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

FORM 10-Q

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

For the quarterly period ended June 30, 2024

☐ **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 July 30, 2024 there were 21,030,069 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 June 30, 2024

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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"), the announcement and pendency of the acquisition of Alimera Sciences, Inc. ("Alimera"), impact of accounting principles, litigation expenses, liquidity and capital resources, the impact of global pandemics 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, 2023 and the following factors:

- our ability to continue to achieve commercial success with Cortrophin Gel, our first rare disease pharmaceutical product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted;
- the ability of our approved products, including Cortrophin Gel, to achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability;
- our ability to complete or achieve any, or all of the intended benefits of acquisitions and investments, including the pending acquisition of Alimera, in a timely manner or at all;
- the risks that our acquisitions and investments, including the pending acquisition of Alimera, could disrupt our business and harm our financial position and operating results;
- delays in production, increased costs and potential loss of revenues if we need to change suppliers due to the limited number of suppliers for our raw materials, active pharmaceutical ingredients ("API"), expedients, and other materials;
- our reliance on single source third party contract manufacturing supply for certain of our key products, including Cortrophin Gel, and post consummation of the acquisition, for Alimera's products;
- 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, United States Drug Enforcement Administration, and other regulatory agencies, including among other things, drug recalls, regulatory approvals, facility inspections and potential enforcement actions;
- our ability to develop, license or acquire, and commercialize new products;
- the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products;
- our ability to protect our intellectual property rights;
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- the impact of any litigation to which we are, or may become, a party;
- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries;
- our ability to maintain the services of our key executives and other personnel; and
- general business and economic conditions, such as inflationary pressures, geopolitical conditions including, but not limited to, the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies.

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, 2023, 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.

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)

Assets	June 30, 2024	December 31, 2023
Current Assets		
Cash and cash equivalents	$ 240,110	$ 221,121
Accounts receivable, net of $102,784 and $97,262 of adjustments for chargebacks and other allowances at June 30, 2024 and December 31, 2023, respectively	166,091	162,079
Inventories	125,448	111,196
Prepaid income taxes	2,867	—
Assets held for sale	—	8,020
Prepaid expenses and other current assets	14,001	17,400
Investment in equity securities	6,943	—
Total Current Assets	555,460	519,816
Non-current Assets		
Property and equipment, net	51,640	44,593
Deferred tax assets, net of deferred tax liabilities and valuation allowance	89,506	90,711
Intangible assets, net	183,078	209,009
Goodwill	28,221	28,221
Derivatives and other non-current assets	12,848	12,072
Total Assets	$ 920,753	$ 904,422
Liabilities, Mezzanine Equity, and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	48,681	36,683
Accrued royalties	20,357	16,276
Accrued compensation and related expenses	16,111	23,786
Accrued government rebates	12,324	12,168
Income taxes payable	—	8,164
Returned goods reserve	33,897	29,678
Current contingent consideration	841	12,266
Accrued expenses and other	6,917	5,606
Total Current Liabilities	139,978	145,477
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	284,394	284,819
Non-current contingent consideration	11,092	11,718
Other non-current liabilities	4,679	4,809
Total Liabilities	$ 440,143	$ 446,823
Commitments and Contingencies (Note 13)		
Mezzanine Equity		
Convertible Preferred Stock, Series A, $0.0001 par value, 1,666,667 shares authorized; 25,000 shares issued and outstanding at June 30, 2024 and December 31, 2023	24,850	24,850
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 21,476,115 shares issued and 21,063,528 outstanding at June 30, 2024; 20,730,896 shares issued and 20,466,953 shares outstanding at December 31, 2023	2	2
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	—	—
Treasury stock, 412,587 shares of common stock, at cost, at June 30, 2024 and 263,943 shares of common stock, at cost, at December 31, 2023	(20,042)	(10,081)
Additional paid-in capital	532,497	514,103
Accumulated deficit	(65,025)	(80,132)
Accumulated other comprehensive income, net of tax	8,328	8,857
Total Stockholders' Equity	455,760	432,749
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 920,753	$ 904,422

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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net Revenues	$ 138,040	$ 116,547	$ 275,470	$ 223,333
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	57,698	42,284	106,855	79,992
Research and development	7,296	7,374	17,807	13,298
Selling, general, and administrative	52,821	38,760	100,842	75,228
Depreciation and amortization	14,697	14,690	29,383	29,390
Contingent consideration fair value adjustment	359	1,035	449	1,996
Restructuring activities	—	2	—	1,132
Gain on sale of building	—	—	(5,347)	—
Total Operating Expenses, net	132,871	104,145	249,989	201,036
Operating Income	5,169	12,402	25,481	22,297
Other Income (Expense), net				
Unrealized (loss) gain on investment in equity securities	(2,712)	—	6,943	—
Interest expense, net	(4,656)	(7,100)	(9,256)	(14,796)
Other expense, net	(88)	(53)	(120)	(87)
(Loss) Income Before Income Tax Expense (Benefit)	(2,287)	5,249	23,048	7,414
Income tax expense (benefit)	—	(996)	7,128	(270)
Net (Loss) Income	$ (2,287)	$ 6,245	$ 15,920	$ 7,684
Dividends on Series A Convertible Preferred Stock	(407)	(407)	(813)	(813)
Net (Loss) Income Available to Common Shareholders	$ (2,694)	$ 5,838	$ 15,107	$ 6,871
Basic and Diluted (Loss) Income Per Share:				
Basic (Loss) Income Per Share	$ (0.14)	$ 0.30	$ 0.71	$ 0.36
Diluted (Loss) Income Per Share	$ (0.14)	$ 0.29	$ 0.70	$ 0.36
Basic Weighted-Average Shares Outstanding	19,321	17,688	19,210	17,044
Diluted Weighted-Average Shares Outstanding	19,321	17,855	19,561	17,177

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

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net (Loss) Income	$ (2,287)	$ 6,245	$ 15,920	$ 7,684
Other comprehensive (loss) income, net of tax:				
Foreign currency translation adjustment	(12)	(17)	(109)	90
(Loss) Gain on interest rate swap	(1,066)	2,612	(420)	1,469
Total other comprehensive (loss) income, net of tax	(1,078)	2,595	(529)	1,559
Total comprehensive (loss) income, net of tax	$ (3,365)	$ 8,840	$ 15,391	$ 9,243

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 June 30, 2024 and 2023
(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 Income, Net of Tax	Accumulated Deficit	Total Mezzanine Equity and Stockholders' Equity
Balance, March 31, 2023	$ 24,850	25	$ 1	18,226	$ —	$ 408,395	234	$ (8,643)	$ 11,131	$ (96,252)	339,482
Stock-based Compensation Expense	—	—	—	—	—	5,249	—	—	—	—	5,249
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	14	(537)	—	—	(537)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	40	—	1,289	—	—	—	—	1,289
Issuance of Restricted Stock Awards	—	—	—	104	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(18)	—	—	—	—	—	—	—
Issuance of Common Stock in Public Offering	—	—	1	2,184	—	80,555	—	—	—	—	80,556
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(407)	(407)
Other Comprehensive Income	—	—	—	—	—	—	—	—	2,595	—	2,595
Net Income	—	—	—	—	—	—	—	—	—	6,245	6,245
Balance, June 30, 2023	$ 24,850	25	$ 2	20,536	$ —	$ 495,488	248	$ (9,180)	$ 13,726	$ (90,414)	$ 434,472
Balance, March 31, 2024	$ 24,850	25	$ 2	21,373	$ —	$ 523,628	393	$ (18,742)	$ 9,406	$ (62,331)	$ 476,813
Stock-based Compensation Expense	—	—	—	—	—	7,864	—	—	—	—	7,864
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	20	(1,300)	—	—	(1,300)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	46	—	1,005	—	—	—	—	1,005
Issuance of Restricted Stock Awards	—	—	—	65	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(8)	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(407)	(407)
Other Comprehensive Loss	—	—	—	—	—	—	—	—	(1,078)	—	(1,078)
Net Loss	—	—	—	—	—	—	—	—	—	(2,287)	(2,287)
Balance, June 30, 2024	$ 24,850	25	$ 2	21,476	$ —	$ 532,497	413	$ (20,042)	$ 8,328	$ (65,025)	$ 480,610

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 Six Months Ended June 30, 2024 and 2023
(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 Income, Net of Tax	Accumulated Deficit	Total Mezzanine Equity and Stockholders' Equity
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	—	—	—	—	—	9,587	—	—	—	—	9,587
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	99	(4,086)	—	—	(4,086)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	45	—	1,446	—	—	—	—	1,446
Issuance of Restricted Stock Awards	—	—	—	624	—	—	—	—	—	—	—
Issuance of Performance Stock Units	—	—	—	67	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(28)	—	—	—	—	—	—	—
Issuance of Common Stock in Public Offering	—	—	1	2,184	—	80,555	—	—	—	—	80,556
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(813)	(813)
Other Comprehensive Income	—	—	—	—	—	—	—	—	1,559	—	1,559
Net Income	—	—	—	—	—	—	—	—	—	7,684	7,684
Balance, June 30, 2023	$ 24,850	25	$ 2	20,536	$ —	$ 495,488	248	$ (9,180)	$ 13,726	$ (90,414)	$ 434,472
Balance, December 31, 2023	$ 24,850	25	$ 2	20,731	$ —	$ 514,103	264	$ (10,081)	$ 8,857	$ (80,132)	$ 457,599
Stock-based Compensation Expense	—	—	—	—	—	14,798	—	—	—	—	14,798
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	149	(9,961)	—	—	(9,961)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	77	—	3,596	—	—	—	—	3,596
Issuance of Restricted Stock Awards	—	—	—	606	—	—	—	—	—	—	—
Issuance of Performance Stock Units	—	—	—	74	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(12)	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(813)	(813)
Other Comprehensive Loss	—	—	—	—	—	—	—	—	(529)	—	(529)
Net Income	—	—	—	—	—	—	—	—	—	15,920	15,920
Balance, June 30, 2024	$ 24,850	25	$ 2	21,476	$ —	$ 532,497	413	$ (20,042)	$ 8,328	$ (65,025)	$ 480,610

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)

	Six Months Ended June 30,	
	2024	**2023**
Cash Flows From Operating Activities		
Net income	$ 15,920	$ 7,684
Adjustments to reconcile net income to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	14,798	9,587
Deferred taxes	1,205	(137)
Depreciation and amortization	29,383	29,390
Unrealized gain on investment in equity securities	(6,943)	—
Non-cash operating lease expense	750	61
Non-cash interest	198	1,973
Contingent consideration fair value adjustment	449	1,996
Gain on sale of building	(5,347)	—
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable, net	(4,012)	(7,486)
Inventories	(14,252)	1,032
Prepaid expenses and other assets	1,777	1,449
Accounts payable	10,379	(800)
Accrued royalties	4,081	(577)
Prepaid income taxes	(11,031)	(261)
Accrued government rebates	156	(1,099)
Returned goods reserve	4,219	(3,601)
Accrued expenses, accrued compensation, and other	(6,047)	2,839
Net Cash and Cash Equivalents Provided by Operating Activities	35,683	42,050
Cash Flows From Investing Activities		
Acquisition of product rights, intangible assets, and other related assets	—	(4,329)
Acquisition of property and equipment, net	(9,030)	(4,850)
Proceeds from the sale of building	13,514	—
Net Cash and Cash Equivalents Provided by (Used in) Investing Activities	4,484	(9,179)
Cash Flows From Financing Activities		
Payments on borrowings under credit agreements	(1,500)	(1,500)
Series A convertible preferred stock dividends paid	(813)	(813)
Proceeds from stock option exercises and ESPP purchases	3,596	1,446
Proceeds from public offering	—	80,555
Treasury stock purchases for restricted stock vests	(9,961)	(4,086)
Payments on contingent consideration	(12,500)	—
Net Cash and Cash Equivalents (Used in) Provided by Financing Activities	(21,178)	75,602
Net Change in Cash, Cash Equivalents, and Restricted Cash	18,989	108,473
Cash, cash equivalents, and restricted cash, beginning of period	221,121	53,234
Cash and cash equivalents, end of period	$ 240,110	$ 161,707
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	$ 221,121	$ 48,228
Restricted cash	—	5,006
Cash, cash equivalents, and restricted cash, beginning of period	$ 221,121	$ 53,234
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 16,155	$ 15,456
Cash paid for income taxes	$ 17,204	$ 141
Right-of-use assets obtained in exchange for lease obligations	$ —	$ 4,499
Supplemental non-cash investing and financing activities:		
Property and equipment purchased and included in accounts payable	$ 1,618	$ 539

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

NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Tabular Dollars in Thousands, Except Share and per Share Data)
(Unaudited)

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 branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. The Company is focused on delivering growth by scaling up the Rare Disease business through the launch of Cortrophin Gel, strengthening its generics business with enhanced development capability, innovation in established brands and leveraging its U.S. based manufacturing capabilities. The Company's 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. The Company has ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. The Company has fully completed the transition of the products manufactured or packaged in Oakville to one of the three U.S. based manufacturing sites. In February 2024, the Company entered into an agreement for the sale of the Oakville site, for a price of $19.2 million Canadian Dollars, or approximately $14.2 million, based on the exchange rate at closing. The sale closed on March 28, 2024 (see Note 4).

The Company's 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.

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") for interim financial information. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, comprehensive (loss) income, and cash flows. The consolidated balance sheet at December 31, 2023 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"). Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and notes thereto previously distributed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (the "2023 Form 10-K"), as filed with the SEC.

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

The Company has ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. The Company currently has 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 India-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. The 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 and six months ended June 30, 2024 and 2023. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar. The Company's asset and liability accounts are translated using the current exchange rate as of the balance sheet date, except for shareholders' equity accounts, which are translated using historical rates. Net revenues and expense accounts are translated using an average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are accumulated as a separate component of shareholders' equity within accumulated other comprehensive (loss) income, net of tax.

