaceuticals, Inc., which was pending trial in the United States District Court for the District of Minnesota. Under the terms of the agreement, ANI paid Arbor $8.4 million and Arbor dismissed the action with prejudice. Neither party admitted wrongdoing in reaching this settlement. The Company paid the settlement from cash on the balance sheet.

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 were substantively identical. The plaintiffs in these actions alleged 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. Under the terms of the 2020 Asset Purchase Agreement, Amerigen agreed to indemnify ANI for certain liabilities relating to Bystolic, including liabilities that arose prior to closing of the asset purchase. The complaints alleged that the 2013 patent litigation settlement agreement between Forest and Amerigen violated federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs alleged they paid higher prices as a result of delayed generic competition. Plaintiffs sought damages, trebled or otherwise multiplied under applicable law, injunctive relief, litigation costs and attorneys' fees. The complaints did not specify the amount of damages sought from the Company or other defendants and the Company. at this stage of the litigation cannot reasonably estimate the potential damages that the plaintiffs will seek. The cases were 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. On January 24, 2022, the court dismissed all claims brought by the plaintiffs without prejudice. The court granted the plaintiffs until February 22, 2022 to file amended complaints, which were filed in federal court in the Southern District of New York, on that date. The newly amended complaints contained substantially similar claims. On April 19, 2022, the Company and other defendants filed motions to dismiss the newly amended complaints. On May 23, 2022, the plaintiffs filed oppositions to the motions to dismiss and, on June 24, 2022, the Company and other defendants filed replies to those oppositions. On February 21, 2023, the Company and the defendants' motions to dismiss all actions were granted with prejudice. Plaintiffs have filed notices of appeal in the Second Circuit and the matter is pending. ANI continues to dispute any liability in this matter.

On March 24, 2021, Azurity Pharmaceuticals, Inc. ("Azurity") filed a complaint in the United States District Court for the District of Minnesota against ANI, asserting that ANI's vancomycin hydrochloride oral solution drug product infringes U.S. Patent No. 10,688,046. The complaint sought injunctive relief, damages, including lost profits and/or royalty, treble damages, and attorneys' fee and costs. On February 15, 2022, the Company entered into a settlement agreement with Azurity to resolve all claims related to this action. Under the terms of the agreement, Azurity granted ANI a non-exclusive, non-transferable, non-sublicensable, royalty-bearing license under its patents to sell ANI product in the United States and dismissed the action with prejudice. In exchange, ANI paid Azurity $1.9 million of royalties from past sales and will pay Azurity a royalty equal to 20% of gross margin of sales of the ANI product for a contractually defined term.

On April 1, 2021, United Therapeutics Corp. and Supernus Pharmaceuticals, Inc. (“UTC/Supernus”) filed a complaint in the United States District Court for the District of Delaware against ANI, asserting that ANI’s proposed Treprostinil extended release drug product, which is subject to ANI’s Abbreviated New Drug Application No. 215667, infringes U.S. Patent Nos. 7,417,070, 7,544,713, 8,252,839, 8,349,892, 8,410,169, 8,747,897, 9,050,311, 9,278,901, 9,393,203, 9,422,223, 9,593,066 and 9,604,901 (“the Asserted Patents”). The complaint seeks injunctive relief, attorneys' fee and costs. ANI filed its answer and counterclaims on May 28, 2021, denying UTC/Supernus’ allegations and seeking declaratory judgment that ANI has not infringed any valid and enforceable claim of the Asserted Patents, that the Asserted Patents are invalid, and an award of attorneys’ fees and costs. On May 26, 2022, the parties’ respective claims and counterclaims were dismissed pursuant to a confidential settlement agreement.

On October 3, 2022, Azurity filed a complaint in the United States District Court for the District of New Jersey against Novitium, asserting that Novitium’s manufacture, use, sale, importation and/or offer to sell Bionpharma Inc.’s (“Bionpharma”) enalapril maleate oral solution drug product (the “Product”) infringes U.S. Patents Nos. 11,040,023 and 11,141,405 (the “Novitium Action”). The complaint seeks injunctive relief, and an award of Azurity’s costs and expenses. On October 12, 2022, Bionpharma filed a motion in United States District Court for the District of New Jersey to intervene on Novitium’s behalf in the litigation and on October 14, 2022, Novitium and Bionpharma filed a joint motion to transfer venue to the District of Delaware, which motion to transfer was granted on January 20, 2023. On March 27, 2023, the transferred Novitium Action (assigned Delaware Civil Action No. 23-163-MSG) was consolidated with the Delaware Third Wave Suits against Bionpharma (Civil Action Nos. 21-1286-MSG, 21-1455-MSG), which include Azurity’s infringement claims against Bionpharma involving the same patents asserted in the Novitium Action, as well as Bionpharma’s antitrust claims against Azurity. Trial is scheduled for June 17, 2024 and the parties are currently proceeding through fact discovery. Bionpharma has agreed to indemnify Novitium under the terms of its manufacturing and supply agreement for any damages, costs, and expenses relating to actual or alleged infringement of intellectual property rights or sale of the Product by Bionpharma. ANI and Novitium dispute any liability in this matter.

Ranitidine Related Litigation

State of New Mexico Litigation. In July 2020, ANI and Novitium were served with a complaint brought in the First Judicial Court, County of Santa Fe, State of New Mexico 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 ANI and Novitium. 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. Novitium is named as a Defendant in the amended complaint. According to Novitium’s records, Novitium did not ship any ranitidine product to New Mexico, and received no funds from any state funded health care plan or Medicaid. The Defendants filed a motion to dismiss the claims asserted in the New Mexico litigation based primarily on preemption. The motion was denied in August 2021. A motion for reconsideration was denied on September 22, 2022. The case is currently in discovery. ANI and Novitium dispute any liability in this matter.

