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 September 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 November 1, 2024 there were 21,017,775 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended September 30, 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 closing 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, and products acquired in the acquisition of Alimera, 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 acquisition of Alimera, in a timely manner or at all;
- the risks that our acquisitions and investments, including the recent 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 products acquired in the acquisition of Alimera;
- 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;
- risks that we may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason;
- the ability of our manufacturing partners to meet our product demands and timelines;
- the impact of changes or fluctuations in exchange rates;
- 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 in the Middle East, 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	September 30, 2024	December 31, 2023
Current Assets		
Cash and cash equivalents	$ 144,982	$ 221,121
Restricted cash	35	—
Accounts receivable, net of $91,008 and $97,262 of adjustments for chargebacks and other allowances at September 30, 2024 and December 31, 2023, respectively	196,361	162,079
Inventories	148,042	111,196
Prepaid income taxes	6,104	—
Assets held for sale	—	8,020
Prepaid expenses and other current assets	17,475	17,400
Investment in equity securities	8,298	—
Total Current Assets	521,297	519,816
Non-current Assets		
Property and equipment, net	56,704	44,593
Deferred tax assets, net of deferred tax liabilities and valuation allowance	67,661	90,711
Intangible assets, net	569,825	209,009
Goodwill	60,426	28,221
Derivatives and other non-current assets	11,464	12,072
Total Assets	$ 1,287,377	$ 904,422
Liabilities, Mezzanine Equity, and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 7,152	$ 850
Accounts payable	60,890	36,683
Accrued royalties	23,447	16,276
Accrued compensation and related expenses	29,777	23,786
Accrued government rebates	10,693	12,168
Income taxes payable	—	8,164
Returned goods reserve	37,068	29,678
Current contingent consideration	1,283	12,266
Accrued licensor payment	1,809	—
Accrued expenses and other	17,814	5,606
Total Current Liabilities	189,933	145,477
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	312,918	284,819
Non-current convertible notes, net of deferred financing costs	305,293	—
Non-current contingent consideration	20,175	11,718
Accrued licensor payment, net of current	21,316	—
Other non-current liabilities	6,944	4,809
Total Liabilities	$ 856,579	$ 446,823
Commitments and Contingencies (Note 15)		
Mezzanine Equity		
Convertible Preferred Stock, Series A, $0.0001 par value, 1,666,667 shares authorized; 25,000 shares issued and outstanding at September 30, 2024 and December 31, 2023	24,850	24,850
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 21,493,799 shares issued and 21,069,863 outstanding at September 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 September 30, 2024 and December 31, 2023, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Treasury stock, 423,936 shares of common stock, at cost, at September 30, 2024 and 263,943 shares of common stock, at cost, at December 31, 2023	(20,722)	(10,081)
Additional paid-in capital	510,899	514,103
Accumulated deficit	(89,597)	(80,132)
Accumulated other comprehensive income, net of tax	5,366	8,857
Total Stockholders' Equity	405,948	432,749
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 1,287,377	$ 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net Revenues	$ 148,332	$ 131,829	$ 423,802	$ 355,162
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	63,075	48,101	169,930	128,093
Research and development	10,128	11,121	27,935	24,419
Selling, general, and administrative	79,075	42,007	179,917	117,235
Depreciation and amortization	15,748	15,207	45,131	44,597
Contingent consideration fair value adjustment	825	(2,555)	1,274	(559)
Restructuring activities	—	—	—	1,132
Gain on sale of building	—	—	(5,347)	—
Total Operating Expenses, net	168,851	113,881	418,840	314,917
Operating (loss) income	(20,519)	17,948	4,962	40,245
Other (Expense) Income, net				
Unrealized gain on investment in equity securities	1,355	—	8,298	—
Interest expense, net	(2,331)	(6,398)	(11,587)	(21,194)
Other expense, net	(2,535)	(39)	(2,655)	(126)
Loss on extinguishment of debt	(7,468)	—	(7,468)	—
(Loss) Income Before Income Tax (Benefit) Expense	(31,498)	11,511	(8,450)	18,925
Income tax (benefit) expense	(7,332)	1,571	(204)	1,301
Net (Loss) Income	$ (24,166)	$ 9,940	$ (8,246)	$ 17,624
Dividends on Series A Convertible Preferred Stock	(406)	(406)	(1,219)	(1,219)
Net (Loss) Income Available to Common Shareholders	$ (24,572)	$ 9,534	$ (9,465)	$ 16,405
Basic and Diluted (Loss) Income Per Share:				
Basic (Loss) Income Per Share	$ (1.27)	$ 0.46	$ (0.49)	$ 0.84
Diluted (Loss) Income Per Share	$ (1.27)	$ 0.45	$ (0.49)	$ 0.83
Basic Weighted-Average Shares Outstanding	19,404	18,883	19,275	17,663
Diluted Weighted-Average Shares Outstanding	19,404	19,125	19,275	17,823

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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net (Loss) Income	$ (24,166)	$ 9,940	$ (8,246)	$ 17,624
Other comprehensive (loss) income, net of tax:				
Foreign currency translation adjustment	(100)	(38)	(209)	52
(Loss) Gain on interest rate swap	(2,862)	388	(3,282)	1,857
Total other comprehensive (loss) income, net of tax	(2,962)	350	(3,491)	1,909
Total comprehensive (loss) income, net of tax	$ (27,128)	$ 10,290	$ (11,737)	$ 19,533

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 September 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, June 30, 2023	$ 24,850	25	$ 2	20,536	$ —	$ 495,488	248	$ (9,180)	$ 13,726	$ (90,414)	434,472
Stock-based Compensation Expense	—	—	—	—	—	5,444	—	—	—	—	5,444
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	12	(670)	—	—	(670)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	125	—	5,581	—	—	—	—	5,581
Issuance of Restricted Stock Awards	—	—	—	24	—	—	—	—	—	—	—
Restricted Stock Awards and Performance Stock Units Forfeitures	—	—	—	(31)	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(406)	(406)
Other Comprehensive Income	—	—	—	—	—	—	—	—	350	—	350
Net Income	—	—	—	—	—	—	—	—	—	9,940	9,940
Balance, September 30, 2023	$ 24,850	25	$ 2	20,654	$ —	$ 506,513	260	$ (9,850)	$ 14,076	$ (80,880)	$ 454,711
Balance, June 30, 2024	$ 24,850	25	$ 2	21,476	$ —	$ 532,497	413	$ (20,042)	$ 8,328	$ (65,025)	$ 480,610
Stock-based Compensation Expense	—	—	—	—	—	7,484	—	—	—	—	7,484
Capped Call Transaction, net of tax	—	—	—	—	—	(30,275)	—	—	—	—	(30,275)
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	11	(680)	—	—	(680)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	3	—	1,193	—	—	—	—	1,193
Issuance of Restricted Stock Awards	—	—	—	62	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(47)	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(406)	(406)
Other Comprehensive Loss	—	—	—	—	—	—	—	—	(2,962)	—	(2,962)
Net Loss	—	—	—	—	—	—	—	—	—	(24,166)	(24,166)
Balance, September 30, 2024	$ 24,850	25	$ 2	21,494	$ —	$ 510,899	424	$ (20,722)	$ 5,366	$ (89,597)	$ 430,798