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

The Company defines 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, the Company records 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 the condensed consolidated statements of operations.

Investment in Equity Securities

The Company accounts for its investment in equity securities with a readily determinable fair value in accordance with the guidance in ASC 321, *Investments – Equity Securities*. The Company presents unrealized gains and losses related to the equity securities, within Unrealized gain on investment in equity securities in its unaudited condensed consolidated statements of operations. Fair values are obtained from quoted prices on the NASDAQ Stock Market, Inc. ("NASDAQ").

Assets Held-for-Sale

The Company classifies assets held-for-sale if all held-for-sale criteria is met pursuant to ASC 360-10, *Property, Plant and Equipment*. Criteria include management commitment to sell the disposal group in its present condition and the sale being deemed probable of being completed within one year. Assets classified as held-for-sale are not depreciated and are measured at the lower of their carrying amount or fair value less cost to sell. The Company assesses the fair value of a disposal group, less any costs to sell, each reporting period it remains classified as held-for-sale and reports any subsequent changes as an adjustment to the carrying value of the disposal group, as long as the new carrying value does not exceed the initial carrying value of the disposal group. The Company determined that the Oakville, Ontario, Canada property met the held-for-sale criteria. As of December 31, 2023, approximately $8.0 million of assets held for sale were recorded on the consolidated balance sheets. The Oakville, Ontario property was sold on March 28, 2024 (see Note 4).

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and are adopted by the Company as of the specified effective date. The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption.

In November 2023, the FASB issued Accounting Standards Update ("ASU") 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which improves reportable segment disclosure requirements, primarily through enhanced disclosures related to significant segment expenses. The guidance in this ASU is effective for all public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The guidance is applied retrospectively to all periods presented in the financial statements, unless it is impracticable. The Company is currently evaluating the effect the adoption of this ASU may have on its disclosures in the notes to the consolidated financial statements.

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which includes guidance to expand the disclosure requirements for income taxes, specifically related to the rate reconciliation and income taxes paid. These amendments are effective for all public entities for fiscal periods beginning after December 15, 2024, with early adoption permitted. These amendments apply on a prospective basis, but entities have an option to apply it retrospectively for all periods presented. The Company does not expect that the adoption of this guidance will have a material impact on its consolidated financial statements.

Recent Securities and Exchange Commission Final Rules Issued but Not Yet Effective

On March 6, 2024, the SEC adopted new rules that will require registrants to disclose certain climate-related information in their annual reports. The final rule requires disclosure of, among other things: material climate-related risks and their material impacts; activities to mitigate or adapt to such risks; information about a registrant's board of directors' oversight of climate-related risks and management's role in managing material climate-related risks; and information on any climate-related targets or goals that are material to the registrant's business, results of operations, or financial condition. In addition, certain disclosures related to severe weather events and other natural conditions will be required in a registrant's audited financial statements. The required information about climate-related risks will also include disclosure of a registrant's greenhouse gas emissions. The Company will be subject to the applicable requirements of the final rule in our annual reports for fiscal years beginning on January 1, 2025. In April 2024, the SEC voluntarily stayed the rules pending judicial review. The Company is currently evaluating the potential impact of these rules on its consolidated financial statements and related disclosures.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers*. Revenue is recognized 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.

Revenues are primarily derived from sales of generic, rare disease, and established brand pharmaceutical products, royalties, and other pharmaceutical services. Revenue is recognized when obligations under the terms of contracts with customers are satisfied, which generally occurs when control of the products sold are transferred to the customer. Variable consideration is estimated after the consideration of applicable information that is reasonably available. The Company generally does not have incremental costs to obtain contracts that would otherwise not have been incurred. The Company does 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 June 30,		Six Months Ended June 30,	
Products and Services (in thousands)	**2024**	**2023**	**2024**	**2023**
Sales of generic pharmaceutical products	$ 73,964	$ 63,317	$ 144,181	$ 127,030
Sales of established brand pharmaceutical products, royalties, and other pharmaceutical services	14,883	28,926	45,159	55,669
Sales of rare disease pharmaceutical products	49,193	24,304	86,130	40,634
Total net revenues	$ 138,040	$ 116,547	$ 275,470	$ 223,333

	Three Months Ended June 30,		Six Months Ended June 30,	
Timing of Revenue Recognition (in thousands)	**2024**	**2023**	**2024**	**2023**
Performance obligations transferred at a point in time	$ 138,040	$ 116,547	$ 275,470	$ 222,958
Performance obligations transferred over time	—	—	—	375
Total	$ 138,040	$ 116,547	$ 275,470	$ 223,333

In the three and six months ended June 30, 2024 and 2023, the Company did not incur, and therefore did not defer, any material incremental costs to obtain or fulfill contracts. The Company recognized a decrease of $1.5 million to net revenue from performance obligations satisfied in prior periods during the six months ended June 30, 2024, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. The Company recognized an increase of $5.0 million to net revenue from performance obligations satisfied in prior periods during the six months ended June 30, 2023, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. Additionally, as of June 30, 2024, and December 31, 2023, there was no deferred revenue recorded on the condensed consolidated balance sheets.

As of June 30, 2024, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $3.0 million, which consists of firm orders for contract manufactured products. The Company recognizes revenue for these performance obligations as they are satisfied, which is anticipated within six months.

Variable consideration

Sales of 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 condensed consolidated balance sheets for accruals and allowances for the six months ended June 30, 2024 and 2023, 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, 2022	$ 148,562	$ 10,872	$ 33,399	$ 9,442	$ 6,488
Accruals/Adjustments	290,826	11,100	5,995	25,606	11,028
Credits Taken Against Reserve	(362,253)	(10,001)	(9,596)	(25,177)	(12,653)
Balance at June 30, 2023 (1)	$ 77,135	$ 11,971	$ 29,798	$ 9,871	$ 4,863
Balance at December 31, 2023	$ 84,208	$ 12,168	$ 29,678	$ 11,412	$ 4,865
Accruals/Adjustments	267,779	13,324	21,895	29,970	11,422
Credits Taken Against Reserve	(262,541)	(13,168)	(17,676)	(29,656)	(11,243)
Balance at June 30, 2024 (1)	$ 89,446	$ 12,324	$ 33,897	$ 11,726	$ 5,044

(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

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

During the three and six months ended June 30, 2024, there were four customers that accounted for 10% or more of net revenues. During the three months ended June 30, 2023, there were four customers that accounted for 10% or more of net revenues. During the six months ended June 30, 2023, there were three customers that accounted for 10% or more of net revenues. As of June 30, 2024, accounts receivable from these customers totaled 79% of Accounts receivable, net.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Customer 1	24 %	32 %	29 %	32 %
Customer 2	12 %	14 %	12 %	14 %
Customer 3	13 %	13 %	11 %	13 %
Customer 4	17 %	10 %	15 %	9 %

3. PENDING MERGER AGREEMENT

On June 21, 2024, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Alimera Sciences, Inc., a Delaware corporation ("Alimera") and ANIP Merger Sub INC., a Delaware corporation and a wholly owned indirect subsidiary of the Company ("Merger Sub"), providing for the merger of Merger Sub with and into Alimera (the "Merger"), with Alimera surviving the Merger as a wholly owned indirect subsidiary of the Company. Capitalized terms used herein, but not otherwise defined, have the meanings set forth in the Merger Agreement.

At the effective time of the Merger (the "Effective Time"), each outstanding share of common stock, par value $0.01 per share, of Alimera, outstanding immediately prior to the Effective Time will automatically be converted into the right to receive (i) $5.50 in cash, without interest and (ii) one contingent value right (a "CVR"), which shall represent the right to receive the Milestone Payments (as defined below) subject to the terms and conditions set forth in the CVR Agreement (as defined below) (the consideration contemplated by (i) and (ii), together, the "Merger Consideration").

At or immediately prior to the Effective Time, the Company will enter into a contingent value rights agreement (the "CVR Agreement"), pursuant to which each holder of Alimera Common Stock, as well as holders of Alimera Warrants, Alimera Options, Alimera PSUs, Alimera RSAs and Alimera RSUs, may become entitled to contingent cash payments per CVR (each, a "Milestone Payment"), such payment(s) being contingent upon, and subject to, satisfaction of the Milestones (as defined below).

When issued, each CVR will entitle the holder (the "Holder") to receive Milestone Payments for 2026 and 2027, upon satisfaction of the applicable Milestones. The Milestone Payments for each CVR will equal the product (rounded to the nearest 1/100 of $0.01) of $0.25 multiplied by a fraction (which in no case will exceed one), and (i) for 2026, equals the amount, if any, by which the 2026 Net Revenue exceeds $140.0 million, divided by $10.0 million (subject to adjustment for the exercise price of Eligible Options), and (ii) for 2027, equals the amount, if any, by which the 2027 Net Revenue exceeds $160.0 million, divided by $15.0 million (subject to adjustment for the exercise price of Eligible Options) (the occurrence of the events in clauses (i) and (ii), each, a "Milestone").

The Merger Agreement requires Alimera, as promptly as reasonably practicable, and in any event within 25 business days following the date of the Merger Agreement, to prepare and file with the SEC a proxy statement for the purpose of seeking stockholder approval to the Merger Agreement. Alimera filed their preliminary proxy statement on July 24, 2024 with the SEC.

Consummation of the Merger is subject to certain conditions, including approval by Alimera's stockholders, the absence of any legal restraints restraining, enjoining, preventing, prohibiting or otherwise making illegal the consummation of the Merger, expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any other specified required regulatory approvals that may be required will have been obtained, and each party's performance of its obligations in all material respects under the Merger Agreement.

In connection with the Merger, JPMorgan Chase Bank, N.A. and Blackstone Credit & Insurance (the "Lenders") have committed to provide debt financing for the transaction in an aggregate principal amount equal to $280.0 million, on the terms and subject to the conditions set forth in a commitment letter, dated June 21, 2024 (the "Debt Commitment Letter"). The obligations of the Lenders to provide debt financing under the Debt Commitment Letter are subject to customary conditions, including, without limitation, execution and delivery of definitive documentation consistent with the Debt Commitment Letter.

During the three and six months ended June 30, 2024, the Company incurred approximately $3.5 million in transaction costs related to this pending Merger Agreement, all of which were expensed, and are included in Selling, general, and administrative on the condensed consolidated statements of operations.

4. RESTRUCTURING

On March 31, 2023 the Company ceased operations at the Oakville, Ontario, Canada manufacturing plant. This action was part of ongoing initiatives to capture operational synergies following the acquisition of Novitium in November 2021. ANI has fully completed the transition of the products manufactured or packaged in Oakville to one of the Company's three U.S. based manufacturing sites.

There were no restructuring activities recorded in the three or six months ended June 30, 2024 and as of June 30, 2024, there was no severance or other employee benefits accrued on the unaudited interim condensed consolidated balance sheet.

For the three months ended June 30, 2023, restructuring activities resulted in an immaterial amount of expenses, and for the six months ended June 30, 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.

In conjunction with the exit of the Canadian facility, the Company determined that the land and building at the Oakville, Ontario, Canada plant (the "Property") will be sold together and met the criteria to be classified as held for sale as of June 30, 2023. The land and building had a net carrying value of approximately $8.0 million, which was presented as assets held for sale on the accompanying condensed consolidated balance sheet at December 31, 2023. These assets were part of the Generics, Established Brands, and Other segment. As of June 30, 2024 these assets were sold.

On February 15, 2024, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement (the "Agreement") with 1540700 Ontario Limited ("Buyer") for the sale of the Property for a total purchase price of $19.2 million Canadian Dollars, or approximately $14.2 million, based on the exchange rate at closing. On March 28, 2024 the Company completed the sale of the Property. After payment of commissions, real estate taxes, and other related costs of approximately $0.7 million, the Company received a net proceeds of approximately $13.5 million at closing. The gain on the sale of the Property was approximately $5.3 million, recorded in the unaudited interim condensed consolidated statements of operations for the six months ended June 30, 2024.

5. INDEBTEDNESS

Credit Facility

On November 19, 2021, the Company completed its acquisition of Novitium pursuant to the terms of the Agreement and Plan of Merger, dated as of March 8, 2021 (the "Novitium 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 the Company.

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 Novitium Merger Agreement, repay the existing credit facility, and pay fees, costs and expenses incurred in connection with the merger. The Term Facility matures in November 2027 and the Revolving Facility in November 2026. The Credit Facility has a subjective acceleration clause in case of a material adverse effect.

In July 2023, the Company amended its Credit Agreement to transition from London Interbank Offered Rate ("LIBOR") to the Secured Overnight Finaning Rate ("SOFR") due to the cessation of LIBOR pursuant to the terms of Amendment No.1 to the Credit Agreement ("Amendment No. 1"). SOFR was applied to the Credit Facility for the interest period (as defined in the Credit Agreement) beginning on August 1, 2023 and replaced all LIBOR terms.

The Credit Facility permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread as defined in the Credit Facility. As of June 30, 2024, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

The interest rate under the Term Facility was 11.44% at June 30, 2024.

The Company 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. A commitment fee of 0.5% per annum is assessed on any unused portion of the Revolving Facility.

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 June 30, 2024 and December 31, 2023 are:

	Current	
(in thousands)	**June 30, 2024**	**December 31, 2023**
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)	**June 30, 2024**	**December 31, 2023**
Non-current borrowing on debt	$ 289,500	$ 291,000
Deferred financing costs	(5,106)	(6,181)
Non-current debt, net of deferred financing costs and current component	$ 284,394	$ 284,819

As of June 30, 2024, outstanding principal was $292.5 million on the Term Facility. Of the $0.6 million of unamortized deferred debt issuance costs allocated to the Revolving Facility, $0.3 million is included in other non-current assets in the unaudited interim condensed consolidated balance sheets, and $0.3 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets.