Federal Court Personal Injury Litigation. In June 2020, ANI was 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 the existing MDL concerning ranitidine-containing drugs pending in the Southern District of Florida, *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 ANI and Novitium as defendants. ANI 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 MPIC was filed on February 8, 2021, which did not name ANI but did name Novitium. By opinion dated July 8, 2021, the district court dismissed all claims against the generic manufacturer defendants with prejudice on preemption grounds. That decision is on appeal to the Eleventh Circuit Court of Appeals. In addition, by opinion and order dated December 6, 2022, the district court granted the brand manufacturer defendants' *Daubert* motion to exclude the plaintiffs' expert testimony on general causation for the "designated cancers" that the plaintiffs' leadership team claimed to be caused by ranitidine. The district court also granted the brand manufacturer defendants' motion for summary judgment because the plaintiffs had failed to produce admissible primary evidence of general causation. The plaintiffs have appealed to the Eleventh Circuit Court of Appeals.

ANI and Novitium were named in other individual personal injury complaints filed in the MDL in which plaintiffs allege that they developed cancer after taking prescription and over the counter medication containing ranitidine. ANI was 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). ANI informed counsel for the plaintiffs that ANI 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. ANI's 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, from the *Bird* action on March 15, 2021, and from the *Hightower* action on March 29, 2021.

Prior to the district court's July 8, 2021 preemption decision, Novitium had been named in 158 short form complaints filed by claimants in the MDL. Those complaints were effectively dismissed with prejudice with the MPIC on July 8, 2021. Counsel for the plaintiffs have been notified that Novitium did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited period of time, from December 2018 until September 2019. Novitium's product was voluntarily recalled in October 2019. Out of the 158 short form complaints, approximately 114 plaintiffs either were diagnosed with cancer before Novitium began manufacturing the product, only took over the counter ranitidine, or took ranitidine before Novitium began manufacturing it. Two of those 114 plaintiffs dismissed Novitium from their short form complaints. In light of the Court's dismissal of all claims with prejudice, Novitium has not pursued dismissal of the short form complaints against it at this time. Following the district court's *Daubert* decision, plaintiffs began filing additional short form complaints in the MDL. Novitium currently is named as a defendant in more than 700 short form complaints.

ANI and Novitium dispute any liability in these matters.

State Court Personal Injury Litigation

Illinois. On February 3, 2022, a complaint was filed in Cook County, Illinois, naming Novitium as a defendant. The complaint incorrectly identifies Novitium as a "repackager." The case is styled *Ross v. Boehringer Ingelheim Pharmaceuticals, Inc., et. al*. The complaint asserts claims of strict liability/failure to warn, strict liability/design defect, negligent failure to warn, negligent product design, general negligence, negligent misrepresentation, breach of express and implied warranties, and unjust enrichment. The plaintiff alleges that he was diagnosed with prostate cancer in 2017, before Novitium began selling generic ranitidine products, and that he took over the counter ranitidine that he purchased at Walgreens from 2008 to 2019. At this point, the allegations show that the plaintiff's alleged cancer injury could not have come from a Novitium product. The generic manufacturer defendants filed a motion to dismiss on preemption grounds. That motion is pending.

In August 2022, the Keller Postman law firm commenced six multi-plaintiff actions in Illinois state court naming generic ranitidine manufacturers, including ANI and/or Novitium, as defendants. Those cases are: (1) *Jodee Gillespie v. Walgreen Co., et. al.*, Circuit Court of the Third Judicial Circuit, Madison County, Illinois, Case No. 2022LA001007 (naming both Novitium and ANI); (2) *John Jackson v. Walgreen Co., et. al.*, Circuit Court of the Third Judicial Circuit, Madison County, Illinois, Case No. 2022LA001012 (naming Novitium); (3) *Ayesha Salahuddin v. Walgreen Co., et. al.,* Circuit Court of the Twentieth Judicial Circuit, St. Clair County, Illinois, Case No. 22LA0709 (naming Novitium); (4) *Lashanda McGruder v. Walgreen Co., et. al.,* Circuit Court of the Third Judicial Circuit, Madison County, Illinois, Case No. 22LA0710 (naming both Novitium and ANI); (5) *Richard Devriendt v. Walgreen Co., et. al.,* Circuit Court of Cook County, Illinois, Case No. 2022L007429 (naming Novitium); (6) *Anthony Stigger v. Walgreen Co., et. al.,* Circuit Court of Cook County, Illinois, Case No. 2022L007396 (naming both Novitium and ANI). The complaints allege causes of action for failure to warn, design defect, general negligence, loss of consortium and wrongful death. Pursuant to an Order of the Illinois Supreme Court dated October 25, 2022, the pending ranitidine personal injury actions in Illinois have been consolidated in Cook County for coordinated pre-trial proceedings. Those pre-trial proceedings are pending in the Circuit Court of Cook County. On January 12, 2023, Judge Trevino directed the plaintiffs to dismiss the multi-plaintiff actions and refile each individual plaintiff action under a separate case number. At a status conference held on February 16, 2023, the court required that the plaintiffs re-file within 60 days. The court also authorized use of a master complaint. Plaintiffs filed a master long-form complaint on March 9, 2023 naming Novitium as a defendant. ANI is not named as a defendant. The Keller Postman firm has confirmed that its clients are no longer pursuing claims against ANI. The counts in the master complaint include strict liability for failure to warn/design defects, general negligence, negligent misrepresentation, negligent storage and transport, apparent manufacturer liability, common law fraud, unjust enrichment, civil conspiracy, and breach of express and implied warranties. The complaint further alleges violations of the Illinois Consumer Fraud Act. Pursuant to the court's standing order, the generic defendants filed a motion to dismiss pursuant to IL 2-615 (failure to state a claim on the face of the complaint) on April 13, 2023, claiming preemption by federal law. In addition, the generic defendants argue that Plaintiffs failed to meet Illinois' fact pleading standards, as the complaint fails to specifically allege the misconduct of any generic defendant.