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 Nine Months Ended September 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	—	—	—	—	—	15,031	—	—	—	—	15,031
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	111	(4,756)	—	—	(4,756)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	170	—	7,027	—	—	—	—	7,027
Issuance of Restricted Stock Awards	—	—	—	648	—	—	—	—	—	—	—
Issuance of Performance Stock Units	—	—	—	85	—	—	—	—	—	—	—
Restricted Stock Awards and Performance Stock Units Forfeitures	—	—	—	(77)	—	—	—	—	—	—	—
Issuance of Common Stock in Public Offering	—	—	1	2,184	—	80,555	—	—	—	—	80,556
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(1,219)	(1,219)
Other Comprehensive Income	—	—	—	—	—	—	—	—	1,909	—	1,909
Net Income	—	—	—	—	—	—	—	—	—	17,624	17,624
Balance, September 30, 2023	$ 24,850	25	$ 2	20,654	$ —	$ 506,513	260	$ (9,850)	$ 14,076	$ (80,880)	$ 454,711
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	—	—	—	—	—	22,283	—	—	—	—	22,283
Capped Call Transaction, net of tax	—	—	—	—	—	(30,275)	—	—	—	—	(30,275)
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	160	(10,641)	—	—	(10,641)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	80	—	4,788	—	—	—	—	4,788
Issuance of Restricted Stock Awards	—	—	—	669	—	—	—	—	—	—	—
Issuance of Performance Stock Units	—	—	—	74	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(60)	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(1,219)	(1,219)
Other Comprehensive Loss	—	—	—	—	—	—	—	—	(3,491)	—	(3,491)
Net Loss	—	—	—	—	—	—	—	—	—	(8,246)	(8,246)
Balance, September 30, 2024	$ 24,850	25	$ 2	21,494	$ —	$ 510,899	424	$ (20,722)	$ 5,366	$ (89,597)	$ 430,798

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)

	Nine Months Ended September 30, 2024	2023
Cash Flows From Operating Activities		
Net (loss) income	$ (8,246)	$ 17,624
Adjustments to reconcile net (loss) income to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	22,283	15,031
Deferred taxes	(4,383)	(3,394)
Depreciation and amortization	45,131	44,597
Unrealized gain on investment in equity securities	(8,298)	—
Non-cash operating lease expense	1,134	888
Non-cash interest	319	2,970
Contingent consideration fair value adjustment	1,274	(559)
Gain on sale of building	(5,347)	—
Loss on debt extinguishment	7,468	—
Amortization of inventory step up	3,224	—
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable, net	4,426	(13,404)
Inventories	(20,612)	(1,236)
Prepaid expenses and other assets	3,822	(636)
Accounts payable	7,300	4,772
Accrued royalties	7,171	(2,668)
Prepaid income taxes	(14,268)	4,426
Accrued government rebates	(1,475)	(51)
Returned goods reserve	4,296	(1,961)
Accrued expenses, accrued compensation, and other	2,938	7,820
Net Cash and Cash Equivalents Provided by Operating Activities	48,157	74,219
Cash Flows From Investing Activities		
Acquisition of Alimera, net of cash acquired	(393,079)	—
Acquisition of product rights, intangible assets, and other related assets	(631)	(7,143)
Acquisition of property and equipment, net	(13,842)	(6,589)
Proceeds from the sale of building	13,514	—
Net Cash and Cash Equivalents Used in Investing Activities	(394,038)	(13,732)
Cash Flows From Financing Activities		
Proceeds from convertible notes	316,250	—
Proceeds from term loan	325,000	—
Purchase of capped call transaction	(40,575)	—
Repayment on borrowings under credit agreement	(292,500)	—
Debt issuance costs	(15,376)	—
Principal payments on borrowings under credit agreements	(1,500)	(2,250)
Series A convertible preferred stock dividends paid	(1,219)	(1,219)
Proceeds from stock option exercises and ESPP purchases	4,788	7,027
Proceeds from public offering	—	80,555
Treasury stock purchases for restricted stock vests	(10,641)	(4,756)
Payments on contingent consideration	(12,500)	—
Payment of accrued licensor payments	(1,875)	—
Net Cash and Cash Equivalents Provided by Financing Activities	269,852	79,357
Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash	(75)	—
Net Change in Cash, Cash Equivalents, and Restricted Cash	(76,104)	139,844
Cash, cash equivalents, and restricted cash, beginning of period	221,121	53,234
Cash. cash equivalents, and restricted cash end of period	$ 145,017	$ 193,078

	Nine Months Ended September 30,	
	2024	2023
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 19,232	$ 23,426
Cash paid for income taxes	$ 17,214	$ 930
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	$ 635	$ 247
Purchase consideration for Alimera Acquisition	$ (16,523)	$ —
Accrued deferred financing costs	$ (1,976)	$ —

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 committed to its mission of "Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high-quality therapeutics.

On September 16, 2024, the Company completed its previously announced acquisition of Alimera Sciences, Inc., a Delaware corporation ("Alimera") pursuant to the terms of the Agreement and Plan of Merger, dated as of June 21, 2024, by and among the Company, Alimera and ANIP Merger Sub INC., a Delaware corporation and wholly-owned subsidiary of the Company. Pursuant to the Merger Agreement, Merger Sub merged with and into Alimera, with Alimera surviving the merger as a wholly-owned subsidiary of the Company. In connection with the acquisition, the Company added two new products, ILUVIEN® and YUTIQ®, both of which are indicated for the treatment of chronic retinal diseases. See Note 3 "Business Combination" to the Notes to Condensed Consolidated Financial Statements for further information on the acquisition.

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 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 the 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 of such transaction. The sale closed on March 28, 2024 (see Note 4 "Restructuring Canada Operations" to the Notes to Condensed Consolidated Financial Statements). 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 currently has subsidiaries located in India, Ireland, Germany, and the United Kingdom. The India-based subsidiary generally conducts its transactions in Indian upees, which is also its functional currency. The Ireland and Germany locations generally conduct their transactions in Euros, which is also their functional currency. The United Kingdom subsidiary conducts its transactions in Euros and British Pounds, and their functional currency is Euros. The Company has ceased operations at its subsidiary in Oakville, Ontario, Canada as of March 31, 2023. The Canada-based subsidiary conducted its transactions in U.S. dollars and Canadian dollars, but its functional currency was the U.S. dollar.

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 (loss) 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 nine months ended September 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 and contingent value rights 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.

Business Combination and Goodwill

The Company accounted for its acquisition of Alimera using the acquisition method of accounting prescribed by Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 805, *Business Combinations*, whereby the results of operations, including the revenues and earnings of Alimera, are included in the financial statements from the date of acquisition. Assets acquired and liabilities assumed as of the date of acquisition are recognized at their fair values based on widely accepted valuation techniques in accordance with ASC 820, *Fair Value Measurements*. Goodwill is recognized for the excess of the consideration transferred over the net fair values of assets acquired and liabilities assumed. Management's assessment of qualitative factors affecting goodwill for each acquisition includes estimates of market share at the date of purchase, ability to grow in the market, synergy with existing Company operations and the payor profile in the markets. The fair value assigned to the intangible assets was determined using the income approach, specifically the multi-period excess earnings methodology. The process for estimating fair values requires the use of significant estimates, assumptions and judgments, including determining the timing and estimates of future cash flows and developing appropriate discount rates. The estimates of fair value are based upon assumptions believed to be reasonable using the best information available. These assumptions are inherently uncertain and unpredictable and, as a result, actual results may differ materially from estimates.