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

(in thousands)	**Term Facility**
2024 (remainder of the year)	$ 1,500
2025	3,000
2026	3,000
2027	285,000
Total	$ 292,500

The following table sets forth the components of total interest expense related to the Term Facility during the three and six months ended June 30, 2024 and 2023, as recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three and six months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Contractual coupon	$ 6,848	$ 7,620	$ 13,761	$ 14,970
Amortization of finance fees	591	591	1,182	1,182
Capitalized interest	(151)	(277)	(263)	(298)
	$ 7,288	$ 7,934	$ 14,680	$ 15,854

6. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

In April 2020, the Company entered into an interest rate swap with Citizens Bank, N.A. to manage its exposure to changes in LIBOR-based interest rates underlying total borrowings under term facilities related to the prior credit agreement, and 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.

As described further below, the Company amended its Credit Agreement to transition from LIBOR to SOFR due to the cessation of LIBOR, and accordingly, the interest rate swap transitioned from LIBOR to SOFR. The swap is used to manage changes in SOFR-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 June 30, 2024, the notional amount of the interest rate swap was $139.4 million and decreased quarterly by approximately $4.0 million until December 2023, after which it remains static until maturity in December 2026. As of June 30, 2024, the fair value of the interest rate swap asset recorded in other non-current assets in the unaudited interim condensed consolidated balance sheets was $7.4 million. As of June 30, 2024, $8.5 million was recorded in accumulated other comprehensive (loss) income, net of tax in the unaudited interim condensed consolidated balance sheets.

During the three and six months ended June 30, 2024, the loss on the fair value of the interest rate swaps, net of tax recorded in accumulated other comprehensive (loss) income in the unaudited interim condensed consolidated statements of comprehensive income was approximately $1.1 million and $0.5 million, respectively. Differences between the hedged SOFR 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 SOFR rate. In the three and six months ended June 30, 2024, the Company recorded a reduction in interest expense of $1.6 million and $3.2 million in relation to the interest rate swaps, respectively. In the three and six months ended June 30, 2023, the Company recorded a reduction in interest expense of $0.6 million and $1.1 million in relation to the interest rate swaps, respectively. Included in this amount for the three and six months ended June 30, 2024 are reclassifications out of accumulated other comprehensive (loss) income of $0.2 million of interest income and $0.4 million, respectively, related to terminated and de-designated cash flow hedges. Included in this amount for the three and six months ended June 30, 2023 are reclassifications out of accumulated other comprehensive (loss) income of $0.7 million of interest income and $0.7 million, respectively, related to terminated and de-designated cash flow hedges.

In conjunction with the amendment of the Credit Agreement (see Note 5), the Company's derivative positions automatically transitioned to SOFR, the designated fallback terms, as determined by the International Swaps and Derivatives Association on August 1, 2023. Concurrently, the Company updated its hedge documentation to reflect the change of the benchmark index, which changed solely as a result of reference rate reform. Under ASC 848, *Reference Rate Reform*, hedge accounting may continue without de-designation if certain criteria are met. For cash flow hedges in which the designated hedged risk is LIBOR (or another rate that is expected to be discontinued), the guidance allows an entity to assert that it remains probable that the hedged forecasted transaction will occur. The Company applied the optional expedient within ASC 848 to conclude the updates to the hedge relationship due to reference rate reform did not have a material impact on the Company's consolidated financial statements.

7. EARNINGS PER SHARE

Basic earnings per share is computed by dividing net income 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, diluted earnings per share is calculated 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 the 2016 Employee Stock Purchase Plan ("ESPP"), 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.

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. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for the three months ended June 30, 2024, diluted net loss per share attributable to common shareholders is the same as basic net loss per share attributable to common shareholders for this period.

Earnings per share for the three and six months ended June 30, 2024 and 2023 are calculated for basic and diluted earnings per share as follows:

	Basic		Diluted		Basic		Diluted	
(in thousands, except per share amounts)	**Three Months Ended June 30,**		**Three Months Ended June 30,**		**Six Months Ended June 30,**		**Six Months Ended June 30,**	
	2024	**2023**	**2024**	**2023**	**2024**	**2023**	**2024**	**2023**
Net (loss) income available to common shareholders	$ (2,694)	$ 5,838	$ (2,694)	$ 5,838	$ 15,107	$ 6,871	$ 15,107	$ 6,871
Earnings allocated to participating securities	—	(589)	—	(589)	(1,499)	(716)	(1,474)	(716)
Net (loss) income available to common shareholders	$ (2,694)	$ 5,249	$ (2,694)	$ 5,249	$ 13,608	$ 6,155	$ 13,633	$ 6,155
Basic Weighted-Average Shares Outstanding	19,321	17,688	19,321	17,688	19,210	17,044	19,210	17,044
Dilutive effect of common stock options, ESPP, and performance stock units			—	167			351	133
Diluted Weighted-Average Shares Outstanding			19,321	17,855			19,561	17,177
(Loss) earnings per share	$ (0.14)	$ 0.30	$ (0.14)	$ 0.29	$ 0.71	$ 0.36	$ 0.70	$ 0.36

The number of shares of potentially dilutive securities excluded from the computation of diluted net loss per share attributable to common stockholders was 2.8 million for the three months ended June 30, 2024 because including them would have been anti-dilutive.

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, was 2.3 million for the six months ended June 30, 2024.

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, was 2.5 million for the three and six months ended June 30, 2023.

8. INVENTORIES

Inventories consist of the following as of:

(in thousands)	**June 30, 2024**	**December 31, 2023**
Raw materials	$ 62,584	$ 62,237
Packaging materials	10,434	9,617
Work-in-progress	4,775	3,144
Finished goods	47,655	36,198
Inventories	$ 125,448	$ 111,196

Vendor Concentration

Raw materials are sourced for 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, the Company is dependent upon our current vendors to reliably supply the API required for on-going product manufacturing. During the three and six months ended June 30, 2024, approximately 27% and 24%, respectively, of our raw material purchases were from one supplier. During the three and six months ended June 30, 2023, no single vendor represented more than 10% of our raw material inventory purchases.

9. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of the 2013 merger with BioSante Pharmaceuticals, Inc., the Company recorded goodwill of $1.8 million. As a result of the acquisition of WellSpring Pharma Services Inc. in 2018, the Company recorded goodwill of $1.7 million. From the acquisition of Novitium in 2021, the Company recorded goodwill of $24.6 million. As of June 30, 2024, the Company has two operating segments, which were also deemed the Company's two reporting units, Generics, Established Brands, and Other reporting unit and the Rare Disease reporting unit. All of the goodwill is recorded in the Generics, Established Brands, and Other reporting unit.

Goodwill is reviewed for impairment at least annually, at October 31, or more frequently if a triggering event occurs between impairment testing dates. The Company's impairment assessment begins with a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying value. Qualitative factors may include, macroeconomic conditions, industry and market considerations, cost factors, and other relevant entity and Company specific events. If, based on the qualitative test, the Company determines that it is "more likely than not" that the fair value of a reporting unit is less than its carrying value, then we evaluate goodwill for impairment by comparing the fair value of our reporting unit to its respective carrying value, including its goodwill. If it is determined that it is "not likely" that the fair value of the reporting unit is less than its carrying value, then no further testing is required. There have been no events or changes in circumstances that would have reduced the fair value of the Generics, Established Brands, and Other reporting unit below its carrying value during the three and six months ended June 30, 2024 and 2023, no impairment charges have been recognized.

Intangible Assets

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

	June 30, 2024			December 31, 2023			Remaining Weighted Average Amortization Period(1)
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Definite-Lived Intangible Assets:							
Acquired ANDAs intangible assets	$ 209,780	$ (112,742)	$ 97,038	$ 209,780	$ (100,660)	$ 109,120	4.8 years
NDAs and product rights	244,871	(196,451)	48,420	244,871	(184,861)	60,010	2.8 years
Marketing and distribution rights	17,157	(14,752)	2,405	17,157	(14,271)	2,886	2.5 years
Customer relationships	24,900	(9,485)	15,415	24,900	(7,707)	17,193	4.3 years
Total Definite-Lived Intangible Assets	496,708	(333,430)	163,278	496,708	(307,499)	189,209	4.1 years
Indefinite-Lived Intangible Assets:							
In process research and development	19,800	—	19,800	19,800	—	19,800	Indefinite
Total Intangible Assets, net	$ 516,508	$ (333,430)	$ 183,078	$ 516,508	$ (307,499)	$ 209,009	

(1) Weighted average amortization period as of June 30, 2024.

Definite-lived intangible assets arising from business combinations and other asset acquisitions include intangibles such as Abbreviated New Drug Applications ("ANDAs"), New Drug Applications ("NDAs") and product rights, marketing and distribution rights, customer relationships, and non-compete agreements. Definite-lived intangible assets are amortized over the estimated period during which the asset is expected to contribute directly or indirectly to future cash flows. Definite-lived intangible assets are stated at cost, net of amortization, and generally amortized over their remaining estimated useful lives, ranging from seven to ten years, based on the straight-line amortization method. In the case of certain NDAs and product rights assets, an accelerated amortization method is used to better match the anticipated economic benefits expected to be provided. Definite-lived intangible assets are tested for impairment when events or changes in circumstances indicate that these asset might be impaired.

Amortization expense for definite-lived intangibles was $13.0 million and $12.8 million for the three months ended June 30, 2024 and 2023, respectively. Amortization expense for definite-lived intangibles was $25.9 million and $25.7 million for the six months ended June 30, 2024 and 2023, respectively.

No impairment losses were recognized in the three and six months ended June 30, 2024 and 2023.
Indefinite-lived intangible assets other than goodwill include primarily In-Process Research & Development ("IPR&D") projects. IPR&D intangible assets represent the fair value of technology acquired in a business combination or asset acquisition for which the technology projects are incomplete but have substance or alternative future use. When an IPR&D project is completed (generally upon receipt of regulatory approval), then the IPR&D will be accounted for as a definite-lived intangible asset.

Indefinite-lived intangible assets are not amortized, and the Company tests for impairment of indefinite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable, and the Company performs an asset impairment analysis annually, as of October 31. No impairment losses were recognized in the three and six months ended June 30, 2024 and 2023, respectively.

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

(in thousands)		
2024 (remainder of the year)	$	24,896
2025		47,592
2026		34,107
2027		25,140
2028		18,359
2029 and thereafter		13,184
Total	$	163,278

10. MEZZANINE AND STOCKHOLDERS' EQUITY

Stockholders' Equity

Authorized shares

The Company is 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 June 30, 2024.

There were 21.5 million and 21.1 million shares of common stock issued and outstanding as of June 30, 2024, respectively, and 20.7 million and 20.5 million shares of common stock issued and outstanding as of December 31, 2023, respectively.

Class C Special Stock

There were 11 thousand shares of class C special stock issued and outstanding as of June 30, 2024 and December 31, 2023. 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 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 upon liquidation, dissolution, or winding-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 Novitium Merger Agreement, and as financing for a portion of the acquisition, on March 8, 2021, the Company entered into an Equity Commitment and Investment Agreement with Ampersand 2020 Limited Partnership (the "PIPE Investor"), pursuant to which the PIPE Investor purchased 25,000 shares of 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 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 within the Company's 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 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 the 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 June 30, 2024, the PIPE shares are currently convertible into a maximum of 602,901 shares of common stock.

In case of a liquidation event, the holder of the PIPE Shares will be entitled to receive, in preference to holders of the Company's 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 common stock. The PIPE Shares will have voting rights, voting as one series with the holders of 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, 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 PIPE Investor would have received if it had converted into shares of common stock.

There were 25,000 shares of Series A convertible preferred stock outstanding as of June 30, 2024.

11. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, the Company commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of June 30, 2024, the Company had 0.1 million shares of common stock available under the ESPP. Under the ESPP, participants can purchase common shares of the Company's stock at a 15% discount on the lowest share price on the first day of the purchase period or the last day of the purchase period.

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Selling, general, and administrative	$ 137	$ 70	$ 276	$ 143
Cost of sales	30	18	60	30
Research and development	12	12	23	19
Total	$ 179	$ 100	$ 359	$ 192

Stock Incentive Plan

During the 2024 Annual Meeting of Stockholders held on May 21, 2024, the stockholders of the Company approved an amendment to the Amended and Restated Stock Incentive Plan (the "2022 Plan") (such amendment, the "2024 Stock Plan Amendment" and the 2022 Plan, after giving effect to the 2024 Stock Plan Amendment, the "Amended 2022 Stock Plan"). Subject to adjustment, the 2024 Stock Plan Amendment authorizes the issuance of an additional 1,610,000 shares.

As of June 30, 2024, 2.0 million shares of common stock were available for issuance under the Amended 2022 Stock Plan.

Stock Options

Outstanding stock options to purchase shares of common stock are 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.

From time to time, stock options are granted to employees through an inducement grant outside of the Amended 2022 Stock Plan to induce prospective employees to accept employment with the Company (the "Inducement Grants"). The options are granted at an exercise price equal to the fair market value of a share of 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 and RSAs granted to non-officer directors generally vest over a period of one year.

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. Upon vesting, unrestricted shares of common stock are delivered to employees and directors.

Performance-Based Restricted Stock Units

February 28, 2023 Performance-Based Restricted Stock Units Grant

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 common stock or a combination of both, contingent upon the achievement of specified performance objectives during a specified performance period. PSUs granted to date vest over a three-year performance period. On February 28, 2023, as part of the Company's 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% (83,942 shares, net of forfeitures) 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% (83,942 shares, net of forfeitures) 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. The Company 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.