California. In August and September 2022, the Keller Postman law firm commenced seven multi-plaintiff actions in California state court, Alameda County, naming generic ranitidine manufacturers, including ANI and/or Novitium, as defendants. Those cases are: (1) *Carlos Ascencio v. ANI Pharmaceuticals, et. al.,* Superior Court of California, County of Alameda, Case. No. 22CV016230 (naming both Novitium and ANI); (2) *Andre Lebeau v. Actavis Mid Atlantic, LLC et. al.,* Superior Court of California, County of Alameda, Case No. 22CV016448 (naming Novitium); (3) *Roque Torres v. ANI Pharmaceuticals, Inc., et. al.,* Superior Court of California, County of Alameda, Case No. 22CV016338 (naming both Novitium and ANI); (4) *Deborah Hinds v. ANI Pharmaceuticals, Inc., et. al.,* Superior Court of California, County of Alameda, Case No. 22CV016123 (naming both Novitium and ANI); (5) *Mark Cruz v. ANI Pharmaceuticals, Inc., et. al.,* Superior Court of California, County of Alameda, Case No. 22CV016338 (naming both Novitium and ANI); (6) *Bent Olsen v. ANI Pharmaceuticals, Inc., et. al.,* Superior Court of California, County of Alameda, Case No. 22CV016402 (naming both Novitium and ANI); (7) *John Norman v. Actavis Mid Atlantic, LLC, et. al.,* Superior Court of California, County of Alameda, Case No. 22CV018334 (naming Novitium). The complaints allege causes of action for failure to warn, design defect, general negligence, loss of consortium and wrongful death. By stipulation and order dated December 28, 2022, the cases were transferred to an existing civil case coordination docket for pretrial proceedings (JCCP) pending in Alameda County. By order dated January 19, 2023, the court ordered that counsel for the plaintiffs must dismiss the individual plaintiffs (other than the first-named plaintiff) from each of the multi-plaintiff complaints and that each of the dismissed plaintiffs must re-file their claims in a single plaintiff complaint. As of April 25, 2023, ANI and Novitium had not yet been served with any of these single-plaintiff complaints. As of April 25, 2023, the Company is aware of three single-plaintiff cases in which Novitium is named as a defendant: *David Duncan v. GSK Holdings*, No. T23-507; *Charmaine Sili v. GSK Holdings*, No. T23-355; and *Charles Crippen v. Boehringer,* No. T23-349.

Pennsylvania. In September 2022, two single-plaintiff complaints were filed in Pennsylvania state court, Philadelphia County, naming Novitium as a defendant: (1) *William Titus v. Glaxo SmithKline LLC, et. al.*, Court of Common Pleas, Philadelphia County, Pennsylvania, Case No. 220902548; and (2) *Jodi Woodard v. Ajanta Pharma USA, Inc., et. al.*, Court of Common Pleas, Philadelphia County, Pennsylvania, Case No. 220902329. These complaints allege causes of action for negligence, failure to warn, negligent storage and transportation, breach of express and implied warranties, negligent misrepresentation, and fraud. On February 16, 2023, the Pennsylvania plaintiffs filed a consolidated long-form complaint against the generic defendants, *Plaintiffs v. Actavis, et. al.* Civil Action No. 1364. The long-form complaint names Novitium as a defendant. The long form complaint asserts causes of action for negligence, failure to warn, negligent storage and transportation, breach of express warranties, breach of implied warranties, negligent misrepresentation, fraud, strict products liability, wrongful death and survivor actions, and loss of consortium. The complaint includes a prayer for punitive damages. The generic defendants filed their preliminary objections to Plaintiffs' consolidated long-form generic complaint on March 20, 2023. The arguments advanced in the preliminary objections include preemption and failure to properly state a claim for fraud under Pennsylvania law. Arguments in support of the preliminary objections for all defendant groups were held on April 27, 2023 and the court ruling is pending.

ANI and Novitium dispute any liability in these 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.

13. FAIR VALUE DISCLOSURES

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Facility bears 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, 2023.

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

Contingent Value Rights

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, 2023 and December 31, 2022. We also determined that the changes in such fair value were immaterial in the three months ended March 31, 2023 and 2022.

Interest Rate Swap

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 $6.9 million asset as of March 31, 2023.

Contingent Consideration

In connection with the acquisition of Novitium, we may pay up to $46.5 million in additional consideration related to the achievement of certain milestones, including milestones on gross profit of Novitium portfolio products over a 24-month period, regulatory filings completed during this 24-month period, and a percentage of net profits on certain products that are launched in the future.