ASC 805, *Business Combinations*, establishes a measurement period to provide the Company with a reasonable amount of time to obtain the information necessary to identify and measure various items in a business combination and cannot extend beyond one year from the acquisition date. Measurement period adjustments are recognized in the reporting period in which the adjustments are determined and calculated as if the accounting had been completed as of acquisition date. The Company expects to complete the final fair value determination of the assets acquired and liabilities assumed as soon as practicable within the measurement period, but not to exceed one year from the acquisition date.

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 “Restructuring Canada Operations” to the Notes to Condensed Consolidated Financial Statements).

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the 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. While this ASU will increase and enhance disclosures, it will not have a material impact on the Company's 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.

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 rare disease, generic, 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 September 30,		Nine Months Ended September 30,	
Products and Services (in thousands)	**2024**	**2023**	**2024**	**2023**
Rare Disease				
Sales of Cortrophin Gel	$ 52,555	$ 29,734	$ 138,685	$ 70,368
Sales of ILUVIEN and YUTIQ	3,871	—	3,871	—
Total sales of rare disease pharmaceutical products	$ 56,426	$ 29,734	$ 142,556	$ 70,368
Generics, Established Brands, and Other				
Sales of generic pharmaceutical products	$ 78,223	$ 70,593	$ 222,404	$ 197,623
Sales of established brand pharmaceutical products, royalties, and other pharmaceutical services	13,683	31,502	58,842	87,171
Total sales of generic and established brand pharmaceutical products, royalties, and other pharmaceuticals services	91,906	102,095	281,246	284,794
Total net revenues	$ 148,332	$ 131,829	$ 423,802	$ 355,162

	Three Months Ended September 30,		Nine Months Ended September 30,	
Timing of Revenue Recognition (in thousands)	**2024**	**2023**	**2024**	**2023**
Performance obligations transferred at a point in time	$ 148,332	$ 131,829	$ 423,802	$ 354,787
Performance obligations transferred over time	—	—	—	375
Total	$ 148,332	$ 131,829	$ 423,802	$ 355,162

In the three and nine months ended September 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 $3.3 million to net revenue from performance obligations satisfied in prior periods during the nine months ended September 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 $8.5 million to net revenue from performance obligations satisfied in prior periods during the nine months ended September 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 September 30, 2024, and December 31, 2023, there was deferred revenue of approximately $5.0 million and $0.0 million, respectively, recorded on the condensed consolidated balance sheets in accrued expenses and other.

As of September 30, 2024, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $3.8 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 nine months ended September 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	437,671	16,998	13,048	40,815	17,024
Credits Taken Against Reserve	(501,841)	(16,947)	(15,009)	(39,316)	(18,366)
Balance at September 30, 2023 (1)	$ 84,392	$ 10,923	$ 31,438	$ 10,941	$ 5,146
Balance at December 31, 2023	$ 84,208	$ 12,168	$ 29,678	$ 11,412	$ 4,865
Impact of Alimera acquisition	95	—	3,095	671	—
Accruals/Adjustments	403,201	19,757	28,737	44,622	17,159
Credits Taken Against Reserve	(410,508)	(21,232)	(24,442)	(43,486)	(17,218)
Balance at September 30, 2024 (1)	$ 76,996	$ 10,693	$ 37,068	$ 13,219	$ 4,806

(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, pharmaceutical companies, hospitals, and healthcare providers.

During the three and nine months ended September 30, 2024, there were four customers that accounted for 10% or more of net revenues. During the three and nine months ended September 30, 2023, there were four customers that accounted for 10% or more of net revenues. As of September 30, 2024, accounts receivable from five customers totaled 71% of Accounts receivable, net.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Customer 1	20 %	35 %	26 %	33 %
Customer 2	10 %	12 %	12 %	13 %
Customer 3	14 %	12 %	12 %	13 %
Customer 4	17 %	13 %	15 %	10 %

3. BUSINESS COMBINATION

Summary

On September 16, 2024 (the "Closing Date"), the Company completed the previously announced acquisition (the "Acquisition" or the "Merger") of Alimera Sciences, Inc., a Delaware corporation ("Alimera") pursuant to the terms of the Agreement and Plan of Merger, dated as of June 21, 2024 (the "Merger Agreement"), by and among the Company, Alimera and ANIP Merger Sub INC., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"). Pursuant to the Merger Agreement, Merger Sub merged with and into Alimera, with Alimera surviving the Merger as a wholly owned subsidiary of the Company.

At the effective time of the Merger, each share of common stock, par value $0.01 per share, of Alimera (the "Alimera Common Stock") outstanding, including each Alimera RSA (as defined below), but excluding any treasury shares or shares owned by the Company, Merger Subs or any other subsidiary of the Company or Alimera, was canceled and ceased to exist and was converted into the right to receive (i) $5.50 in cash ("Closing Cash Consideration"), and (ii) one contingent value right (a "CVR"), which represents the right to receive the milestone payments (as defined below) subject to the terms and conditions set forth in the CVR Agreement entered into on September 16, 2024 (collectively, the "Merger Consideration").

Each CVR entitles the holder to receive milestone payments for 2026 and 2027. The milestone payments for each CVR equals 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 (as defined in the Merger Agreement) exceeds $140.0 million, divided by $10.0 million (subject to adjustment for the exercise price of eligible options). If the Net Revenue for 2026 were $151.0 million, then the fraction would exceed one and would count as one, multiplied by $0.25, and the Milestone Payment for 2026 would be $0.25. For the avoidance of doubt, in no circumstance will more than $0.25 per CVR be payable in respect of the Net Revenue for 2026.

For 2027, the milestone payments for each CVR 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 applicable Alimera Options). If the Net Revenue for 2027 were $176.0 million, then the fraction would exceed one and would count as one, multiplied by $0.25, and the Milestone Payment for 2027 would be $0.25. For the avoidance of doubt, in no circumstance will more than $0.25 per CVR be payable in respect of the Net Revenue for 2027.

In addition to the amounts payable to the holders thereof in connection with the Closing, all of the outstanding awards of restricted stock with respect to shares of Alimera Common Stock (each, an "Alimera RSA"), each Alimera Performance Stock Unit ("Alimera PSU"), each Alimera Restricted Stock Unit ("Alimera RSU") and each Alimera Warrant that were outstanding immediately prior to the Effective Time were automatically canceled and converted into the right to receive one (1) CVR per share of Alimera Common Stock then underlying the applicable instrument.

Each stock option previously granted by Alimera to purchase Alimera Common Stock (each, an "Alimera Option") that was outstanding and unexercised as of the Effective Time and which had a per share exercise price that was less than the Closing Cash Consideration was, in addition to the amounts payable to the holders thereof in connection with the Closing, automatically canceled and converted into the right to receive one (1) CVR per share of Alimera Common Stock then underlying such Alimera Option. No other Alimera Options were cancelled and converted into the right to receive a CVR, provided that each Alimera Option with a per share exercise price greater than or equal to the Closing Cash Consideration but less than the Total Consideration (as defined in the Merger Agreement) may receive a payment in connection with the payout of the CVRs (if any).