February 14, 2024 Performance-Based Restricted Stock Units Grant

On February 14, 2024, the Company granted 73,588 PSUs to officers and employees of the Company under the 2022 Plan (66,433 to officers of the Company). PSU performance will be measured over a three-year performance period from January 1, 2024 through December 31, 2026 and will cliff-vest contingent upon the achievement of specified performance objectives. Of these PSUs, 50% were MPRSUs, vesting of which is contingent upon the Company meeting certain TSR levels as compared to a select peer group over the over three years starting January 1, 2024, and 50% of the PSUs were 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, 2024. Both the MPRSUs and the PRSUs have a maximum potential to vest at 200%.

The estimated grant date fair value per share of the MPRSUs was $85.65 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 estimated grant date fair value per share of the PRSUs was $56.10 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 Amended 2022 Stock Plan and Inducement Grants included in the accompanying unaudited interim condensed consolidated statements of operations:

(in thousands)	**Three Months Ended June 30,**		**Six Months Ended June 30,**	
	2024	**2023**	**2024**	**2023**
Selling, general, and administrative	$ 7,069	$ 4,766	$ 13,301	$ 8,673
Research and development	334	213	606	413
Cost of sales	282	170	532	309
Total	$ 7,685	$ 5,149	$ 14,439	$ 9,395

A summary of stock options (including Inducement Grants), RSA, and PSU activity under the Amended 2022 Stock Plan and Inducement Grants during the six months ended June 30, 2024 and 2023 is presented below:

(in thousands)	Options	PSUs	RSAs
Outstanding at December 31, 2022	907	—	1,141
Granted	3	85	624
Options Exercised/RSAs Vested	(26)	—	(338) [1]
Forfeited	(24)	—	(46)
Outstanding at June 30, 2023	860	85	1,381
Outstanding at December 31, 2023	689	84	1,351
Granted	—	74	606
Options Exercised/RSAs Vested	(54)	—	(433) [2]
Forfeited	—	—	(12)
Outstanding at June 30, 2024	635	158	1,512

[1] Includes 99 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 $4.1 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

[2] Includes 149 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 $10.0 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

12. INCOME TAXES

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

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of June 30, 2024, a valuation allowance was recorded 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.

The Company uses 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. The Company has not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. The Company recognizes interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; the Company did not have any such amounts accrued as of June 30, 2024 and December 31, 2023. The Company is subject to taxation in various U.S. jurisdictions, Canada, and India and all of its income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

For interim periods, the Company recognizes an income tax expense (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 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 permanent differences and discrete items result in variances to the effective tax rate from period to period. The Company's estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, and changes in 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 the Company has elected to treat GILTI inclusions as a period cost.

For the three months ended June 30, 2024, the Company recognized an income tax expense of $0.0 million. The Company's effective tax rate was 0.0% after discrete items for the three months ended June 30, 2024. The effective tax rate differed from the federal statutory rate of 21% primarily due to state taxes, stock based compensation, and non-deductible expenses related to the pending business combination.

For the three months ended June 30, 2023, the Company recognized an income tax benefit of $1.0 million. The Company's effective tax rate was (19.0)% for the three months ended June 30, 2023. The effective tax rate differed from the federal statutory rate of 21% primarily due to the recognition of the U.S. federal research and development credit, permanent differences, and discrete tax benefit primarily related to remeasurement of its gross deferred assets due to change in state deferred effective tax rate.

For the six months ended June 30, 2024, the Company recognized an income tax expense of $7.1 million. The Company's effective tax rate was 30.9% after discrete items for the six months ended June 30, 2024. The effective tax rate differed from the federal statutory rate of 21% primarily due to state taxes, stock based compensation, tax on the sale of the Oakville, Ontario manufacturing site, and recording of a withholding tax liability on the proceeds of the sale, and non-deductible expenses related to the pending business combination.

For the six months ended June 30, 2023, the Company recognized an income tax benefit of $0.3 million. The Company's effective tax rate was (3.7)% for the six months ended June 30, 2023. The effective tax rate differed from the federal statutory rate of 21% primarily due to the recognition of the U.S. federal research and development credit, permanent differences, and discrete tax benefit primarily related to remeasurement of gross deferred assets due to change in state deferred effective tax rate.

The Company does not expect that any law changes enacted during the period will have a material impact on the provision for income taxes.

13. COMMITMENTS AND CONTINGENCIES

Operating Leases

In April 2023, the Company entered into an agreement to lease additional warehouse space in East Windsor, New Jersey. The lease has a term of five years, and was classified as an operating lease. The lease was capitalized and included in other non-current assets on the accompanying unaudited condensed consolidated balance sheets. Additionally, during October 2023, the Company entered into an amendment for the Middleton, Wisconsin location which expanded the Company's square footage and also extended the termination date to December 2028.

Government Regulation

The Company's 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 ANI's products. The DEA and NCB maintain oversight over products that are considered controlled substances.

Unapproved Products
Four products, Esterified Estrogens and Methyltestosterone ("EEMT"), Opium Tincture, Thyroid Tablets, and Hyoscyamine are sold without approved NDAs or ANDAs. If the FDA took enforcement action against the Company, the Company may be required to seek FDA approval for the group of products or withdraw them from the market. During the three and six months ended June 30, 2024, net revenues from commercial sales of these products for these products totaled $6.8 million and $10.9 million, respectively.

During the three and six months ended June 30, 2023, net revenues from EEMT and Opium Tincture totaled $3.5 million and $7.2 million, respectively.

On December 27, 2023, the Company acquired from Alvogen, Inc. the rights to Hyoscyamine for total cash consideration of $2.0 million, which product was launched commercially in February 2024. Contract manufacturing revenues for Hyoscyamine, for both the three and six months ended June 30, 2024 were less than $0.1 million. Contract manufacturing revenues for Hyoscyamine, for three and six months ended June 30, 2023 were $0.5 million and $1.1 million, respectively.

Legal proceedings

The Company is, 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. While we believe that we have valid claims and/or defenses in the litigation and other matters described below, litigation is inherently unpredictable, particularly where the damages sought are substantial or indeterminate or when the proceedings, investigations or inquiries are in the early stages, 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 2023 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

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. The cases were consolidated in the United States District Court for the Southern District of New York. 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. After full briefing and oral argument, on February 21, 2023, the court granted the Company and the defendants' motion to dismiss all actions with prejudice. Plaintiffs filed an appeal in the Second Circuit. On May 13, 2024, the Second Circuit affirmed the district court's judgment, dismissing plaintiffs' claims with prejudice.

On March 4, 2024, ANI commenced a civil action against CG Oncology, Inc. f/k/a Cold Genesys, Inc. ("CG Oncology") in the Superior Court of the State of Delaware ("Delaware Action"). ANI's complaint alleges that, under an Assignment and Technology Transfer Agreement dated as of November 15, 2010 (the "November 2010 Agreement"), CG Oncology is liable to pay ANI a running royalty of 5% of the worldwide net sales of cretostimogene made by CG Oncology or any affiliate or sublicensee thereof; and that in February 2024, CG Oncology wrongfully repudiated its royalty obligation to ANI. On April 2, 2024, CG Oncology filed an answer and counterclaim (the "CGON Answer and Counterclaim") and concurrently moved for judgment on the pleadings or, in the alternative, for partial summary judgment (the "Motion for Summary Judgment"). CG Oncology's Motion for Summary Judgment seeks judgment declaring that the November 2010 Agreement does not "oblige CGON to pay royalties after expiration of the latest-running assigned patent." CG Oncology also seeks judgment awarding compensatory damages and punitive damages on counterclaims for alleged breach of the November 2010 Agreement and for alleged misappropriation of trade secrets under federal and Delaware state law. On April 22 and 25, 2024, ANI filed its reply to CG Oncology's counterclaims, denying any liability to CG Oncology and asserting additional counterclaims against CG Oncology ("Reply Counterclaims") for alleged breach of the November 2010 Agreement and, in the alternative, for unjust enrichment. ANI's Reply Counterclaims seek judgment (i) declaring that, under Section 3.3 of the November 2010 Agreement, CG Oncology is contractually obligated to pay ANI 5% of the worldwide net sales of cretostimogene made by CG Oncology or any affiliate or sublicensee thereof; (ii) dismissing CG Oncology's counterclaims with prejudice; (iii) awarding ANI compensatory damages as provided by law, including damages grounded in restitution and unjust enrichment; (iv) in the event of a judgment in ANI's favor on ANI's fourth counterclaim for unjust enrichment, ordering CG Oncology to re-transfer to ANI ownership of all assets that ANI sold to CG Oncology under the November 2010 Agreement, including, without limitation, all data and documentation comprising IND 12154; and (v) in the event of a judgment in ANI's favor on ANI's fourth counterclaim for unjust enrichment, imposing a constructive trust on all fruits of CG0070-related assets that ANI sold to CG Oncology under the November 2010 Agreement including, without limitation, all data and documentation comprising IND 12154 and any other IND that CG Oncology may have for CG0070. On May 15, 2024, CG Oncology filed a reply to ANI's counterclaims, which generally maintains the positions in the CGON Answer and Counterclaim. The parties are currently engaged in pretrial discovery. On June 7, 2024, CG Oncology filed a motion to stay discovery pending a decision by the court on its Motion for Summary Judgment. The court denied CG Oncology's motion to stay discovery at the conclusion of an oral hearing held on July 11, 2024. The hearing on CG Oncology's Motion for Summary Judgment is currently scheduled for August 22, 2024. ANI intends to vigorously pursue this matter.

On March 5, 2024, a complaint was filed against ANI by Acella Pharmaceuticals, LLC, in the United States District Court of Minnesota, asserting, among other things, false advertising under the Lanham Act, and unfair trade practices and false advertising under Minnesota law, relating to ANI's natural desiccated thyroid tablets USP. The complaint seeks injunctive relief, actual and consequential damages, disgorgement of profits, and attorneys' fees and costs. On April 16, 2024, ANI filed an answer to Acella's complaint, denying all claims, and asserting certain affirmative defenses, and counterclaims against Acella for false advertising of its thyroid product marketed as NP Thyroid® Tablets, under the Lanham Act, common law unfair competition and unfair and deceptive trade practices and false advertising under Minnesota and Georgia law. ANI seeks injunctive relief, compensatory damages, punitive damages and attorneys' fees and costs. On May 17, 2024, Acella filed a motion to dismiss ANI's counterclaims. On June 7, 2024, ANI filed an amended answer to Acella's complaint and counterclaims. Acella filed a motion to dismiss ANI's amended counterclaims on July 31, 2024. A hearing date has been set for September 11, 2024 on Acella's motion to dismiss. The case is currently in fact discovery until February 1, 2025. ANI disputes any liability in this matter and intends to defend this lawsuit vigorously.

Patent Litigation

On November 21, 2023, a complaint was filed against Novitium and certain other defendants in the case of Harmony Biosciences, LLC, Bioprojet Societe Civile de Recherche and Bioprojet Pharma SAS v. AET Pharma US, Inc., Annora Pharma Private Limited, Novitium Pharma LLC, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited in the United States District Court for the District of Delaware, asserting, among other things, that Novitium's proposed pitolisant hydrochloride drug product, which is subject to Novitium's Abbreviated New Drug Application, infringes certain U.S. patents. The complaint seeks damages, injunctive relief, attorneys' fees and costs. On January 29, 2024, Novitium filed its answer, denying all allegations and asserting counterclaims of non-infringement and invalidity. On February 16, 2024, plaintiffs filed their answer, denying Novitium's counterclaims and asserting certain affirmative defenses against Novitium. On April 15, 2024, the court consolidated Novitium's case and two other cases brought by plaintiffs against Lupin Limited et al, and MSN Pharms. Inc. et al., into one consolidated matter filed in C.A. No. 23-1286-JLH. The case is currently in discovery. The court set a trial date of February 2026. Novitium disputes any liability in this matter.

Ranitidine Related Litigation

Federal Court Multi District Litigation

ANI and Novitium were named as defendants, along with numerous other brand and generic pharmaceutical manufacturers, wholesale distributors, retail pharmacy chains, and repackagers of ranitidine-containing products, in *In re: Zantac/Ranitidine NDMA Litigation* (MDL No, 2924), filed in the United District Court for the Southern District of Florida (the "MDL Court"). Plaintiffs allege that defendants failed to disclose and/or concealed the alleged inherent presence of N-Nitrosodimethylamine (or "NDMA") in brand-name Zantac or generic ranitidine and the alleged associated risk of cancer. While ANI was initially a defendant, the lead plaintiff attorneys voluntarily dismissed ANI as a defendant in the Master Complaint. On July 8, 2021, the MDL Court dismissed all claims by all plaintiffs against the generic drug manufacturers with prejudice , on preemption grounds. The MDL Court also dismissed all claims by all plaintiffs against the brand manufacturers on summary judgment. Plaintiffs appealed the MDL Court's dismissals to the Eleventh Circuit Court of Appeals. On November 7, 2022, the Eleventh Circuit affirmed the MDL Court's dismissal of cases brought by third-party payors. The Eleventh Circuit raised questions in the appeals of the other cases about the finality of the MDL Court's judgments, which were resolved in September 2023. Plaintiffs filed opening briefs on April 10, 2024 and generics defendants filed their response on July 25, 2024.

ANI and Novitium dispute any liability in this matter.

State Court Personal Injury Litigation

ANI and Novitium have also been named as defendants in various state lawsuits.