The discounted cash flow method used to value this contingent consideration includes inputs of not readily observable market data, which are Level 3 inputs. The recurring Level 3 fair value measurements of contingent consideration for which a liability is recorded include the following significant unobservable inputs:

Payment Type	Valuation Technique	Unobservable Input	Assumptions
Profit-based milestone payments	Probability-weighted discounted cash flow	Discount rate	13.0%
		Projected fiscal year of payment	2024-2029
Product development-based milestone payments	Probability-weighted discounted cash flow	Discount rate	8.6%
		Probability of payment	95.0%
		Projected fiscal year of payment	2024

The following table presents the changes in contingent consideration balances classified as Level 3 balances for the three months ended March 31, 2023 and 2022:

(in thousands)	Three Months Ended March 31, 2023	2022
Beginning balance	$ 35,058	$ 31,000
Measurement period adjustment	—	300
Change in fair value	961	753
Ending balance	$ 36,019	$ 32,053

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of March 31, 2023 and December 31, 2022, by level within the fair value hierarchy:

(in thousands) Description	Fair Value at March 31, 2023	Level 1	Level 2	Level 3
Assets				
Interest rate swap	$ 6,855	$ —	$ 6,855	$ —
Liabilities				
Contingent consideration	$ 36,019	$ —	$ —	$ 36,019
CVRs	$ —	$ —	$ —	$ —

Description	Fair Value at December 31, 2022	Level 1	Level 2	Level 3
Assets				
Interest rate swap	$ 8,759	$ —	$ 8,759	$ —
Liabilities				
Contingent consideration	$ 35,058	$ —	$ —	$ 35,058
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, right-of-use (“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, 2023 and 2022.

Acquired Non-Financial Assets Measured at Fair Value

On July 21, 2022, we acquired four ANDAs from Oakrum Pharma, LLC for total consideration of $8.0 million plus an immaterial amount for the purchase of finished goods inventory. The transaction was funded from cash on hand. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. The product portfolio included one commercial product, one approved product with a launch completed in September and two filed products, with approval pending. We recognized $7.2 million as acquired ANDA intangible assets and $1.2 million as research and development expense because certain of the generic products have significant remaining work required in order to be commercialized and the products do not have an alternative future use. The payment was allocated to the acquired intangible assets and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. We used the present value of the estimated cash flows related to the products, using a discount rate of 13% to determine the fair value of the acquired intangible assets and in-process research and development. The inventory acquired was immaterial. Contingent liabilities are accrued when they are both estimable and probable. As of March 31, 2023, we accrued $0.2 million in contingent payments due to a third party upon the launch of a product completed in September. This was accrued and recorded in the fair value of acquired intangible assets as it was probable at the acquisition date. The ANDA's will be amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to March 31, 2023, and therefore no impairment loss was recognized for the three months ended March 31, 2023.

14. RELATED PARTY TRANSACTIONS

On March 8, 2021, we entered into an Equity Commitment and Investment Agreement with the PIPE Investor, pursuant to which we agreed to issue and sell 25,000 shares of our PIPE Shares for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million. This agreement closed and the shares were sold and issued for $25.0 million on November 19, 2021. The Chairman of our board of directors is an operating partner of Ampersand Capital Partners, an affiliate of the PIPE Investor.

In connection with our acquisition of Novitium, we entered into employment agreements with the two executives and founders of Novitium, Muthusamy Shanmugam and Chad Gassert. Both serve as executive officers of the Company and Mr. Shanmugam also serves on the Company's board of directors. Mr. Shanmugam holds a minority interest in Scitus Pharma Services ("Scitus"), which provides clinical research services to Novitium; majority interest in SS Pharma LLC ("SS Pharma"), which acquires and supplies API to Novitium; majority interest in Esjay Pharma LLC ("Esjay"), which provided research and development and facilities consulting services; and a minority interest in Nuray Chemical Private Limited ("Nuray"), which manufactures and supplies API to Novitium. As of September 30, 2022, Esjay no longer provided research and development and facilities consulting services to Novitium or ANI. Mr. Gassert holds a minority interest in Scitus.

A summary of our payments to related parties is presented below:

	Three Months Ended March 31,	
	2023	2022
Scitus Pharma Services	$ 717	$ 560
SS Pharma LLC	1,601	959
Esjay Pharma LLC	—	74
Nuray Chemical Private Limited	—	868
	$ 2,318	$ 2,461

As of March 31, 2023, the outstanding balances due to Scitus and SS Pharma were $0.5 million and $0.6 million, respectively. There was no outstanding balance due to Nuray at March 31, 2023.

15. SEGMENT REPORTING

An operating segment is defined as a component of an entity that engages in business activities from which it may recognize revenues and incur expense, its operating results are regularly reviewed by the entity's chief operating decision maker ("CODM") to make decisions about resources to be allocated to the segment and assess its performance, and its discrete financial information is available. We determined that we have two operating segments as follows:

- **Generics, Established Brands, and Other** – Consists of operations related to the development, manufacturing, and marketing of generic and established brand pharmaceuticals, including those sold through traditional channels, contract manufactured products, product development services, royalties, and other.

- **Rare Disease** – Consists of operations related to the development, manufacturing and marketing of pharmaceuticals used in the treatment of patients with rare conditions. The rare disease segment currently consists of operations related to Cortrophin Gel.

Our CODM evaluates our two operating segments based on revenues and earnings before interest, income taxes, depreciation, and amortization ("EBITDA"), exclusive of corporate expenses and other expenses not directly allocated or attributable to an operating segment. These expenses include, but are not limited to, certain management, legal, accounting, human resources, insurance, and information technology expenses.

We do not manage assets of the Company by operating segment and our CODM does not review asset information by operating segment. Accordingly, we do not present total assets by operating segment.