This acquisition was accounted for as a business combination. Purchase consideration consisted of the following:

(In thousands, except share price and exchange ratio)	**Purchase Consideration**
Alimera common shares outstanding	53,971
Alimera warrants outstanding after exercise	989
Alimera common shares and warrants outstanding	54,960
Cash consideration per share	$ 5.50
Cash consideration for Alimera Common Stock	$ 302,280
Repayment of Alimera Debt	78,540
Payment of Alimera transaction costs	20,172
Cash settlement for pre-acquisition equity awards	9,535
Fair value of CVRs	8,322
Total Merger Consideration	$ 418,849

The cash payment was funded through the New Credit Facility, see Note 6 "New Credit Agreement" to the Notes to Condensed Consolidated Financial Statements for further details.

As part of the purchase consideration the Company paid approximately $78.5 million for the repayment of the outstanding term loan Alimera had with SLR Investment Corp., including interest payable, prepayment and end of term fees. Furthermore, the Company repaid $20.2 million of transaction costs incurred by Alimera.

In accordance with the terms of the Merger Agreement, the Company settled all outstanding equity awards held by Alimera employees, for a total cash amount of $19.3 million, of which, $1.3 million was paid in cash at the close of the Merger. Of the $19.3 million, $9.5 million was determined to be related to the pre-Merger services provided and as a result was allocated to the purchase consideration transferred. The remaining amounts were attributed to the post-Merger period and deemed to be for the benefit of ANI the Company. As a result, $8.8 million was recognized as selling, general, and administrative and $1.0 million as research and development expense, respectively, for the three and nine months ended September 30, 2024.

The CVRs represent a form of contingent consideration and are included as part of the purchase consideration transferred. The CVRs represent the right to future cash payments for the former Alimera shareholders based on certain 2026 and 2027 revenue targets. Management determined the contingent consideration to be liability classified and will measure the liability at fair value each reporting period. The fair value of the CVRs have been estimated using a monte carlo simulation under an option pricing framework, $8.3 million of the total $8.7 million was related to the pre-combination period and recognized as consideration transferred. The remaining $0.4 million of the fair value of the CVR was allocated to post-merger period and recognized as selling, general, and administrative for the three and nine months ended September 30, 2024.

The preliminary allocation of the fair value of the Alimera acquisition is shown in the table below. The allocation of the fair value will be finalized when the valuation is completed, and the differences will be trued up for the final allocated amounts.

		Fair Value
Cash and cash equivalents	$	9,247
Accounts receivable		38,605
Prepaid expenses and other assets		2,618
Inventories		19,457
Property and equipment		3,086
Intangible assets		400,000
Deferred tax asset, net of deferred tax liabilities and valuation allowance		198
Derivative and other non-current assets		1,224
Total assets	$	474,435
Accounts payable	$	8,001
Accrued expenses and other		11,396
Returned goods reserve		3,095
Current accrued licensor payment		3,684
Accrued licensor payment, net of current		21,316
Deferred tax liability		37,932
Other non-current liabilities		2,364
Total liabilities	$	87,788
Total fair value of consideration transferred	$	418,849
Less: fair value of net acquired identifiable assets and liabilities		386,647
Goodwill	$	32,202

The net assets were recorded at their estimated fair value. In valuing acquired assets and liabilities, fair value estimates were based primarily on future expected cash flows, market rate assumptions for contractual obligations, and appropriate discount rates.

The preliminary fair value of finished goods inventory utilizes a sales comparison approach which estimates the selling price of the inventory in completed condition less costs of disposal and a reasonable profit allowance for the selling effort.

As part of the Merger, the Company acquired the product rights to YUTIQ and ILUVIEN. The preliminary fair value of the acquired intangible assets was determined using an income approach, and more specifically, the multi-period excess earnings methodology.

The identifiable intangible assets acquired are amortized on a straight-line basis over their estimated useful lives. The following table summarizes the estimated fair value of identifiable intangible assets acquired and their remaining amortization period (in years):

	Fair Value (in thousands)	Useful Life
ILUVIEN	$ 230,000	12
YUTIQ	$ 170,000	12

The estimated deferred tax liability, recognized based on the estimated tax impact of the differences between the financial reporting and tax bases of the assets and liabilities acquired, is included in Deferred tax assets, net of deferred tax liabilities and valuation allowance in the consolidated balance sheet as of September 30, 2024.

Goodwill is calculated as the difference between the fair value of the preliminary aggregate purchase consideration and the values assigned to the identifiable tangible and intangible assets acquired and liabilities assumed. Goodwill represents the workforce acquired, as well as future operating efficiencies and cost savings. The actual amount of goodwill will depend upon the final determination of the fair value of the assets acquired and liabilities assumed and may differ materially from this preliminary determination. Goodwill established as a result of the acquisition is tax deductible in the U.S.

Alimera operations generated approximately $3.9 million of net revenue and recorded a net loss of approximately $(8.1) million from the date of acquisition through September 30, 2024.

Transaction Costs

In conjunction with the acquisition, the Company incurred approximately $12.2 million in transaction costs during the nine months ended September 30, 2024, all of which were recognized as selling, general, and administrative expense in the consolidated statement of operations.

Pro Forma Financial Information (unaudited)

The following unaudited pro forma financial information summarizes the results of operations for the periods indicated as if the Acquisition had been completed as of January 1, 2023.

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Net revenues	$ 162,700	$ 155,193	$ 488,180	$ 409,610
Net (loss) income	$ (18,749)	$ 2,327	$ (17,754)	$ (44,164)

The unaudited pro forma financial information includes, where applicable, adjustments for (i) the amortization of the inventory step-up, (ii) additional amortization expense related to acquired intangible assets, (iii) transaction costs and other one-time non-recurring costs, (iv) additional interest expense for borrowings related to the Acquisition, and (v) associated tax-related impacts of adjustments. These pro forma adjustments are based on the available information as of the date hereof and upon assumptions that the Company believes are reasonable to reflect the impact of the Acquisition with the Company's historical financial information on a pro forma basis. Adjustments do not include costs related to integration activities, cost savings or synergies that have been or may be achieved by the combined business.

4. RESTRUCTURING CANADA OPERATIONS

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 nine months ended September 30, 2024 and as of September 30, 2024, there was no severance or other employee benefits accrued on the unaudited interim condensed consolidated balance sheet.

There were no restructuring activities recognized in the three months ended September 30, 2023. For the nine months ended September 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 September 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 September 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 nine months ended September 30, 2024.

5. TRUIST CREDIT FACILITY

In connection with the acquisition of Novitium on November 19, 2021, the Company, as borrower, entered into a credit agreement (the "Credit Agreement") with Truist Bank and other lenders, which provided 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 provided for revolving credit loans, swingline loans and letters of credit (the "Revolving Facility," and together with the Term Facility, the "Credit Facility").

The Company incurred $14.0 million in deferred debt issuance costs associated with the Credit Facility. Costs allocated to the Term Facility were 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 were classified as other current and other non-current assets, depending on their nature. A commitment fee of 0.5% per annum was assessed on any unused portion of the Revolving Facility.