California. The pending cases in California state court naming generic ranitidine manufacturers were transferred to an existing civil case coordination docket for pretrial proceedings (JCCP) in Alameda County. On September 21, 2023, plaintiffs filed a master complaint in the JCCP alleging strict liability, negligent failure to warn and general negligence, but not naming any generic defendants. In December 2023, the Keller Postman firm filed approximately 200 individual plaintiff short form complaints that name generic defendants. Novitium is named in 28 of the short form complaints which reference the claims for the master complaint, but has not been served. ANI is not named. On February 1, 2024, the generic defendants filed an omnibus demurrer challenging the sufficiency of the Keller Postman complaints, largely on the basis of preemption. On April 23, 2024, the California court granted the demurrer in part, dismissing all design defect claims against the generic defendants with prejudice on preemption grounds, but the court otherwise granted plaintiffs an opportunity for leave to amend their other claims against the generic defendants. Plaintiffs filed an amended master complaint on April 29, 2024. Novitium is named in one case and discovery is currently ongoing.

Pennsylvania. In September 2022, two complaints were filed naming Novitium as a defendant in Pennsylvania state court, Philadelphia County. 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 court dismissed all claims related to failure to warn/design defects on preemption grounds. The court also sustained the generics' preliminary objections relating to the counts of strict liability-design defect and breach of implied warranty to the extent Pennsylvania substantive law applies, effectively dismissing the generic defendants from the case unless and until a non-resident plaintiff names a generic in a short form complaint. Out of an abundance of caution, however, the generics, including Novitium, all filed answers to the long form complaint in June 2023. In January 2024, plaintiffs filed short form complaints naming generic defendants, including Novitium in one complaint. Generic defendants filed joint preliminary objections to the short form complaints based on preemption. The deadline for filing responses to these objections has passed and no amended complaint or response has been filed by plaintiffs against Novitium.

ANI and Novitium dispute any liability in these matters.

14. 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 SOFR and, because the variable interest rates approximate market borrowing rates available to us, we believe the carrying values of these borrowings approximated their fair values at June 30, 2024.

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

Money Market Funds

Money market funds are readily convertible into cash and the net asset value of each fund on the last day of the reporting period is used to determine its fair value. Money market funds are included in Cash and cash equivalents within the Consolidated Balance Sheet, and is classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. The Company does not adjust the quoted market price for such financial instruments. The fair value of the money market funds as of June 30, 2024 was approximately $166.5 million.

Interest Rate Swap

The fair value of the interest rate swap is estimated based on the present value of projected future cash flows using the SOFR forward rate curve (see Note 6). 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 6, the fair value of the interest rate swap was $7.4 million as of June 30, 2024, and was classified as a non-current asset.

CG Oncology Equity Securities
The Company currently holds 219,925 shares of common stock in CG Oncology (Nasdaq: CGON). The Company accounts for its investment in CG Oncology equity securities as an equity investment with a readily determinable fair value, as the securities are publicly traded on the Nasdaq Global Select Market. The fair value of the equity securities is based on its closing price on the Nasdaq and is classified within Level 1 of the fair value hierarchy because the equity securities are valued using quoted market prices. The Company does not adjust the quoted market price for such financial instruments. The fair value of the CG Oncology equity securities as of June 30, 2024 was approximately $6.9 million based on a closing market price of $31.57 on June 28, 2024. This amount is classified on the unaudited condensed consolidated statements of operations as Unrealized gain on investment in equity securities. Between 2013 and 2023, CG Oncology securities held by the Company were valued at zero under U.S. GAAP.

Contingent Consideration

In connection with the acquisition of Novitium, the Company may pay up to $46.5 million in additional consideration related to the achievement of certain milestones, such as 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 which are classified as Level 3 inputs, as the inputs are not based on readily available market data.

Pursuant to the terms of the Novitium Merger Agreement, on December 12, 2023, the Company paid $12.5 million of cash consideration to the Company Members, defined as the holders of Novitium ownership interests in the Novitium Merger Agreement, as the holders of Novitium ownership interests, for the achievement of the “ANDA Filing Earn-Out,” as defined in the Agreement (Note 15). Furthermore, on February 22, 2024, the Company paid $12.5 million to Company Members of Novitium upon the achievement of the “Gross Profit Earn-Out,” as defined in the Agreement (Note 15).

The fair value of the contingent consideration was approximately $11.9 million and $24.0 million as of June 30, 2024 and December 31, 2023, respectively, and is reflected as a current and non-current accrued contingent consideration liability in the unaudited interim condensed consolidated balance sheets.

The recurring Level 3 fair value measurements of contingent consideration for which a liability is recorded include the following significant unobservable inputs as of June 30, 2024:

Payment Type	Valuation Technique	Unobservable Input	Assumptions
Profit-based milestone payments	Probability-weighted discounted cash flow	Discount rate	13%
		Projected fiscal year of payment	2025-2035

The following table presents the changes in contingent consideration balances classified as Level 3 for the three and six months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2024	2023	2024	2023
Beginning balance	$ 11,574	$ 36,019	$ 23,984	$ 35,058
Payment of Gross-Profit earn-out	—	—	(12,500)	—
Change in fair value	359	1,035	449	1,996
Ending balance	$ 11,933	$ 37,054	$ 11,933	$ 37,054

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of June 30, 2024 and December 31, 2023, by level within the fair value hierarchy:

(in thousands) Description	Fair Value at June 30, 2024	Level 1	Level 2	Level 3
Assets				
Money Market Fund	$ 166,485	$ 166,485	$ —	$ —
Interest rate swap	$ 7,366	$ —	$ 7,366	$ —
CG Oncology - Investment in equity securities	$ 6,943	$ 6,943	$ —	$ —
Liabilities				
Contingent consideration	$ 11,933	$ —	$ —	$ 11,933

Description	Fair Value at December 31, 2023	Level 1	Level 2	Level 3
Assets				
Money Market Fund	$ 191,841	$ 191,841	$ —	$ —
Interest rate swap	$ 6,236	$ —	$ 6,236	$ —
Liabilities				
Contingent consideration	$ 23,984	$ —	$ —	$ 23,984

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

There are no financial assets or 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

There are no non-financial assets or 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

Long-lived assets, including property, plant, and equipment, right-of-use ("ROU") assets, intangible assets, and goodwill, are measured at fair value on a non-recurring basis, and no such fair value impairment was recognized in the three and six months ended June 30, 2024 and 2023.

15. RELATED PARTY TRANSACTIONS

PIPE Shares

On March 8, 2021, the Company entered into an Equity Commitment and Investment Agreement with the PIPE Investor, pursuant to which 25,000 shares were purchased for $1,000 per share for an aggregate purchase price of $25.0 million on November 19, 2021. The Chairman of the Company's board of directors is an operating partner of Ampersand Capital Partners, an affiliate of the PIPE Investor.

Novitium

In connection with the acquisition of Novitium, the Company entered into employment agreements with the two executives and founders of Novitium, Muthusamy Shanmugam, Head of R&D and COO of NJ Operations of ANI, and Chad Gassert, Sr. Vice President, Corporate Development and Strategy of ANI. 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, a majority interest in SS Pharma LLC ("SS Pharma"), which acquires and supplies API to Novitium, a minority interest in Nuray Chemical Private Limited ("Nuray"), which manufactured and supplied API to Novitium in prior periods, a majority interest in Esjay Pharma LLC ("Esjay"), which provides research and development and facilities consulting services, and a minority interest in SThree Chemicals Pvt Ltd ("SThree"), which acquires and supplies API to Novitium.

A summary of payments to related parties is presented below:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Scitus Pharma Services	$ 580	$ 1,188	$ 1,081	$ 1,905
SS Pharma LLC	176	1,978	1,245	3,579
SThree Chemicals Pvt Ltd	683	—	1,069	—
	$ 1,439	$ 3,166	$ 3,395	$ 5,484

As of June 30, 2024, the outstanding balances due to Scitus, SThree, and Esjay were $0.7 million, $2.2 million, and $46 thousand respectively. There was no outstanding balance due to SS Pharma.

On December 12, 2023, the Company paid $12.5 million of cash consideration to the Company Members of Novitium for the achievement of the "ANDA Filing Earn-Out," as defined in the Novitium Merger Agreement, as discussed in Note 2. The Company paid Mr. Shanmugam and Esjay, and Mr. Gassert's company Chali Properties LLC, approximately $6.7 million and $1.9 million, respectively, for their portion of the cash consideration due to them as part of the Novitium acquisition.

On February 22, 2024, the Company paid $12.5 million of cash consideration to the Company Members of Novitium for the achievement of the "Gross Profit Earn-Out," as defined in the Novitium Merger Agreement, as discussed in Note 2. The Company paid Mr. Shanmugam and Esjay, and Mr. Gassert's company Chali Properties LLC, approximately $6.7 million and $1.9 million, respectively, for their portion of the cash consideration due to them as part of the Novitium acquisition.

16. 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. The CODM for the Company is the Chief Executive Officer. The Company is organized into 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.

The CODM evaluates the 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.

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

Financial information by reportable segment is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Net Revenues				
Generics, Established Brands, and Other	$ 88,847	$ 92,243	$ 189,340	$ 182,699
Rare Disease	49,193	24,304	86,130	40,634
Total net revenues	$ 138,040	$ 116,547	$ 275,470	$ 223,333
Segment earnings before interest, taxes, depreciation and amortization ("EBITDA") and reconciliation to income before income taxes				
Generics, Established Brands, and Other	$ 31,631	$ 39,937	$ 76,937	$ 78,765
Rare Disease	4,344	4,215	4,740	2,964
Depreciation and amortization	(14,697)	(14,690)	(29,383)	(29,390)
Corporate and other unallocated expenses[(1)]	(16,109)	(17,060)	(26,813)	(30,042)
Total operating income	5,169	12,402	25,481	22,297
Unrealized (loss) gain on investment in equity securities	(2,712)	—	6,943	—
Interest expense, net	(4,656)	(7,100)	(9,256)	(14,796)
Other expense, net	(88)	(53)	(120)	(87)
(Loss) Income Before Income Tax Expense (Benefit)	$ (2,287)	$ 5,249	$ 23,048	$ 7,414

(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. This amount also includes the gain on the sale of the Oakville, Ontario site of approximately $5.3 million refer to Note 4 for further information.

Geographic Information

Operations are currently located in the United States and India. The Company has 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)	Three Months Ended June 30,		Six Months Ended June 30,	
Location of Operations	**2024**	**2023**	**2024**	**2023**
United States	$ 138,040	$ 116,547	$ 275,470	$ 222,768
Canada	—	—	—	565
Total Revenue	$ 138,040	$ 116,547	$ 275,470	$ 223,333

The following table depicts the Company's property, plant and equipment, net according to geographic location, which excludes the land and building at the Company's Canada facility, which was classified as held for sale as of December 31, 2023. These assets had a carrying value of approximately $8.0 million. The land and building at the Canada facility was sold on March 28, 2024, refer to Note 4. The Company's property, plant and equipment are as follows:

(in thousands)	June 30, 2024	December 31, 2023
United States	$ 49,887	$ 43,163
India	1,753	1,430
Total property and equipment, net	$ 51,640	$ 44,593

17. SUBSEQUENT EVENTS

On July 12, 2024, the Company filed a Registration Statement on Form S-8 with the SEC, to register under the Securities Act of 1933, as amended, 1,610,000 shares of common stock which may be issued from time to time in accordance with the Company's Amended 2022 Stock Plan.

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, 2023 (the "2023 Form 10-K"), 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 2023 Form 10-K, 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 2023 Form 10-K 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 scaling up our Rare Disease business through the launch of our lead asset, Cortrophin Gel, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our U.S.-based 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. We ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. We have fully completed the transition of the products manufactured or packaged in Oakville to one of our three U.S. based manufacturing sites. In February 2024, our Canadian subsidiary entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of $19.2 million Canadian Dollars, or approximately $14.2 million, based on the exchange rate at closing. The sale closed on March 28, 2024 (see Note 4).

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 overall strategy is enabled by an empowered, collaborative, and purposeful team with high performance-orientation that seeks to deliver on our purpose of "Serving Patients, Improving Lives."

Our growth strategy is driven by the following key growth drivers:

Building a successful Rare Disease platform

On June 24 2024, we announced that we entered into a definitive agreement pursuant to which we will acquire Alimera Sciences, Inc. ("Alimera"), which is currently expected to close late during the third quarter of 2024, subject to customary closing conditions, including receipt of required regulatory approvals and approval by Alimera's shareholders. The acquisition of Alimera is anticipated to strengthen our Rare Disease business and expand our footprint beyond the U.S. with the addition of Alimera's direct marketing operations located in Germany, the United Kingdom, Portugal, and Ireland, as well as its partnerships in Europe, Asia, and the Middle East.

Throughout 2023 and the first half of 2024, we continued to build and invest in our infrastructure to support growth in new areas of opportunity, such as pulmonology, ophthalmology, and gout in the ACTH market. On October 2, 2023, we announced FDA approval and commercial availability of a 1-mLvial of Cortrophin Gel, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares. As a result of the continued investment in our Rare Disease platform, our expenditures were significantly higher during the first half of 2024 as compared to the prior year.

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 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 this timeframe, 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.

We plan to continue to expand our Rare Disease business, through a combination of organic growth, as described above, and acquisition. See below for expanded discussion on our pending business combination with Alimera. While we continue to execute against our strategic initiatives that we believe will result in the long-term, sustainable growth and value to our stockholders, we continue to evaluate potential acquisitions and other strategic transactions of businesses that we believe complement our existing portfolio, infrastructure and capabilities or provide us with the opportunity to expand our existing capabilities.

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 in the Generics, Established Brands, and Other segment was the acquisition of Novitium in 2021, which included 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 ("CGT") designation filings. Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses.During 2023, we acquired two ANDAs and one pipeline product from the Chapter 7 Trustee for the estates of Akorn Holding Company and certain of its affiliates, acquired an ANDA and registered patents and pending patent applications from Slayback Pharma Limited Liability Company, and acquired additional ANDAs and product rights for two products in the second half of 2023. During 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.