Financial information by reportable segment is as follows:

	Three Months Ended March 31,	
(in thousands)	**2023**	**2022**
Net Revenues		
Generics, Established Brands, and Other	$ 90,456	$ 63,185
Rare Disease	16,330	1,292
Total net revenues	$ 106,786	$ 64,477
Segment earnings (loss) before interest, taxes, depreciation and amortization ("EBITDA") and reconciliation to income (loss) before income taxes		
Generics, Established Brands, and Other	$ 38,828	$ 14,531
Rare Disease	(1,251)	(10,448)
Depreciation and amortization	(14,700)	(14,557)
Corporate and other unallocated expenses[(1)]	(12,982)	(8,721)
Total operating income (loss)	9,895	(19,195)
Interest expense, net	(7,696)	(6,613)
Other expense, net	(34)	(89)
Income (loss) before (provision) benefit for income taxes	$ 2,165	$ (25,897)

(1) Includes expenses not directly allocated or attributable to a reporting segment, including certain management, legal, accounting, human resources, insurance, and information technology expenses, and are included in selling, general, and administrative expenses in our unaudited interim consolidated statement of operations.

Geographic Information

Our operations are currently located in the United States and India. We have ceased operations at our Oakville, Ontario, Canada location as of March 31, 2023. 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, 2023	 2022
United States	$ 106,221	$ 63,760
Canada	565	717
Total Revenue	$ 106,786	$ 64,477

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

(in thousands)	March 31, 2023	December 31, 2022
United States	$ 42,024	$ 40,343
Canada[(1)]	—	1,856
India	1,251	1,047
Total property and equipment, net	$ 43,275	$ 43,246

(1) Amounts as of March 31, 2023 exclude the land and building at our Canada facility, which are classified as held for sale as of March 31, 2023. These assets have a carrying value of $8.0 million.

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 on Form 10-Q, 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, 2022 (the "2022 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 2022 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 2022 Annual Report and this Quarterly Report on Form 10-Q.

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by building a successful Cortrophin Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, and one is located in East Windsor, New Jersey, 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. On June 2, 2022, we announced that we intended to cease operations at our Oakville, Ontario, Canada manufacturing plant by the end of the first quarter 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. As of March 31, 2023, we have completed the transition of the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites.

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 growth drivers:

Building a successful Rare Disease platform

We have spent significant time, effort and resources in establishing our Rare Disease platform. 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. During the second quarter of 2021, we submitted a Supplemental New Drug Application ("sNDA") to the FDA.

On October 29, 2021, the FDA approved the Company's sNDA for Purified Cortrophin Gel (Repository Corticotropin Injection USP) for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis ("MS") and rheumatoid arthritis ("RA"), in addition to excess urinary protein due to nephrotic syndrome. Cortrophin Gel is an adrenocorticotropic hormone ("ACTH"), also known as purified corticotropin.

During 2021 and 2022, we invested significantly in leadership, expertise and infrastructure in the areas of commercialization of rare disease therapies and developed a launch strategy and commercial plan for this product. During 2021 and throughout 2022, we hired a significant number of new employees and assembled and trained our Rare Disease field force. On January 24, 2022, we announced the commercial launch of Cortrophin Gel in the U.S as our foundational Rare Disease asset. As a result of the build out of our Rare Disease team, our expenditures in support of these efforts were significantly higher in 2022 as compared to 2021, and we plan to continue to invest behind Cortrophin Gel and our Rare Disease platform in 2023 and beyond.

Strengthening our Generics, Established Brands, and Other segment through continued investment in our generic 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 business and asset acquisitions. Our most recent business acquisition was Novitium, including its portfolio of commercial and pipeline generic products, manufacturing and development facilities and expert workforce. The Novitium acquisition significantly increased our generic pharmaceutical research and development and manufacturing capabilities. We have begun to increase our focus on niche lower competition opportunities such as injectables, Paragraph IV, and Competitive Generic Therapy designation filings. Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses. On July 21, 2022, we completed an asset acquisition of four ANDAs from Oakrum Pharma, including two that were commercial at the time of acquisition.

We have grown our established brand product offerings through acquisition. We have acquired the NDAs for and market Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, InnoPran XL, Oxistat, Veregen, and Pandel. We are innovating in our go-to-market strategy through creative partnerships.

Our overall strategy is enabled by an empowered, collaborative, and purposeful team with a high performance-orientation.

Generic 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 to more closely control the economic inputs and outputs of our products.

- ***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

Restructuring Update

On June 2, 2022, we announced that we intended to cease operations at our Oakville, Ontario, Canada manufacturing plant by the first quarter of 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium in November 2021. As of March 31, 2023, we have completed the transition of the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites. We are seeking to find potential buyers for the Oakville site, though there can be no assurance as to when or if that will occur or the amount of any net proceeds that may be received.

Product Launches

Refer to our website at www.anipharmaceuticals.com for information on the products, including indications/treatments.

GENERAL

Impacts to our 2023 and 2022 results of operations, including to net revenues, operating expenses, interest and other expense, net, and income taxes are described below.