The carrying value of the current and non-current components of the Term Facility as of September 30, 2024 and December 31, 2023 are:

	Current	
(in thousands)	**September 30, 2024**	**December 31, 2023**
Current borrowing on debt	$ —	$ 3,000
Deferred financing costs	—	(2,150)
Current debt, net of deferred financing costs	$ —	$ 850

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Contractual coupon	$ 2,883	$ 7,864	$ 16,644	$ 22,834
Amortization of deferred financing costs	295	591	1,477	1,773
Capitalized interest	(138)	(142)	(401)	(440)
	$ 3,040	$ 8,313	$ 17,720	$ 24,167

Extinguishment of the Credit Facility

On August 13, 2024, the Company entered into an indenture with U.S. Bank Trust Company, National Association, as trustee, for the issuance of the 2.25% Convertible Senior Notes due 2029 (as described in Note 7 "2.25% Convertible Senior Notes" to the Notes to Condensed Consolidated Financial Statements). The proceeds of the Convertible Senior Notes and cash on-hand were used to repay the Credit Facility in its entirety, approximately $294.0 million, comprised of $292.5 million of unpaid principal, $1.2 million in accrued and unpaid interest, and $0.3 million of legal fees. In connection with the issuance of the Convertible Senior Notes, the Company recorded a loss on debt extinguishment in the unaudited interim consolidated statement of operations for the three and nine months ended September 30, 2024, amounting to approximately $7.5 million, comprised of the write-off unamortized deferred financing fees related to the Credit Facility as of August 13, 2024.

6. New Credit Agreement

On August 13, 2024, the Company, as lead borrower, and ANIP Acquisition Company, as initial subsidiary borrower ("ANIP") entered into a credit agreement (the "New Credit Agreement") with JPMorgan Chase Bank, N.A., as administrative agent, and the financial institutions party thereto as lenders (together, the "Lenders"), which provides for aggregate principal commitments consisting of (i) a senior secured delayed-draw term loan facility in an aggregate principal amount of $325.0 million (the "Term Loan A" or "TLA"), and (ii) a senior secured revolving credit facility in an aggregate commitment amount of $75.0 million, which may be used for revolving credit loans, swingline loans and letters of credit (the "TLA Revolver" and together with the TLA, the "New Credit Facility").

On September 16, 2024 (the "Closing Date"), ANIP drew the full $325.0 million of Term Loan A principal, with proceeds used to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the acquisition. As of September 30, 2024, the TLA Revolver remains undrawn, and $75.0 million is available for borrowing, subject to the satisfaction of certain conditions. The TLA and the TLA Revolver mature on September 16, 2029. The New Credit Facility contains certain contingent acceleration clauses that could result in an earlier maturity date, none of which have been triggered as of September 30, 2024.

The cash interest rate and effective rate under the Term Loan A was approximately 7.95% and 8.37% per annum at September 30, 2024, respectively.

The Company incurred $5.0 million in deferred debt issuance costs associated with the TLA, which costs are classified as a direct reduction to the current and non-current portion of debt. The Company incurred $1.1 million in deferred debt issuance costs associated with the TLA Revolver, which costs are classified as other non-current assets. A commitment fee accrues on the unutilized commitments under the TLA Revolver and, from and after the date that is two months after the closing date of the New Credit Agreement, the TLA at a per annum rate equal between 0.25% and 0.40% depending on the Company's first lien net leverage ratio.

The New Credit Facility is secured by a lien on substantially all of the Company's and its principal domestic subsidiary's assets and any future domestic subsidiary guarantors' assets. The New Credit Facility is subject to customary financial and nonfinancial covenants.

The Company is required to make quarterly principal payments, beginning on December 31, 2024, in the amount of (i) 0.625% of the original principal amount of the Term Loan A on each quarterly payment date on or prior to the one year anniversary of the Closing Date, (ii) 1.25% of the original principal amount of the Term Loan A on each quarterly payment date following the one year anniversary of the Closing Date and 1.875% of the original principal amount of the Term Loan A on each quarterly payment date following the three year anniversary of the Closing Date and with the remaining unpaid principal amount due on the maturity date of the Term Loan A.

The carrying value of the current and non-current components of the New Credit Facility as of September 30, 2024 and December 31, 2023 are:

	Current	
(in thousands)	**September 30, 2024**	**December 31, 2023**
Current borrowing on debt	$ 8,125	$ —
Deferred financing costs	(973)	—
Current debt, net of deferred financing costs	$ 7,152	$ —

(in thousands)	Non-Current	
	September 30, 2024	December 31, 2023
Non-current borrowing on debt	$ 316,875	$ —
Deferred financing costs	(3,957)	—
Non-current debt, net of deferred financing costs and current component	$ 312,918	$ —

Of the $1.1 million of unamortized deferred debt issuance costs allocated to the New Credit Facility, $0.9 million is included in other non-current assets in the unaudited interim condensed consolidated balance sheets, and $0.2 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets.

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

(in thousands)	New Term Facility
2024 (remainder of the year)	$ 2,031
2025	10,156
2026	18,281
2027	24,375
2028	24,375
2029	245,782
Total	$ 325,000

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

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Contractual coupon	$ 530	$ —	$ 530	$ —
Amortization of deferred financing costs	49	—	49	—
	$ 579	$ —	$ 579	$ —

7. 2.25% CONVERTIBLE SENIOR NOTES

Offering of Convertible Senior Notes

On August 7, 2024, the Company entered into a purchase agreement (the "Purchase Agreement") with the initial purchasers (the "Initial Purchasers") relating to the issuance of the $275.0 million aggregate principal amount of the Company's Convertible Senior Notes due 2029 (the "Notes"). Pursuant to the terms of the Purchase Agreement, the Company granted the Initial Purchasers an option to purchase up to an additional $41.25 million aggregate principal amount of Notes (the "Option") for settlement at any time during the thirteen days beginning on, and including August 7, 2024, which Option was exercised in full on August 8, 2024.

On August 13, 2024 (the "Closing Date" or "Issue Date"), the Company completed an offering of $316.25 million aggregate principal amount of Notes. The Notes were issued pursuant to an indenture (the "Indenture") dated as of August 13, 2024 between the Company and U.S. Bank Trust Company, National Association ("Trustee"). The Notes are due September 1, 2029, unless earlier repurchased, redeemed, or converted. The Notes will accrue interest at a rate of 2.25% per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2025. After deducting the initial purchasers' discounts and commissions of approximately $9.5 million, but before deducting the Company's offering expenses, the net proceeds to the Company from the offering of the Notes was approximately $306.8 million. After payment of the cost of entering into the Capped Call Transactions (as defined below), the Company used the remainder of the net proceeds from the Notes offering, together with cash on hand, to repay the Company's existing senior secured credit agreement, dated as of November 19, 2021, by and among the Company, certain of the Company's subsidiaries, as guarantors, Truist Bank, as administrative agent, and other parties thereto, as amended, supplemented or otherwise modified from time to time (as amended, the "Credit Agreement"). Refer to Note 5 "Truist Credit Facility" to the Notes to Condensed Consolidated Financial Statements for the details of the extinguishment of the Credit Agreement.

The Notes are the Company's senior, unsecured obligations and are (i) equal in right of payment with the Company's existing and future senior, unsecured indebtedness; (ii) senior in right of payment to the Company's existing and future indebtedness that is expressly subordinated to the Notes; (iii) effectively subordinated to the Company's existing and future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent the Company is not a holder thereof) preferred equity, if any, of the Company's subsidiaries.