Generic Product Development Considerations

We consider a variety of criteria in determining which products to develop. These criteria include:

- ***Formulation Complexity***. Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are differentiated and include high potency, modified release, combination, and hormonal products. This ability to manufacture a variety of differentiated products is a competitive strength that we intend to leverage in selecting products to develop and commercialize.
- ***Market Size and Patient Need***. When determining whether to develop or acquire an individual product, we review the current and expected market size for that product. and competitive environment. We endeavor to pursue products with sufficient market size to enable us to enter the market with a strong likelihood of serving patients in need and thus being able to price our products both competitively and at a profit.
- ***Profit Potential.*** In determining the potential profit of a product, we forecast our anticipated market share, pricing, competitive environment and the estimated cost to manufacture the products.
- ***Manufacturing.*** We generally seek to develop and manufacture products at our own manufacturing plants to ensure quality control of our products, supply chain reliability 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 manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies typically compete.

Recent Developments

Pending merger agreement

On June 21, 2024, the Company entered into an Agreement and Plan of Merger with Alimera and ANIP Merger Sub INC. ("Merger Sub"), providing for the merger of Merger Sub with and into Alimera (the "Merger"), with Alimera surviving the Merger as a wholly owned indirect subsidiary of the Company. Capitalized terms used herein, but not otherwise defined, have the meanings set forth in the Merger Agreement.

At the effective time of the Merger (the "Effective Time"), each outstanding share of common stock, par value $0.01 per share, of Alimera, outstanding immediately prior to the Effective Time will automatically be converted into the right to receive (i) $5.50 in cash, without interest and (ii) one contingent value right (a "CVR"), which shall represent the right to receive the Milestone Payments (as defined below) subject to the terms and conditions set forth in the CVR Agreement (as defined below) (the consideration contemplated by (i) and (ii), together, the "Merger Consideration").

At or immediately prior to the Effective Time, the Company will enter into a contingent value rights agreement (the "CVR Agreement"), pursuant to which each holder of Alimera Common Stock, as well as holders of Alimera Warrants, Alimera Options, Alimera PSUs, Alimera RSAs and Alimera RSUs, may become entitled to contingent cash payments per CVR (each, a "Milestone Payment"), such payment(s) being contingent upon, and subject to, satisfaction of the Milestones (as defined below).

When issued, each CVR will entitle the holder (the "Holder") to receive Milestone Payments for 2026 and 2027, upon satisfaction of the applicable Milestones. The Milestone Payments for each CVR will equal the product (rounded to the nearest 1/100 of $0.01) of $0.25 multiplied by a fraction (which is no case will exceed one), and (i) for 2026, equals the amount, if any, by which the 2026 Net Revenue exceeds $140.0 million, divided by $10.0 million (subject to adjustment for the exercise price of Eligible Options), and (ii) for 2027, equals the amount, if any, by which the 2027 Net Revenue exceeds $160.0 million, divided by $15.0 million (subject to adjustment for the exercise price of Eligible Options) (the occurrence of the events in clauses (i) and (ii), each, a "Milestone").

The Merger Agreement requires Alimera, as promptly as reasonably practicable, and in any event within 25 business days following the date of the Merger Agreement, to prepare and file with the SEC a proxy statement for the purpose of seeking stockholder approval to the Merger Agreement.

Consummation of the Merger is subject to certain conditions, including approval by Alimera's stockholders, the absence of any legal restraints restraining, enjoining, preventing, prohibiting or otherwise making illegal the consummation of the Merger, expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and any other specified required regulatory approvals that may be required will have been obtained, and each party's performance of its obligations in all material respects under the Merger Agreement.

In connection with the Merger, JPMorgan Chase Bank, N.A. and Blackstone Credit & Insurance (the "Lenders") have committed to provide debt financing for the transaction in an aggregate principal amount equal to $280.0 million, on the terms and subject to the conditions set forth in a commitment letter, dated June 21, 2024 (the "Debt Commitment Letter"). The obligations of the Lenders to provide debt financing under the Debt Commitment Letter are subject to customary conditions, including, without limitation, execution and delivery of definitive documentation consistent with the Debt Commitment Letter.

During the three and six months ended June 30, 2024, the Company incurred approximately $3.5 million, respectively, in transaction costs related to this pending Merger Agreement, all of which were expensed.

Restructuring

On February 15, 2024, ANI Pharmaceuticals Canada, Inc., a wholly owned subsidiary of the Company, entered into an agreement (the "Agreement") with 1540700 Ontario Limited ("Buyer") for the sale of ANI's Oakville, Ontario former manufacturing site (the "Property") for a total purchase price of $19.2 million Canadian Dollars, or approximately $14.2 million, based on the exchange rate at closing. During February 2024, and in accordance with the Agreement, the Buyer deposited a total of approximately $1.9 million Canadian Dollars, or approximately $1.4 million in refundable deposits in escrow as part of the total purchase price.

On March 28, 2024 the Company completed the sale of the Property. After payment of commissions, taxes, and other related costs of approximately $0.6 million, the Company received a net cash amount of approximately $13.5 million at closing. The gain on the sale of the Property was approximately $5.3 million, recorded in the unaudited interim condensed consolidated statements of operations.

GENERAL

Impacts to our second quarter 2024 and 2023 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 June 30,		Six Months Ended June 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Net Revenues	$ 138,040	$ 116,547	$ 275,470	$ 223,333
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	57,698	42,284	106,855	79,992
Research and development	7,296	7,374	17,807	13,298
Selling, general, and administrative	52,821	38,760	100,842	75,228
Depreciation and amortization	14,697	14,690	29,383	29,390
Contingent consideration fair value adjustment	359	1,035	449	1,996
Restructuring activities	—	2	—	1,132
Gain on sale of building	—	—	(5,347)	—
Operating Income	5,169	12,402	25,481	22,297
Unrealized (loss) gain on investment in equity securities	(2,712)	—	6,943	—
Interest expense, net	(4,656)	(7,100)	(9,256)	(14,796)
Other expense, net	(88)	(53)	(120)	(87)
(Loss) Income Before Income Tax Expense (Benefit)	(2,287)	5,249	23,048	7,414
Income tax expense (benefit)	—	(996)	7,128	(270)
Net (Loss) Income	$ (2,287)	$ 6,245	$ 15,920	$ 7,684

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Net Revenues	100 %	100 %	100 %	100 %
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	41.8 %	36.3 %	38.8 %	35.8 %
Research and development	5.3 %	6.3 %	6.5 %	6.0 %
Selling, general, and administrative	38.3 %	33.3 %	36.6 %	33.7 %
Depreciation and amortization	10.6 %	12.6 %	10.7 %	13.2 %
Contingent consideration fair value adjustment	0.3 %	0.9 %	0.2 %	0.9 %
Restructuring activities	— %	0.0%	— %	0.5 %
Gain on sale of building	— %	— %	(1.9)%	— %
Operating Income	3.7 %	10.6 %	9.1 %	9.9 %
Unrealized (loss) gain on investment in equity securities	(2.0)%	— %	2.5 %	— %
Interest expense, net	(3.4)%	(6.1)%	(3.4)%	(6.6)%
Other expense, net	(0.0)%	(0.0)%	(0.0)%	(0.0)%
(Loss) Income Before Income Tax Expense (Benefit)	(1.7)%	4.5 %	8.2 %	3.3 %
Income tax expense (benefit)	— %	(0.9)%	2.6 %	(0.1)%
Net (Loss) Income	(1.7)%	5.4 %	5.6 %	3.4 %

RESULTS OF OPERATIONS

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2024 AND 2023

Net Revenues

(in thousands)	Three Months Ended June 30, 2024	2023	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 73,964	$ 63,317	$ 10,647	16.8 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	14,883	28,926	(14,043)	(48.5)%
Generics, established brands, and other segment total net revenues	$ 88,847	$ 92,243	$ (3,396)	(3.7)%
Rare Disease Segment				
Rare disease pharmaceutical products	$ 49,193	$ 24,304	$ 24,889	102.4 %
Total net revenues	$ 138,040	$ 116,547	$ 21,493	18.4 %

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 June 30, 2024 were $138.0 million compared to $116.5 million for the same period in 2023, an increase of 18.4%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $74.0 million during the three months ended June 30, 2024, an increase of 16.8% compared to $63.3 million for the same period in 2023, driven by increased volumes and the inclusion of 2023 launches and new product launches in 2024. From a product perspective, the increase was principally driven by revenues from year over year increases in products such as Colestipol, Estradiol, Pentoxifylline, Pirfenidone, Thyroid, and various other products tempered by a decrease in revenues of Famotidine, Paliperidone, Misoprostol, and Nebivolol among others.

- Net revenues for branded pharmaceutical products, royalties, and other pharmaceutical services were $14.9 million during the three months ended June 30, 2024, a decrease of 48.5% compared to $28.9 million for the same period in 2023, driven by a net decrease in volume. During the three months ended June 30, 2023, we benefited from supplying incremental volume in markets that were experiencing supply chain disruptions for competing products.

- Net revenues of rare disease pharmaceutical products, which consists entirely of sales of Cortrophin Gel, were $49.2 million during the three months ended June 30, 2024, an increase of $24.9 million from $24.3 million for the same period in 2023. This increase was driven by increased volume in this third year of launch (product was launched in late January 2022).

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended June 30, 2024	2023	Change	% Change
Cost of sales (excluding depreciation and amortization)	$ 57,698	$ 42,284	$ 15,414	36.5 %

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

For the three months ended June 30, 2024, cost of sales increased to $57.7 million from $42.3 million for the same period in 2023, an increase of $15.4 million, or 36.5%. The increase is primarily due to significant net growth in sales volumes of pharmaceutical products and significant growth of royalty bearing products, including Cortrophin Gel.

Cost of sales, as a percentage of net revenues, increased to 41.8% from 36.3% for the three months ended June 30, 2024, compared to the same period in 2023, primarily due to a shift in product mix year over year, increase in sales volume, and increase in sales of products that bear a royalty payable.

During the three months ended June 30, 2024, approximately 27% of our raw material purchases were from one supplier. During the three months ended June 30, 2023, no single vendor represented more than 10% of our raw material inventory purchases.

Other Operating Expenses, net

(in thousands)	Three Months Ended June 30, 2024	2023	Change	% Change
Research and development	$ 7,296	$ 7,374	$ (78)	(1.1)%
Selling, general, and administrative	52,821	38,760	14,061	36.3 %
Depreciation and amortization	14,697	14,690	7	— %
Contingent consideration fair value adjustment	359	1,035	(676)	(65.3)%
Restructuring activities	—	2	(2)	(100.0)%
Total other operating expenses, net	$ 75,173	$ 61,861	$ 13,312	21.5 %

For the three months ended June 30, 2024, other operating expenses, net increased to $75.2 million from $61.9 million for the same period in 2023, an increase of $13.3 million, or 21.5%, primarily as a result of the following factors:

- Research and development expenses decreased from $7.4 million to $7.3 million, a nominal decrease of approximately $0.1 million or 1.1% when comparing the three months ended June 30, 2024 to the same period in 2023.
- Selling, general, and administrative expenses increased from $38.8 million to $52.8 million, an increase of $14.1 million, or 36.3%, due to increased employment related costs, continued investment in our Rare Disease segment sales and marketing activities, legal expenses, expenses related to the pending acquisition of Alimera, as well as an overall increase in activities required to support the growth of our business.
- Depreciation and amortization expense was $14.7 million for the three months ended June 30, 2024, compared to $14.7 million for the same period in 2023.

- We recognized losses of $0.4 million and $1.0 million in the three months ended June 30, 2024 and 2023, respectively, for the contingent consideration fair value adjustment. The change in the fair value adjustment during the three months ended June 30, 2024 is primarily related to changes in the anticipated timing of cash flows (i.e., moving closer to the anticipated payment dates of the consideration for the third milestone in connection with the acquisition of Novitium). Additionally, the fair value measurement adjustment in the three months ended June 30, 2024 is related to only the third milestone, whereas the fair value adjustment at June 30, 2023 related to all three milestones.

Other Expense, net

	Three Months Ended June 30,			
(in thousands)	2024	2023	Change	% Change
Unrealized loss on investment in equity securities	$ (2,712)	$ —	$ (2,712)	(100.0)%
Interest expense, net	(4,656)	(7,100)	2,444	(34.4)%
Other expense, net	(88)	(53)	(35)	66.0 %
Total other expense, net	$ (7,456)	$ (7,153)	$ (303)	4.2 %

For the three months ended June 30, 2024, we recognized total other expense of $7.5 million as compared to total other expense of $7.2 million for the same period in 2023, an increase of $0.3 million.

- We recorded an unrealized loss on our investment in equity securities held in CG Oncology of approximately $2.7 million is due to the mark to market to fair value of equity securities as of the balance sheet date. There was no comparable loss on investment in the three months ended June 30, 2023.

- Interest expense, net for the three months ended June 30, 2024 consists primarily of interest expense on borrowings under our Term Facility of approximately $8.5 million and amortization of deferred debt issuance costs of approximately $0.6 million, offset by dividend income earned on our money market funds and interest earned on our cash balances of approximately $2.6 million, the effects of the interest rate swap of approximately $1.6 million, and interest capitalized into construction in progress. The decrease in interest expense is primarily related to the increase in the dividend income and interest income earned on our larger cash balances during the current period, as interest expense on borrowing under our Term Facility and amortization of deferred debt issuance costs are consistent with the three months ended June 30, 2023.

Income Tax Expense (Benefit)

(in thousands)	Three Months Ended June 30, 2024	2023	Change	% Change
Income tax expense (benefit)	$ —	$ (996)	$ 996	(100.0)%

Income tax expense (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 June 30, 2024, we recognized an income tax expense of approximately $0.0 million. The Company's effective tax rate was 0.0% after discrete items for the three months ended June 30, 2024. The effective tax rate differed from the federal statutory rate of 21% primarily due to state taxes, stock based compensation, and non-deductible expenses related to the pending business combination which were treated as a discrete item during the quarter which affects the estimated tax rate.