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

	Three Months Ended March 31,	
(in thousands)	2023	2022
Net Revenues	$ 106,786	$ 64,477
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	37,708	34,271
Research and development	5,924	5,274
Selling, general, and administrative	36,468	28,817
Depreciation and amortization	14,700	14,557
Contingent consideration fair value adjustment	961	753
Restructuring activities	1,130	—
Operating Income (Loss)	9,895	(19,195)
Interest expense, net	(7,696)	(6,613)
Other expense, net	(34)	(89)
Income (Loss) Before Income Tax (Provision) Benefit	2,165	(25,897)
Income tax (provision) benefit	(726)	5,767
Net Income (Loss)	$ 1,439	$ (20,130)

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,	
	2023	2022
Net Revenues	100.0 %	100.0 %
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	35.3 %	53.2 %
Research and development	5.5 %	8.2 %
Selling, general, and administrative	34.2 %	44.7 %
Depreciation and amortization	13.8 %	22.6 %
Contingent consideration fair value adjustment	0.9 %	1.2 %
Restructuring activities	1.1 %	— %
Operating Income (Loss)	9.2 %	(29.9)%
Interest expense, net	(7.2)%	(10.3)%
Other expense, net	— %	(0.1)%
Income (Loss) Before Income Tax (Provision) Benefit	2.0 %	(40.3)%
Income tax (provision) benefit	(0.7)%	8.9 %
Net Income (Loss)	1.3 %	(31.4)%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2023 AND 2022

Net Revenues

(in thousands)	Three Months Ended March 31, 2023	2022	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 63,713	$ 49,107	$ 14,606	29.7 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	26,743	14,078	12,665	90.0 %
Generics, established brands, and other segment total net revenues	$ 90,456	$ 63,185	$ 27,271	43.2 %
Rare Disease Segment				
Rare disease pharmaceutical products	$ 16,330	1,292	$ 15,038	NM (1)
Total net revenues	$ 106,786	$ 64,477	$ 42,309	65.6 %

(1) Not meaningful

We derive substantially all of our revenues from sales of generic, rare disease, and established brand pharmaceutical products, royalties on net sales of certain products, and other pharmaceutical services. Many of our established brand products as well as our generic products face competition from generic products and we expect them to continue to face competition from generic products in the future. The primary means of competition among generic manufacturers are pricing, contract terms, service levels, and reliability. Increased competition generally results in decreased average selling prices of generic and brand products over time. In addition, due to strategic partnerships between wholesalers and pharmacy chains, we have experienced, and expect to continue to experience, increases in net sales to the wholesalers, with corresponding decreases in net sales to the pharmacy chains.

Net revenues for the three months ended March 31, 2023 were $106.8 million compared to $64.5 million for the same period in 2022, an increase of 65.6%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $63.7 million during the three months ended March 31, 2023, an increase of 29.7% compared to $49.1 million for the same period in 2022, driven by increased volume from the annualization of 2022 launches and favorable product mix. From a product perspective, the increase was principally driven by revenues from year over year increases in Digoxin, Famotidine, Fesoterodine, Glipizide, Levocarnitine Tablets, Misoprostol, Meloxicam, Nebivolol, Penicillamine, Prochlorperazine, and various other products tempered by a decrease in revenues of Cholestyramine, Mesalamine, Mixed Amphetamine Salts ER, Oxybutynin Chloride, and Prazosin, among others.

- Net revenues for established brand products, royalties, and other pharmaceutical services were $26.7 million during the three months ended March 31, 2023, an increase of 90.0% compared to $14.1 million for the same period in 2022, driven by an increase in volume.

- Net revenues of rare disease pharmaceutical products, which consist entirely of sales of Cortrophin Gel, were $16.3 million during the three months ended March 31, 2023 an increase of $15.0 million from $1.3 million for the same period in 2022. This increase was driven by increased volume as the product was launched in late January 2022.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended March 31, 2023	2022	Change	% Change
Cost of sales (excluding depreciation and amortization)	$ 37,708	$ 34,271	$ 3,437	10.0 %

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

For the three months ended March 31, 2023, cost of sales increased to $37.7 million from $34.3 million for the same period in 2022, an increase of $3.4 million, or 10.0%. The increase is primarily due to a shift in product mix and increased volumes of sales of generic and rare disease pharmaceutical products. During the three months ended March 31, 2022, we recognized $3.8 million in cost of sales representing the excess of fair value over cost for inventory acquired in acquisitions and subsequently sold during the three months ended March 31, 2022. There are no comparable expenses in the three months ended March 31, 2023.

Cost of sales, as a percentage of net revenues, decreased from 53.2% to 35.3% for the three months ended March 31, 2022, compared to the same period in 2023. The decrease was primarily due to the non-recurrence of $3.8 million expense recognized in the three months ended March 31, 2022, related to the excess of fair value over cost for inventory acquired in a business combination, as well as the increased sales of Cortrophin Gel.

During the three months ended March 31, 2023, no single vendor represented more than 10% of inventory purchases. During the three months ended March 31, 2022, one vendor represented 16% of inventory purchases.

Other Operating Expenses

(in thousands)	Three Months Ended March 31, 2023	2022	Change	% Change
Research and development	$ 5,924	$ 5,274	$ 650	12.3 %
Selling, general, and administrative	36,468	28,817	7,651	26.6 %
Depreciation and amortization	14,700	14,557	143	1.0 %
Contingent consideration fair value adjustment	961	753	208	27.6 (1)
Restructuring activities	1,130	—	1,130	NM (1)
Total other operating expenses	$ 59,183	$ 49,401	$ 9,782	19.8 %

(1) Not meaningful

For the three months ended March 31, 2023, other operating expenses increased to $59.2 million from $49.4 million for the same period in 2022, an increase of $9.8 million, or 19.8%, primarily as a result of the following factors:

- Research and development expenses increased from $5.3 million to $5.9 million, an increase of $0.7 million or 12.3%, primarily due to year over year timing of work associated with generic projects coupled with an increase associated with projects related to Cortrophin Gel in the three months ended March 31, 2023.
- Selling, general, and administrative expenses increased from $28.8 million to $36.5 million, an increase of $7.7 million, or 26.6%, primarily due to a $3.4 million increase in sales and marketing expenses related to Cortrophin Gel and increased headcount related costs tempered by a $0.7 million decrease in transaction expenses related to the Novitium acquisition.
- Depreciation and amortization expense was $14.7 million for the three months ended March 31, 2023, compared to $14.6 million for the same period in 2022, an increase of $0.1 million.
- As described in Note 13, *Fair Value Disclosures*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized a contingent consideration fair value adjustment of $1.0 million and $0.8 million expense in the three months ended March 31, 2023 and 2022, respectively. The expense is principally due to the passage of time (i.e. moving closer to the ultimate payment date of the consideration, rather than the change in any other variables).
- We recognized restructuring activities of $1.1 million of expense in the three months ended March 31, 2023, in relation to the closure of our Oakville, Ontario, Canada facility. Costs included severance and other employee benefits costs of $0.2 million, $0.7 million of accelerated depreciation costs and $0.2 million for other miscellaneous costs accrued in 2022.