Conversion Options

Prior to the close of business on the business day immediately preceding June 1, 2029, holders of the Notes will have the right to convert their Notes only upon the occurrence of certain events as set forth in the Indenture. All or any portion of the Notes may be converted prior to June 1, 2029 at the holders' option upon the occurrence of any of the following: (i) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on September 30, 2024, if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price of the Notes for each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter; (ii) during the five consecutive business days immediately after any ten consecutive trading day period (such ten consecutive trading day period, the "measurement period") in which the trading price per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate of the Notes on such trading day; (iii) upon the occurrence of certain corporate events or distributions on the Company's common stock, as described in the Indenture; or (iv) if the Company calls such Notes for redemption.

On or after June 1, 2029 until the close of business on the second scheduled trading day immediately before the maturity date of the Notes, holders may convert all or any portion of their Notes at any time at their election. The initial conversion rate for the Notes is 13.4929 shares of the Company's common stock per $1,000 principal amount of Notes, which represents an initial conversion price of approximately $74.11 per share of the Company's common stock. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for holders that convert their Notes in connection with such Make-Whole Fundamental Change, as described in the Indenture.

Upon conversion of the Notes, the Company will pay cash up to the aggregate principal amount of the Notes to be converted and pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, in respect of the remainder, if any, of the Company's conversion obligation.

The Notes will be redeemable, in whole or in part (subject to certain limitations described below), at the Company's option at any time, and from time to time, on or after September 1, 2027 and on or before the 61st scheduled trading day immediately before the maturity date, but only if (i) the notes are "Freely Tradable" (as defined in the Indenture) as of the date the Company sends the related redemption notice and all accrued and unpaid additional interest, if any, has been paid in full as of the first interest payment date occurring on or before the date the Company sends the related redemption notice; and (ii) the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price on (1) each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the trading day immediately before the date the Company sends such redemption notice; and (2) the trading day immediately before the date the Company sends such redemption notice. However, the Company may not redeem less than all of the outstanding Notes unless at least $75.0 million aggregate principal amount of Notes are outstanding and not called for redemption as of the time the Company sends the related redemption notice. The redemption price will be a cash amount equal to the principal amount of the Notes to be redeemed, plus accrued and unpaid interest, if any, to, but excluding, the redemption date. In addition, calling any Note for redemption will constitute a Make-Whole Fundamental Change with respect to that Note, in which case the conversion rate applicable to the conversion of that Note will be increased in certain circumstances if it is converted with a conversion date that is on or after the date the Company sends the related redemption notice and on or before the second business day immediately before the related redemption date.

If certain corporate events that constitute a "Fundamental Change" (as defined in the Indenture) occur, then, subject to a limited exception for certain cash mergers, holders of the Notes may require the Company to repurchase their Notes at a cash repurchase price equal to the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any, to, but excluding, the fundamental change repurchase date. The definition of Fundamental Change includes certain business combination transactions involving the Company and certain de-listing events with respect to the Company's common stock.

Events of Default

The Notes include customary provisions relating to the occurrence of "Events of Default" (as defined in the Indenture), including breaches of covenants, breaches of warranty, change of control, nonpayment, bankruptcy, assignment, foreclosure, cessation of business, and defaults under ancillary documents. Certain of the Events of Default are subject to notice and cure periods. As of September 30, 2024, the Company was in compliance with all covenants associated with the Notes.

Debt issuance costs related to the Notes totaled $11.2 million at inception and were comprised of discounts and commissions payable to the initial purchasers and third-party offering costs and will be amortized to interest expense using the effective interest method over the contractual term. As of September 30, 2024, the unamortized debt discount and debt issuance cost of the Notes was approximately $11.0 million on the unaudited interim condensed consolidated balance sheets. The effective interest rate during the quarter ended September 30, 2024 was 3.01%.

During the quarter ended September 30, 2024, the Notes did not meet any of the circumstances that would allow for a conversion. The Notes were therefore not convertible as of September 30, 2024, and were classified as long-term debt on the Company's unaudited interim condensed consolidated balance sheet as of September 30, 2024.

As of September 30, 2024, the total estimated fair value (which represents a Level 2 valuation) of the Notes is approximately $334.8 million.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Contractual coupon	$ 969	$ —	$ 969	$ —
Amortization of finance fees	281	—	281	—
	$ 1,250	$ —	$ 1,250	$ —

Capped Call Transactions

In connection with the offering of Notes, on August 7, 2024 and August 8, 2024, the Company entered into capped call transactions with certain financial institutions ("Capped Calls"). The Capped Calls each have an initial cap price of $114.02, which represents a premium of 100% over the last reported sale price of the Company's common stock on August 7, 2024. The Company used approximately $40.6 million of the net proceeds from the offering of the Notes to pay premiums on the Capped Calls.

The Capped Calls are expected to generally to reduce potential dilution to the Company's common stock upon any conversion of the Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted Notes. The Capped Calls cover, subject to anti-dilution adjustments, approximately 4.3 million shares of the Company's common stock.

The Capped Calls will expire upon the maturity of the Notes. The Capped Calls are separate transactions entered into by the Company with the financial institution counterparties thereto, the Capped Calls are not part of the terms of the Notes and the Capped Calls do not change the holders' rights under the Notes. The Capped Calls do not meet the criteria for separate accounting as a derivative as they meet the criteria for equity classification, and the capped call transaction premiums are recorded as a reduction to Additional Paid-In Capital within Shareholders' Equity, net of deferred income taxes.

8. 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 the London Interbank Offered Rate ("LIBOR")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. The Company amended its Credit Agreement to transition from LIBOR to the Secured Overnight Financing Rate ("SOFR") due to the cessation of LIBOR in the third quarter of 2023, and accordingly, the interest rate swap transitioned from LIBOR to SOFR. The interest rate swap is used to manage changes in SOFR-based interest rates underlying a portion of the borrowing under the Term Facility. 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 became the new counterparty.

On August 30, 2024, in connection with the New Credit Facility, the interest rate swap with a notional value of $139.4 million was transferred from Truist Bank to JPMorgan Chase Bank, N.A., as the new counterparty. The interest rate swap is used to manage changes in SOFR-based interest rates underlying a portion of the borrowing under the New Term Facility. The interest rate swap provides an effective fixed interest rate of 2.313% and is designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of September 30, 2024, the notional amount of the interest rate swap was $139.4 million, and will remain static until maturity in December 2026. As of September 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 is $3.6 million. As of September 30, 2024, $5.6 million was recorded in accumulated other comprehensive (loss) income, net of tax in the unaudited interim condensed consolidated balance sheets.

During the three and nine months ended September 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 $2.8 million and $3.3 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 nine months ended September 30, 2024, the Company recorded a reduction in interest expense of $1.7 million and $4.9 million in relation to the interest rate swaps, respectively. In the three and nine months ended September 30, 2023, the Company recorded a reduction in interest expense of $0.7 million and $1.8 million in relation to the interest rate swaps, respectively. Included in this amount for the three and nine months ended September 30, 2024 are reclassifications out of accumulated other comprehensive (loss) income of $0.2 million of interest income and $0.6 million, respectively, related to terminated and de-designated cash flow hedges. Included in this amount for the three and nine months ended September 30, 2023 are reclassifications out of accumulated other comprehensive (loss) income of $0.7 million of interest income and $2.1 million, respectively, related to terminated and de-designated cash flow hedges.