For the three months ended June 30, 2023, we recognized an income tax benefit of $1.0 million. The income tax expense resulted from applying an estimated annual worldwide effective tax rate of (19.0)% to pre-tax consolidated income of $5.2 million reported during the period. There were no material discrete items occurring during the three months ended June 30, 2023.

RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2024 AND 2023

Net Revenues

(in thousands)	Six Months Ended June 30, 2024	2023	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 144,181	$ 127,030	$ 17,151	13.5 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	$ 45,159	$ 55,669	(10,510)	(18.9)%
Generics, established brands, and other segment total net revenues	$ 189,340	$ 182,699	$ 6,641	3.6 %
Rare Disease Segment				
Rare disease pharmaceutical products	86,130	40,634	45,496	112.0 %
Total net revenues	$ 275,470	$ 223,333	$ 52,137	23.3 %

Net revenues for the six months ended June 30, 2024 were $275.5 million compared to $223.3 million for the same period in 2023, an increase of 23.3%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $144.2 million during the six months ended June 30, 2024, an increase of 13.5% compared to $127.0 million for the same period in 2023, driven by increased volumes and the inclusion of 2023 launches and new product launches in 2024. From a product perspective, the increase was principally driven by revenues from year over year increases in products such as Colestipol, Estradiol,Lacosamide, Nitrofurantoin, Pentoxifylline, Pirfenidone, Prednisone, Tranexamic Acid, and various other products tempered by a decrease in revenues of Famotidine, Meloxicam, Nebivolol, Paliperidone, and Prochlorperazine among others.

- Net revenues for branded pharmaceutical products, royalties, and other pharmaceutical services were $45.2 million during the six months ended June 30, 2024, a decrease of 18.9% compared to $55.7 million for the same period in 2023, driven by a net decrease in volume. During the first quarter of 2024, we were successful in supplying incremental volume in markets that were experiencing supply chain disruptions for competing products, which did not continue into the second quarter of 2024.

- Net revenues of rare disease pharmaceutical products, which consists entirely of sales of Cortrophin Gel, were $86.1 million during the six months ended June 30, 2024, an increase of $45.5 million from $40.6 million for the same period in 2023. This increase was driven by increased volume in this third year of launch (product

was launched in late January 2022).

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Six Months Ended June 30, 2024	2023	Change	% Change
Cost of sales (excluding depreciation and amortization)	$ 106,855	$ 79,992	$ 26,863	33.6 %

For the six months ended June 30, 2024, cost of sales increased to $106.9 million from $80.0 million for the same period in 2023, an increase of $26.9 million, or 33.6%. The increase is primarily due to significant net growth in sales volumes of pharmaceutical products and significant growth of royalty bearing products, including Cortrophin Gel.

Cost of sales, as a percentage of net revenues, increased to 38.8% from 35.8% for the six months ended June 30, 2024, compared to the same period in 2023, primarily due to a shift in product mix year over year, increase in sales volume, and increase in sales of products that bear a royalty payable.

During the six months ended June 30, 2024, approximately 24% of our raw material purchases were from one supplier. During the six months ended June 30, 2023, no single vendor represented more than 10% of our raw material inventory purchases.

Other Operating Expenses, net

(in thousands)	Six Months Ended June 30, 2024	2023	Change	% Change
Research and development	$ 17,807	$ 13,298	$ 4,509	33.9 %
Selling, general, and administrative	100,842	75,228	25,614	34.0 %
Depreciation and amortization	29,383	29,390	(7)	— %
Contingent consideration fair value adjustment	449	1,996	(1,547)	(77.5)%
Restructuring activities	—	1,132	(1,132)	(100.0)%
Gain on sale of building	(5,347)	—	(5,347)	100.0 %
Total other operating expenses	$ 143,134	$ 121,044	$ 22,090	18.2 %

For the six months ended June 30, 2024, other operating expenses, net increased to $143.1 million from $121.0 million for the same period in 2023, an increase of $22.1 million, or 18.2%, primarily as a result of the following factors:

- Research and development expenses increased from $13.3 million to $17.8 million, an increase of $4.5 million or 33.9%, primarily due to a higher level of activity associated with ongoing and new projects in the six months ended June 30, 2024.
- Selling, general, and administrative expenses increased from $75.2 million to $100.8 million, an increase of $25.6 million, or 34.0%, due to increased employment related costs, continued investment in our Rare Disease segment sales and marketing activities, legal expenses, expenses related to the pending acquisition of Alimera, as well as an overall increase in activities required to support the growth of our business.
- Depreciation and amortization expense was $29.4 million for the six months ended June 30, 2024, compared to $29.4 million for the same period in 2023.

- We recognized losses of $0.4 million and $2.0 million in the six months ended June 30, 2024 and 2023, respectively, for the contingent consideration fair value adjustment. The change in the fair value adjustment during the six months ended June 30, 2024 is primarily related to changes in the anticipated timing of cash flows (i.e., moving closer to the anticipated payment dates of the consideration for the third milestone in connection with the acquisition of Novitium) and fluctuations in the discount rates, offset by adjustments recorded upon payment of the Gross Profit Earn-Out during the first quarter. Additionally, the fair value measurement adjustment in the six months ended June 30, 2024 is related to only the third milestone, whereas the fair value adjustment at June 30, 2023 related to all three milestones.

- We recognized restructuring activities expenses of $1.1 million in the six months ended June 30, 2023. In 2023 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. There were no restructuring expenses recognized in the six months ended June 30, 2024.

- We recognized a gain related to the sale of the former Oakville, Ontario manufacturing site of approximately $5.3 million during the six months ended June 30, 2024. There was no comparable sale in the six months ended June 30, 2023.

Other Expense, net

	Six Months Ended June 30,			
(in thousands)	2024	2023	Change	% Change
Unrealized gain on investment in equity securities	$ 6,943	$ —	$ 6,943	100.0 %
Interest expense, net	(9,256)	(14,796)	5,540	37.4 %
Other expense, net	(120)	(87)	(33)	37.9 %
Total other expense, net	$ (2,433)	$ (14,883)	$ 12,450	83.7 %

For the six months ended June 30, 2024, we recognized total other expense, net of $2.4 million as compared to total other expense of $14.9 million for the same period in 2023, a decrease of $12.5 million.

- The unrealized gain on investment in equity securities of approximately $6.9 million is due to the mark to market to fair value of equity securities held in CG Oncology as of the balance sheet date. There was no comparable gain on investment in the six months ended June 30, 2023.

- Interest expense, net for the six months ended June 30, 2024 consists primarily of interest expense on borrowings under our Term Facility of approximately $17.0 million and amortization of deferred debt issuance costs of approximately $1.2 million, offset by dividend income earned on our money market funds and interest earned on our cash balances of approximately $5.4 million, the effects of the interest rate swap of approximately $3.2 million, and interest capitalized into construction in progress. The decrease in interest expense is primarily related to the increase in the dividend income and interest income earned on our larger cash balances during the current period, as interest expense on borrowing under our Term Facility and amortization of deferred debt issuance costs are consistent with the six months ended June 30, 2023.

Income Tax Expense (Benefit)

(in thousands)	Six Months Ended June 30, 2024	2023	Change	% Change
Income tax expense (benefit)	$ 7,128	$ (270)	$ 7,398	(2740.0)%

For the six months ended June 30, 2024, we recognized an income tax expense of $7.1 million. The Company's effective tax rate was 30.9% after discrete items for the six months ended June 30, 2024. The effective tax rate differed from the federal statutory rate of 21% primarily due to state taxes, stock based compensation, tax on the sale of the Oakville, Ontario manufacturing site, and recording of a withholding tax liability on the proceeds of the sale, and non-deductible expenses related to a planned acquisition.

For the six months ended June 30, 2023, we recognized an income tax benefit of $0.3 million. The income tax expense resulted from applying an estimated annual worldwide effective tax rate of (3.7)% to pre-tax consolidated income of $7.4 million reported during the period. There were no material discrete items occurring during the six months ended June 30, 2023.

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. As of June 30, 2024, $3.0 million of principal of the loan was recorded as current borrowings in the condensed consolidated balance sheet. As of June 30, 2024, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

On June 21, 2024, in connection with the pending business combination with Alimera, JPMorgan Chase Bank, N.A. and Blackstone Credit & Insurance as Lenders committed to provide debt financing for the Merger in an aggregate principal amount equal to $280.0 million, on the terms and subject to the conditions set forth in the Debt Commitment Letter. Refer to Management's Discussion and Analysis of Financial Condition and Results of Operations in this Quarterly Report on Form 10-Q for further information regarding the Merger.

Equity Financing

In May 2023, through a public offering, we completed the issuance and sale of 2,183,545 shares of ANI common stock, resulting in net proceeds after issuance costs of $80.6 million. The proceeds are intended to be used to in-license, acquire or invest in additional businesses, technologies, products or assets, to fund our commercialization efforts, including, but not limited to, 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, our Credit Facility, under which $40.0 million remains available for borrowing as of June 30, 2024, and the anticipated debt financing provided by the Lenders for the Merger in an aggregate principal amount equal to $280.0 million, 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:

	Six Months Ended June 30,	
(in thousands)	**2024**	**2023**
Operating Activities	$ 35,683	$ 42,050
Investing Activities	$ 4,484	$ (9,179)
Financing Activities	$ (21,178)	$ 75,602

Net Cash Provided by Operations

Net cash provided by operating activities was $35.7 million for the six months ended June 30, 2024, compared to net cash provided by operating activities of $42.1 million during the same period in 2023, a decrease of $6.4 million. The decrease in cash provided by operating activities resulted from an increase in non-cash items such as stock-based compensation offset by non-recurring transactions such as gain on the sale of the Oakville, Ontario manufacturing site, and the gain on investment of equity securities as well as significant fluctuations in our assets and liabilities due to increased activities.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2024 was $4.5 million, principally due to the proceeds received from the sale of the Oakville, Ontario manufacturing site in March 2024 of approximately $13.5 million offset by capital expenditures of approximately $9.0 million. Net cash used in investing activities for the six months ended June 30, 2023 was $9.2 million, principally due to $4.9 million of capital expenditures and acquisitions of ANDAs from the estates of Akorn Holding Company for $4.3 million.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities for the six months ended June 30, 2024 was $21.2 million, principally resulting from $12.5 million paid to the Company Members of Novitium, $10.0 million of treasury stock purchased related to restricted stock vests, $1.5 million maturity payments on the Term Facility, and $0.8 million convertible preferred stock dividends paid, offset by $3.6 million from proceeds from stock option exercises and ESPP purchases. Net cash provided by financing activities for the six months ended June 30, 2023 was $75.6 million, principally due to $80.6 million in proceeds from the May 2023 public offering and $1.4 million from proceeds from stock option exercises and ESPP purchases. This is offset by cash used in financing activities related to $4.1 million of treasury stock purchased in relation to restricted stock vests, $1.5 million maturity payments on the Term Facility, and $0.8 million convertible preferred stock dividends paid.

CRITICAL ACCOUNTING ESTIMATES

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 2023 Form 10-K. 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. There have been no material changes to our critical accounting estimates since the 2023 Form 10-K.

CONTRACTUAL OBLIGATIONS

As of June 30, 2024, our contractual obligations have not changed materially from the amounts reported in our 2023 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks include interest rate risk, equity risk, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, interest rate risk, equity risk, and foreign currency exchange rate risk could have a significant impact on our results of operations. There have been no material changes in our exposure to market risks since the end of the most recent fiscal year as reported in Part II, Item 7A of our 2023 Form 10-K.

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of June 30, 2024. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, during the quarter ended June 30, 2024 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 13, *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 2023 Form 10-K 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.

The following are new significant risk factors related to the pending acquisition of Alimera that could materially harm our business, financial position, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report.

Risks Related to the Merger

The Merger is subject to a number of conditions beyond our control. Failure to complete the Merger within the expected time frame, or at all, could have a material adverse effect on our business, operating results, financial condition and our share price.

On June 21, 2024, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Alimera and ANIP Merger Sub INC., a Delaware corporation and wholly owned indirect subsidiary of us ("Merger Sub"), pursuant to which, and on the terms and subject to the conditions set forth therein, (i) Merger Sub will be merged with and into Alimera (the "Merger"), with Alimera surviving the Merger as a wholly owned subsidiary of ANI and (ii) at the effective time of the Merger, each outstanding share of Alimera common stock, par value $0.01 per share, will automatically be converted into the right to receive (A) $5.50 in cash, without interest and less any applicable withholding taxes, and (B) one contingent value right (a "CVR"). Capitalized terms used herein, but not otherwise defined, have the meanings set forth in the Merger Agreement.

Consummation of the Merger is subject to certain conditions, including approval by Alimera's stockholders, the absence of any legal restraints restraining, enjoining, preventing, prohibiting or otherwise making illegal the consummation of the Merger, expiration or termination of the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, with such waiting period having expired on July 29, 2024 and any other specified required regulatory approvals that may be required will have been obtained, and each party's performance of its obligations in all material respects under the Merger Agreement.

We cannot predict whether and when the conditions to the Merger will be satisfied. If one or more of these conditions are not satisfied, and as a result, we do not complete the Merger, we would remain liable for significant transaction costs, and the focus of our management would have been diverted from seeking other potential strategic opportunities, in each case without realizing any benefits of the Merger. Certain costs associated with the Merger have already been incurred or may be payable even if the Merger is not consummated. Finally, any disruptions to our business resulting from the announcement and pendency of the Merger, including any adverse changes in our relationships with our partners, suppliers and employees, could continue or accelerate in the event that we fail to consummate the Merger.