Other Expense, net

(in thousands)	Three Months Ended March 31, 2023	2022	Change	% Change
Interest expense, net	$ (7,696)	$ (6,613)	$ (1,083)	16.4 %
Other expense, net	(34)	(89)	55	(61.8)%
Total other expense, net	$ (7,730)	$ (6,702)	$ (1,028)	15.3 %

For the three months ended March 31, 2023, we recognized total other expense, net of $7.7 million versus total other expense of $6.7 million for the same period in 2022, an increase of $1.0 million. Interest expense, net for the three months ended March 31, 2023 and 2022 consisted primarily of interest expense on borrowings under our Term Facility. The increase in interest expense is due to an increased borrowing rate on the $300.0 million Term Facility and an increase in amortization of finance fees. For the three months ended March 31, 2023 and 2022, there was less than $0.1 million of interest capitalized into construction in progress.

Income Tax (Provision) Benefit

(in thousands)	Three Months Ended March 31, 2023	2022	Change	% Change
Income tax (provision) benefit	$ (726)	$ 5,767	$ (6,493)	(112.6)%

Our income tax (provision) benefit 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, 2023, we recognized an income tax provision of $0.7 million. The income tax provision resulted from applying an estimated annual worldwide effective tax rate of 34.9% to pre-tax consolidated income of $2.2 million reported during the period. There were no material discrete items occurring during the three months ended March 31, 2023.

For the three months ended March 31, 2022, we recognized an income tax benefit of $5.8 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 22.3% to pre-tax consolidated loss of $25.9 million reported during the period. There were no material discrete items occurring during the three months ended March 31, 2022.

LIQUIDITY AND CAPITAL RESOURCES

Debt Financing

On November 19, 2021, the Company, as borrower, entered into a credit agreement (the "Credit Agreement") with Truist Bank and other lenders, which provides for credit facilities consisting of (i) a senior secured term loan facility in an aggregate principal amount of $300.0 million (the "Term Facility") and (ii) a senior secured revolving credit facility in an aggregate commitment amount of $40.0 million, which may be used for revolving credit loans, swingline loans and letters of credit (the "Revolving Facility," and together with the Term Facility, the "Credit Facility"). The Credit Facility is secured by substantially all our assets and the assets of our domestic subsidiaries.

The Term Facility proceeds were used to finance the cash portion of the consideration for the Novitium acquisition, repay borrowings under our Prior Credit Agreement, and pay fees, costs and expenses incurred in connection with the acquisition of Novitium. Proceeds from the Revolving Facility are expected to be used, subject to certain limitations, for working capital and other general corporate purposes.

The Term Facility matures in November 2027 and the Revolving Facility in November 2026. Each permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the LIBOR Rate (as defined in the Credit Agreement, which includes a floor of 0.75%) in the case of loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the LIBOR Rate (as defined in the Credit Agreement) in the case of loans under the Revolving Facility. The Credit Facility has a subjective acceleration clause in case of a material adverse effect. The Term Facility includes a repayment schedule, pursuant to which $750 thousand of the loan will be paid in quarterly installments during the 12 months ending March 31, 2023. As of March 31, 2023, $3.0 million of principal of the loan was recorded as current borrowings in the consolidated balance sheet. As of March 31, 2023, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

Equity Financing

Concurrently with the execution of the merger agreement related to the Novitium acquisition, on March 8, 2021, we entered into that certain Equity Commitment and Investment Agreement with Ampersand 2020 Limited Partnership (the "PIPE Investor") pursuant to which, on November 19, 2021, we issued and sold to the PIPE Investor, and the PIPE Investor purchased, 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, in a private placement issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder.

In November 2021, through a public offering, we completed the issuance and sale of 1,500,000 shares of ANI common stock, resulting in net proceeds after issuance costs of $69.7 million. The proceeds are being used to fund our Cortrophin Gel commercialization efforts, including sales and marketing and consulting expenses related thereto, and for general corporate purposes.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue and corresponding collections from customers, and our Credit Facility, under which $40.0 million remains available for borrowing as of March 31, 2024, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months.

Cash Flows

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

	Three Months Ended March 31,	
(in thousands)	2023	2022
Operating Activities	$ 21,424	$ (18,942)
Investing Activities	$ (2,353)	$ (2,178)
Financing Activities	$ (4,548)	$ (2,270)

Net Cash Provided by (Used in) Operations

Net cash provided by operating activities was $21.4 million for the three months ended March 31, 2023, compared to $18.9 million used in operating activities during the same period in 2022, a change of $40.4 million. The increase was driven by net income coupled with favorable year over year changes in deferred taxes.

Net Cash Used in Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2023 was $2.4 million, principally due to $2.3 million of capital expenditures. Net cash used in investing activities for the three months ended March 31, 2022 was $2.2 million, principally due to the $1.9 million of capital expenditures during the period.