9. 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 and nine months ended September 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 nine months ended September 30, 2024 and 2023 are calculated for basic and diluted earnings per share as follows:

(in thousands, except per share amounts)	Basic Three Months Ended September 30,		Diluted Three Months Ended September 30,		Basic Nine Months Ended September 30,		Diluted Nine Months Ended September 30,	
	2024	2023	2024	2023	2024	2023	2024	2023
Net (loss) income available to common shareholders	$ (24,572)	$ 9,534	$ (24,572)	$ 9,534	$ (9,465)	$ 16,405	$ (9,465)	$ 16,405
Earnings allocated to participating securities	—	(891)	—	(881)	—	(1,629)	—	(1,615)
Net (loss) income available to common shareholders	$ (24,572)	$ 8,643	$ (24,572)	$ 8,653	$ (9,465)	$ 14,776	$ (9,465)	$ 14,790
Basic Weighted-Average Shares Outstanding	19,404	18,883	19,404	18,883	19,275	17,663	19,275	17,663
Dilutive effect of common stock options, ESPP, and performance stock units			—	242			—	160
Diluted Weighted-Average Shares Outstanding			19,404	19,125			19,275	17,823
(Loss) earnings per share	$ (1.27)	$ 0.46	$ (1.27)	$ 0.45	$ (0.49)	$ 0.84	$ (0.49)	$ 0.83

The number of shares of potentially dilutive securities excluded from the computation of diluted net loss per share attributable to common stockholders was 2.7 million and 2.3 million for the three and nine months ended September 30, 2024, respectively, because including them would have been anti-dilutive. The Company has also excluded approximately 4.3 million shares from the computation of diluted net loss per share for the three and nine months ended September 30, 2024, representing the maximum number of conversion shares from the Convertible Senior Notes.

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, was 2.1 million and 2.4 million for the three and nine months ended September 30, 2023, respectively.

10. INVENTORIES

Inventories consist of the following as of:

(in thousands)	September 30, 2024	December 31, 2023
Raw materials	$ 67,228	$ 62,237
Packaging materials	10,522	9,617
Work-in-progress	4,144	3,144
Finished goods	66,148	36,198
Inventories	$ 148,042	$ 111,196

Note, the Finished goods include the inventory step-up from the acquisition of Alimera of approximately $11.7 million (represents net step-up after amortization).

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 months ended September 30, 2024, no single vendor represented more than 10% of our raw material inventory purchases. During the nine months ended September 30, 2024, 17%, of our raw material purchases were from one supplier. During the three and nine months ended September 30, 2023, no single vendor represented more than 10% of our raw material inventory purchases.

11. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As of September 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. 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. The goodwill from the transactions with BioSante Pharmaceuticals, Inc., WellSpring Pharma Services Inc., and Novitium is recorded in the Generics, Established Brands, and Other reporting unit. As a result of the acquisition of Alimera, on September 16, 2024, the Company recorded goodwill of $32.2 million in the Rare Disease reporting unit. Refer to Note 3 "Business Combination" to the Notes to Condensed Consolidated Financial Statements for further information related to the acquisition.

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 or the Rare Disease reporting unit below their carrying value during the three and nine months ended September 30, 2024 and 2023, and as a result 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:

	September 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	$ 210,411	$ (118,804)	$ 91,607	$ 209,780	$ (100,660)	$ 109,120	4.6 years
NDAs and product rights	644,871	(203,143)	441,728	244,871	(184,861)	60,010	11.0 years
Marketing and distribution rights	17,157	(14,992)	2,165	17,157	(14,271)	2,886	2.2 years
Customer relationships	24,900	(10,375)	14,525	24,900	(7,707)	17,193	4.1 years
Total Definite-Lived Intangible Assets	897,339	(347,314)	550,025	496,708	(307,499)	189,209	9.8 years
Indefinite-Lived Intangible Assets:							
In process research and development	19,800	—	19,800	19,800	—	19,800	Indefinite
Total Intangible Assets, net	$ 917,139	$ (347,314)	$ 569,825	$ 516,508	$ (307,499)	$ 209,009	

(1) Weighted average amortization period as of September 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 twelve 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.

During the quarter ended September 30, 2024, the Company acquired Alimera, and as a result, acquired two intangible assets for YUTIQ and ILUVIEN, in the amount of $170.0 million and $230.0 million, respectively, which will be amortized over 12 years.

Amortization expense for definite-lived intangibles was $13.9 million and $13.3 million for the three months ended September 30, 2024 and 2023, respectively. Amortization expense for definite-lived intangibles was $39.8 million and $39.0 million for the nine months ended September 30, 2024 and 2023, respectively. No impairment losses were recognized in the three and nine months ended September 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 nine months ended September 30, 2024 and 2023, respectively.

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

(in thousands)		
2024 (remainder of the year)	$	20,647
2025		81,016
2026		67,531
2027		58,564
2028		51,783
2029 and thereafter		270,484
Total	$	550,025

12. 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 September 30, 2024.

There were 21.5 million and 21.1 million shares of common stock issued and outstanding as of September 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 September 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 September 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 September 30, 2024.

13. 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 September 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Selling, general, and administrative	$ 142	$ 109	$ 418	$ 251
Cost of sales	35	16	95	46
Research and development	18	14	42	33
Total	$ 195	$ 139	$ 555	$ 330

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 September 30, 2024, 1.9 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Selling, general, and administrative	$ 6,582	$ 4,914	$ 19,883	$ 13,588
Research and development	423	225	1,029	638
Cost of sales	283	166	816	475
Total	$ 7,288	$ 5,305	$ 21,728	$ 14,701

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

(in thousands)	Options	PSUs	RSAs
Outstanding at December 31, 2022	907	—	1,141
Granted	3	85	648
Options Exercised/RSAs Vested	(151)	—	(369) (1)
Forfeited	(28)	(1)	(76)
Outstanding at September 30, 2023	731	84	1,344
Outstanding at December 31, 2023	689	84	1,351
Granted	—	74	669
Options Exercised/RSAs Vested	(57)	—	(467) (2)
Forfeited	(1)	—	(60)
Outstanding at September 30, 2024	631	158	1,493

(1) Includes 111 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 $4.8 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

(2) Includes 160 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 $10.6 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

14. 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 September 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 September 30, 2024 and December 31, 2023. The Company is subject to taxation in various U.S. jurisdictions, Canada, India, the United Kingdom, Ireland, Portugal, and Germany 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 non-U.S. 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 September 30, 2024, the Company recognized an income tax benefit of $7.3 million. The Company's effective tax rate was 23.3% after discrete items for the three months ended September 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 completed acquisition of Alimera.

For the three months ended September 30, 2023, the Company recognized an income tax expense of $1.6 million. The Company's effective tax rate was 13.6% for the three months ended September 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 stock based compensation.

For the nine months ended September 30, 2024, the Company recognized an income tax benefit of $0.2 million. The Company's effective tax rate was 2.4% after discrete items for the nine months ended September 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 completed acquisition of Alimera.

For the nine months ended September 30, 2023, the Company recognized an income tax expense of $1.3 million. The Company's effective tax rate was 6.9% for the nine months ended September 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 stock based compensation.

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

15. 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 is classified as an operating lease. 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. In connection with the acquisition of Alimera, the Company acquired operating leases for office space in Alpharetta, Georgia, and has a remaining term of approximately five years, and a lease for office space in the United Kingdom, which has a remaining term of less than one year. Rent expense is recognized on a straight-line basis over the lease term. Operating lease ROU assets are included in other non-current assets and operating lease liabilities are included in accrued expenses and other and other non-current liabilities in the consolidated balance sheets.