Our share price may also fluctuate significantly based on announcements by Alimera, other third parties, or us regarding the Merger or based on market perceptions of the likelihood of the satisfaction of the conditions to the consummation of the Merger. Such announcements may lead to perceptions in the market that the Merger may not be completed, which could cause our share price to fluctuate or decline. Other factors outside of our control, such as a governmental entity enacting legislation that prohibits the Merger, could cause us not to satisfy the governmental entity condition and thus the Merger would not be consummated.

If we do not consummate the Merger, the price of our common stock may decline significantly from the current market price, which may reflect a market assumption that the Merger will be consummated. Any of these events could have a material adverse effect on our business, operating results and financial condition and could cause a decline in the price of our common stock.

Actions of activist stockholders or other parties may impair our ability to consummate the Merger.

Activist stockholders could also take actions that disrupt the business of Alimera, divert the time and attention of their management and employees away from their business operations, cause them to incur substantial additional expense, create perceived uncertainties among current and potential customers, clients, suppliers, employees and other constituencies as to their future direction as a consequence thereof, which may result in lost sales, impaired supplier relationships or other business arrangements and the loss of potential business opportunities, and make it more difficult to attract and retain qualified personnel and business partners.

We have incurred, and will continue to incur, direct and indirect costs as a result of the Merger.

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the Merger, including costs that we may not currently expect. We must pay substantially all of these costs and expenses whether or not the transaction is completed. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. To the extent these acquisition and integration expenses are higher than anticipated, we may experience liquidity or cash flow issues. Among other termination rights, and subject to certain limitations, each of Alimera and ANI may terminate the Merger Agreement if the Merger is not consummated by December 21, 2024, and each of Alimera and ANI may mutually agree to terminate the Merger Agreement.

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

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

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

In connection with the acquisition, JP Morgan Chase Bank, N.A. and Blackstone Credit & Insurance have committed to provide debt financing for the transaction in an aggregate principal amount equal to $280.0 million, on the terms and subject the conditions set forth in a commitment letter, dated June 21, 2024 (the "Debt Commitment Letter"). In order to service the debt we incur under the Debt Commitment Letter, we will require a significant amount of cash. Our ability to make scheduled payments of principal and interest depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional debt or equity financing on terms that may not be favorable to us or available to us at all. Our ability to refinance any such debt will depend on the capital markets and our financial condition at that time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default under our current or future indebtedness. Any event of default or inability to otherwise satisfy our obligations could have a material adverse effect on our future operating results and financial condition.

As a result of the Merger, we will record goodwill in connection with our acquisition of Alimera, and if it becomes impaired, our earnings could be significantly impacted.

Under current accounting methods, goodwill is not amortized but, instead, is subject to impairment tests on at least an annual basis and more frequently if an event occurs or circumstances change that reduce the fair value of a reporting unit below its carrying amount. In connection with our acquisition of Alimera we will record goodwill in the fair value amount of such acquisition. Although we do not anticipate impairment charges, if we conclude that some portion of such goodwill is impaired, a non-cash charge for the amount of such impairment would be recorded against earnings.

A goodwill impairment charge could be caused by a decline in our stock price or the occurrence of a triggering event that compounds negative financial results. Therefore, following the Merger, and our recording of goodwill in connection therewith, if such goodwill becomes impaired, our earnings could be significantly and adversely affected.

The Merger may become the target of securities class action and derivative lawsuits that could result in substantial costs and may delay or prevent the Merger from being completed.

Securities class action lawsuits and derivative lawsuits are often brought against public companies that have entered into merger agreements. The outcome of any litigation is uncertain, but regardless of the outcome of any such lawsuits, they could delay or prevent the Merger or otherwise adversely affect us financially.

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

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

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

Further, we intend to enter into the Merger with the expectation that the acquisition will result in, among other things, benefits relating to enhanced revenues, a strengthened market position for the combined company and operating efficiencies. Achieving the benefits of the Merger is subject to a number of uncertainties, including whether we integrate Alimera in an efficient manner, and general competitive factors in the marketplace. The occurrence of any of these Merger-related events individually or in combination could materially and adversely affect our business, results of operations, financial condition and the market price of our common stock.

Following the closing of the Merger, if we fail to successfully manage our international operations, our business, operating results and financial condition could suffer.

Alimera has direct operations and markets its products outside the United States, with international operations that cover the United Kingdom and much of Europe and the Middle East. We have not historically conducted any operations or marketed any of our products outside the United States. As a result, following the closing of the Merger, the percentage of our revenues generated outside of the United States will increase materially, and our new international operations will require significant management attention and financial resources.

There is a high level of regulation in all markets where Alimera's products are sold and great diversity in how those markets operate. Consequently, experience and expertise will be required in understanding the market dynamics of each country, the rules and regulations in place governing the sale of medicines, the codes of practice governing promotion of medicines, different currencies, the financial frameworks applying to taxation (both corporate and value-added tax) and the need to communicate in different languages.

Moreover, Alimera's international operations rely on distributors in many countries to provide adequate levels of experience and expertise on its behalf. We will need to monitor and manage these relationships appropriately to address risks in these markets.

Conducting extensive international operations subjects us to risks that are inherent in international operations, including:

- extended collection timelines for accounts receivable and greater working capital requirements;
- multiple, conflicting legal systems and unexpected changes in legal requirements such as privacy and data protection laws and regulations, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- tariffs, export restrictions, trade barriers and other regulatory or contractual limitations on our ability to sell or develop our products in certain foreign markets, including China and certain other parts of Asia;
- changes in currency exchange rates;
- currency transfer and other restrictions and regulations that may limit our ability to sell our products internationally or repatriate profits to the United States;
- difficulties adapting to new cultures, business customs, and legal systems;
- trade laws and business practices favoring local competition;
- potential tax issues, including restrictions on repatriating earnings, resulting from multiple, conflicting and complex tax laws and regulations;
- weaker intellectual property protection in some countries;
- natural disasters, political, economic, and social instability, including the effects of ongoing U.S.-China diplomatic and trade friction, social unrest in China, the recent conflicts between Russia and Ukraine, Israel and Hamas, and global sanctions imposed in response thereto, the possibility of a wider European or global conflict, or other war or terrorist activities or the threat of war and terrorism; and
- adverse economic conditions, including increasing inflation and the stability and solvency of business financial markets, financial institutions and sovereign nations.

In particular, regulatory oversight of pharmaceutical products, including production, marketing and sales, can vary significantly among countries and will require additional oversight by our compliance and marketing teams. We will need to spend significantly more time and invest in additional resources to ensure compliance with regulatory regimes outside the United States. Similarly, there are often supply chain risks that are specific to a given region, and our expansion outside the United States will expose us to additional risks and expenses related thereto.

In addition, compliance with foreign and U.S. laws and regulations that are applicable to our international operations is complex and may increase our cost of doing business in international jurisdictions, and our international operations could expose us to fines and penalties if we fail to comply with these regulations. These laws and regulations include import and export requirements, U.S. laws such as the Foreign Corrupt Practices Act, and local laws prohibiting corrupt payments to governmental officials. Although we intend to implement policies and procedures designed to help ensure compliance with these laws, there can be no assurance that our employees, partners and other persons with whom we do business will not take actions in violation of our policies or these laws. Any violations of these laws could subject us to civil or criminal penalties, including substantial fines or prohibitions on our ability to offer our products in one or more countries, and could also materially and adversely harm our business and financial condition.

Following the closing of the Merger, we will need to meet certain additional requirements for our international operations, including adequate levels of reimbursement and various regulatory approvals, and our inability to meet these requirements could adversely affect our results of operations.

Following the closing the Merger, we will have certain additional requirements that we will need to meet in order to engage in international operations. For example, in the European Economic Area ("EEA") and the United Kingdom, each country has a different reviewing body that evaluates reimbursement dossiers submitted by marketing authorization holders of new

drugs and then makes recommendations as to whether or not the drug should be reimbursed. Limitations on reimbursement could be imposed at the national, regional or local level or by fiscal intermediaries in each country, either through the initial authorization process or at some point in the future. In addition, due to price referencing within the EEA, the United Kingdom and certain other countries, existing pricing in our current markets could be negatively affected by a change in pricing in a country where Alimera currently has reimbursement or by a new price in a country where we or Alimera obtain reimbursement approval in the future.

Following the closing of the Merger, our business could also be adversely affected if governments, private insurers or other reimbursing bodies or payers limit the indications for reimbursement approval to a smaller subset than we believe our products are effective in treating or establish a limit on the frequency with which our products may be administered that is less often than we believe would be effective. Those actions could limit our revenues and harm our business.

We will also need to maintain or obtain marketing authorization and commercialization rights in countries outside the United States. Certain countries, such as those in the EEA, require minimum sales within three years or licenses may be revoked if extensions are not negotiated. Alimera does not currently have rights in China and certain other parts of Asia. Following the closing of the Merger, to market our products in foreign jurisdictions, we will be required to obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. We may not receive the necessary approvals to commercialize our products in any additional market.

The process of obtaining regulatory approvals and clearances in jurisdictions where our products are not approved will require us to expend substantial time and capital. Despite the time and expense incurred, regulatory approval is never guaranteed. The number of preclinical and clinical tests that will be required for regulatory approval varies depending on the drug candidate, the disease or condition for which the drug candidate is in development, the jurisdiction in which we are seeking approval and the regulations applicable to that particular drug candidate. The applicable regulatory authorities may make requests or suggestions regarding our clinical trials, resulting in an increased risk of difficulties or delays in obtaining regulatory approval. For example, the regulatory authorities may not approve of certain of our methods for analyzing our trial data, including how we evaluate the relationship between risk and benefit. Additionally, the foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. For all of these reasons, following the closing of the Merger, we may not obtain additional foreign regulatory approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

Following the closing of the Merger, our reliance on third parties to manufacture and test certain of our products will increase, and if any of these third parties is unable to satisfy our demand, our business, operating results and financial condition could suffer.

Alimera does not have in-house manufacturing capability and depends entirely on single source third-party manufacturers for the manufacture of its products, including for supply of active pharmaceutical ingredients, the product applicator, the product implants, and the final assembly of the injectors with the implants. In addition, Alimera relies on third parties for the quality release testing. If any of these third-party manufacturers breaches its agreement, is unable to meet its contractual or quality requirements or becomes unwilling to perform for any reason, we may be unable, in a timely manner or at all, to locate alternative acceptable manufacturers or testing facilities, as applicable, enter into favorable agreements with them and ensure that they are approved by the applicable regulatory authorities, such as the FDA. For example, Alimera relies on (subject to certain exceptions) an agreement with an exclusive supplier for the manufacturing and supply of YUTIQ, which has an initial term of two years through May 2025. Following the Merger, if the supplier is unwilling to extend the supply agreement, and we are unable to timely transfer manufacturing to a replacement supplier or make other arrangements to supply product, we may not be able to fulfill demand for YUTIQ. In addition, on July 12, 2024, the supplier of YUTIQ received a warning letter from the FDA alleging violations of current good manufacturing practice (CGMP) requirements in connection with a February 2024 FDA inspection and associated February 2024 Form FDA-483 specifically related to the manufacturing of YUTIQ at the supplier's facility (the "Warning Letter"). The Warning Letter requires the supplier to implement certain corrective and preventive actions. Any failure by the supplier to remediate to the FDA's satisfaction these findings or any future findings the FDA may have, could result in the supply of YUTIQ being adversely effected or terminated, and, if such findings remain unresolved following the Merger, our ability to fulfill demand for YUTIQ could be materially impaired.

Further, Alimera's suppliers and manufacturers rely on additional third parties for the manufacture of component parts. Any inability of Alimera's contract manufacturers to acquire sufficient quantities of the active pharmaceutical ingredients and other component parts in a timely manner from these third parties could delay commercial production of YUTIQ or ILUVIEN.

Any of these events could adversely affect our ability following the Merger to fulfill demand for the acquired products. In addition, any of these events could in turn have a material adverse effect on our business, financial position, and operating results, including an impairment of the acquired assets, or cause a decline in the price of our common stock.

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

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

There were no repurchases of equity securities pursuant to a repurchase plan or program during the three months ended June 30, 2024.

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
April 1 - April 30, 2024	13,259	$ 66.92	—	$ —
May 1 - May 31, 2024	5,816	$ 65.02	—	$ —
June 1 - June 30, 2024	553	$ 62.62	—	$ —
Total	19,628	$ 66.23	—	

(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

Our directors and executive officers may from time to time enter into plans or other arrangements for the purchase or sale of our common stock that are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or may represent a non-Rule 10b5-1 trading arrangement under the Exchange Act. During the quarter ended June 30, 2024, no such plans or other arrangements were adopted or terminated.

Item 6. Exhibits

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

INDEX TO EXHIBITS

Exhibit No.	Description
2.1+	Agreement and Plan of Merger dated June 21, 2024, by and among ANI Pharmaceuticals, Inc., ANIP Merger Sub INC. and Alimera Sciences, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 24, 2024)
10.1+	Voting Agreement, dated June 21, 2024, by and among ANI Pharmaceuticals, Inc., Alimera Sciences, Inc. and Caligan Partners LP, Caligan Partners Master Fund LP and Caligan Partners CV VI LP. (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 24, 2024)
10.2**	Amended and Restated 2022 Stock Incentive Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on April 5, 2024)
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.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* In accordance with SEC Release 33-8238, Exhibit 32.1 is being furnished and not filed.
**Denotes a management contract or compensatory plan contract or arrangement.
+ Portions of these Exhibits have been omitted pursuant to Rule 601(b) of Regulation S-K. For more, see the cover page of such Exhibits.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ANI Pharmaceuticals, Inc. (Registrant)

Date: August 6, 2024

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

Date: August 6, 2024

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: August 6, 2024

/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: August 6, 2024

/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 June 30, 2024 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

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

Dated: August 6, 2024

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

Dated: August 6, 2024

/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.