Net Cash Used in Financing Activities

Net cash used in financing activities for the three months ended March 31, 2023 was $4.5 million, principally due to the $0.8 million maturity payments on the Term Facility, $3.5 million of treasury stock purchased in relation to restricted stock vests, and $0.4 million convertible preferred stock dividends paid. Net cash used in financing activities for the three months ended March 31, 2022 was $2.3 million, principally due to the $0.8 million maturity payments on the Term Facility, $1.1 million of treasury stock purchased in relation to restricted stock vests, and $0.4 million convertible preferred stock dividends paid.

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, 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, including contingent consideration in acquisitions, 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.

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, 2022. 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 II, 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, 2022.

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.

CONTRACTUAL OBLIGATIONS

As of March 31, 2023, our contractual obligations have not changed materially from the amounts reported in our most recent 2022 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

On November 19, 2021, we entered into the Credit Agreement, which is secured by substantially all of the personal property and certain material real property owned by ANI and our wholly-owned domestic subsidiaries, and obligations under the Credit Agreement are guaranteed by certain of our wholly-owned domestic subsidiaries.

The Term Facility proceeds were used to finance a portion of the consideration for the Novitium acquisition, repay our existing credit facility, and pay fees, costs and expenses incurred in connection with the acquisition. Proceeds from the Revolving Facility are expected to be used, subject to certain limitations, for working capital and other general corporate purposes.

The Term Facility matures on the six-year anniversary of November 19, 2021 (the "Closing Date") and the Revolving Facility matures on the five-year anniversary of the Closing Date. The Revolving Facility and the Term Facility each permit both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the LIBOR Rate (as defined in the Credit Facility) in the case of Eurodollar Loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the LIBOR Rate (as defined in the Credit Facility) in the case of Eurodollar Loans under the Revolving Facility.

The Credit Agreement contains usual and customary representations and warranties of the parties for credit facilities of this type, subject to customary exceptions and materiality standards. In addition, we are required to maintain, a total net leverage ratio not to exceed 4.75:1.00 and, solely with respect to the Revolving Facility, (a) during the period beginning on October 1, 2022 and ending on September 30, 2023, a total net leverage ratio not to exceed 4.50:1.00 and (b) for all periods thereafter, a total net leverage ratio not to exceed 4.25:1.00.

The Credit Agreement also contains certain customary covenants and events of default, as well as, in the event of an occurrence of an event of default under the Credit Agreement, customary remedies for the lenders, including the acceleration of any amounts outstanding under the Credit Agreement.

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 term facilities related to our Prior Credit Agreement. The interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Facility with Truist Bank, the interest rate swap with a notional value of $168.6 million at origin on November 21, 2021 was novated and is now with Truist Bank and is used to manage changes in LIBOR-based interest rates underlying a portion of the borrowing under the Term Facility. We are exposed to interest rate risk on the unhedged portion of our Term Facility and if interest rates increased or decreased by 1%, interest expense would have increased or decreased by approximately $1.4 million. If our Revolving Facility were fully drawn and interest rates increased or decreased by 1%, interest expense would have increased or decreased by approximately $0.4 million. The interest rate swap provides an effective fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. 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 quarter ended March 31, 2023 by approximately $22,000.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated and Indian rupee-denominated transactions from ANI Pharmaceuticals Canada Inc. and our Indian subsidiary from the Canadian dollar to the U.S. dollar and the Indian-rupee to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the quarter ended March 31, 2023.

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, 2023. Due to the material weaknesses in internal control over financial reporting, our principal executive officer and principal financial officers concluded that, due to the on-going remediation associated with the material weakness identified in our 2022 Annual Report on Form 10-K (“2022 Form 10-K"), our disclosure controls and procedures were ineffective as of March 31, 2023 to provide reasonable assurance that the information required to be disclosed by us in the reports that we file or submit under the Exchange Act of 1934 is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms, and that such information is accumulated and communicated to management as appropriate to allow timely decisions regarding required disclosure.

For a more comprehensive discussion of the material weaknesses in internal control over financial reporting previously identified by management as of December 31, 2022 and the remedial measures undertaken to address these material weaknesses, investors are encouraged to review Item 9A, Disclosure Controls and Procedures, of our 2022 Form 10-K.

Since March 8, 2023, the date of our 2022 Form 10-K, management has made progress with remediation efforts, including the following:

- Hired a qualified Vice President and Corporate Controller with significant accounting and control expertise,
- Added accounting resources at our Novitium location and in other areas of the overall ANI finance and accounting organization.
- Continued to progress its plans to implement our ERP system at Novitium and incorporate procure to pay cycle into the overall company controls.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2023 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 12, *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 under the heading "Risk Factors" in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2022 in Part I, Item 1A. 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. There have been no material changes to those risk factors since their disclosure in our most recent Annual Report on Form 10-K.

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

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased[1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or approximate dollar value) of Shares that may yet be Purchased Under the Plans or Programs
January 1 - January 31, 2023	3,609	$ 45.93	—	$ —
February 1 - February 28, 2023	4,843	$ 44.58	—	$ —
March 1 - March 31, 2023	76,041	$ 41.16	—	$ —
Total	84,493	$ 41.56	—	

[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
3.1	Second Amended and Restated Bylaws of ANI Pharmaceuticals, Inc. (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 6, 2023).
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, 2023 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 8, 2023

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

Date: May 8, 2023

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 8, 2023

/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 8, 2023

/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, 2023 (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 8, 2023

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

Dated: May 8, 2023

/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.