Finance Leases

In connection with the acquisition of Alimera, the Company acquired finance leases primarily consisting of automobiles. The property and equipment is capitalized at the lesser of fair market value or the present value of the minimum lease payments at the inception of the leases using the Company's incremental borrowing rate. The Company's finance lease agreements do not contain any material residual value guarantees or material restrictive covenants. Finance lease ROU assets are included in other non-current assets, specifically in Property and equipment, net, and finance lease liabilities are included in accrued expenses and other and other non-current liabilities in the consolidated balance sheets.

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 nine months ended September 30, 2024, net revenues from commercial sales of these products totaled $5.5 million and $16.4 million, respectively.

During the three and nine months ended September 30, 2023, net revenues from EEMT and Opium Tincture totaled $9.2 million and $16.4 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 nine months ended September 30, 2024 were less than $0.1 million. Contract manufacturing revenues for Hyoscyamine, for three and nine months ended September 30, 2023 were less than $0.1 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 August 22, 2024, the court heard the parties' oral arguments in a hearing on CG Oncology's Motion for Summary Judgment. The court's decision on the Motion for Summary Judgement is pending. 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 was held on September 11, 2024 on Acella's motion to dismiss. The court's decision is pending. 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 States 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. Plaintiffs filed an amended master complaint on April 29, 2024 and filed a second amended master complaint on July 2, 2024. Defendants filed omnibus demurrers to the complaint. Novitium is named in one case. The court heard arguments for the demurrers on August 22, 2024 and issued its final ruling on August 28, 2024, allowing some counts to survive. The surviving counts as to generic defendants include strict liability (manufacturing defect) and general negligence (storage and transport, failure to warn and product containers). Novitium filed its answer to the second amended master complaint on September 6, 2024.

In December 2023, the Keller Postman firm filed approximately 200 individual plaintiff short form complaints that name generic defendants. Novitium is named in 29 of the short form complaints which reference the claims for the master complaint, but Novitium 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 sustained 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 amended short form complaints on September 20, 2024 and defendants filed responses on October 6, 2024. Pleadings are now closed 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. In addition, Novitium was not named in any amended short form complaint filed by plaintiffs

ANI and Novitium dispute any liability in these matters.

16. 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, which was extinguished on August 13, 2024, and the New Credit Facility bear interest rates 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 September 30, 2024.

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

Alimera Contingent Value Rights Agreement

On September 16, 2024, prior to consummation of the Alimera Acquisition, the Company entered into a CVR pursuant to which holders 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 payments being contingent upon, and subject to, the achievement of: (i) $140.0 million in net revenue (the "2026 Milestone") on third party sales of ILUVIEN and YUTIQ for the Company's 2026 fiscal year (the "2026 Net Revenue") and/or (ii) $160.0 million in net revenue (the "2027 Milestone" and together with the 2026 Milestone, the "Milestones") on third party sales of ILUVIEN and YUTIQ for the Company's 2027 fiscal year (the "2027 Net Revenue"). Each CVR entitles the holder (the "Holder") to receive a Milestone Payment upon satisfaction of the applicable Milestones. The Milestone Payment for each CVR will equal the product (rounded to the nearest 1/100 of $0.01) of (i) $0.25 multiplied by a fraction (not exceeding one), the numerator of which is the amount, if any, by which the 2026 Net Revenue exceeds $140.0 million and the denominator of which is $10.0 million (subject to adjustment for the exercise price of applicable Alimera Options) and/or (ii) $0.25 multiplied by a fraction (not exceeding one), the numerator of which is the amount, if any, by which the 2027 Net Revenue exceeds $160.0 million and the denominator of which is $15.0 million (subject to adjustment for the exercise price of applicable Alimera Options).

If a Milestone is attained, the distributions in respect of the CVRs will be made on or prior to the date that is fifteen (15) business days following the filing by the Company of its audited financial statements with the SEC on Form 10-K in respect of the applicable year in which such Milestone has been achieved, and will be subject to a number of deductions, exceptions and limitations, including, but not limited to, certain taxes.

The fair value of the CVR liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The Company utilized a Monte Carlo simulation model to estimate the fair value of the CVR liability. For each simulated path of future revenue, the payments to the CVR holders were calculated based on the contractual terms of the rights. The average payments from all simulated paths were then discounted to present value at an estimated cost of debt. The CVR liability had an estimated fair value of $8.7 million as of September 30, 2024, and is classified as non-current contingent consideration in the Company's unaudited interim condensed consolidated balance sheet.

The following table presents the changes in the CVR balances classified as Level 3 for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2024	2023	2024	2023
Beginning balance	$ —	$ —	$ —	$ —
CVR Agreement	8,700	—	8,700	—
Ending balance	$ 8,700	$ —	$ 8,700	$ —

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 September 30, 2024 was approximately $83.3 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 New Credit Agreement" to the Notes to Condensed Consolidated Financial Statements). The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in further detail in Note 8 "Derivative Financial Instrument and Hedging Activity" to the Notes to Condensed Consolidated Financial Statements. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in further detail in Note 8, the fair value of the interest rate swap was $3.6 million as of September 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 September 30, 2024 was approximately $8.3 million based on a closing market price of $37.73 on September 30, 2024. This amount is classified on the unaudited condensed consolidated statements of operations as Unrealized gain on investment in equity securities for the nine months ended September 30, 2024. Between 2013 and 2023, CG Oncology securities held by the Company were valued at zero under U.S. GAAP.

Novitium 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 "Commitments and Contingencies" to the Notes to Condensed Consolidated Financial Statements). 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 17 "Related Party Transactions" to the Notes to Condensed Consolidated Financial Statements).

The fair value of the contingent consideration was approximately $12.8 million and $24.0 million as of September 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 September 30, 2024:

Payment Type	Valuation Technique	Unobservable Input	Assumptions
Profit-based milestone payments	Probability-weighted discounted cash flow	Discount rate	12%
		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 nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Beginning balance	$ 11,933	$ 37,054	$ 23,984	$ 35,058
Payment of Gross-Profit earn-out	—	—	(12,500)	—
Change in fair value	825	(2,555)	1,274	(559)
Ending balance	$ 12,758	$ 34,499	$ 12,758	$ 34,499

Accrued Licensor Payments

On May 17, 2023, Alimera entered into a product rights agreement with EyePoint Parent which granted Alimera an exclusive and sublicensable right and license under EyePoint Parent's and its affiliates' interest in certain of EyePoint Parent's and its affiliates' intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa, where the Company already has such rights pursuant to the New Collaboration Agreement, and except for China, Hong Kong, Macau, Taiwan, Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, South Korea, Thailand and Vietnam, where Ocumension holds a license from EyePoint Parent. Pursuant to the agreement, Alimera paid EyePoint Parent an upfront payment of $75.0 million and has also made three quarterly guaranteed payments to EyePoint Parent totaling $5.6 million during 2024, with one remaining payment of $1.9 million due at December 31, 2024.

The Company will also pay royalties to EyePoint Parent from 2025 to 2028 at a percentage of mid-to-low double digits of annual U.S. net sales of certain products (including YUTIQ and ILUVIEN) in excess of certain thresholds, beginning at $70.0 million in 2025, increasing annually thereafter. Upon making the quarterly payments in the aggregate amount of $7.5 million in 2024, the licenses and rights granted to the Company will automatically become perpetual and irrevocable.

For the quarter ended September 30, 2024, the Company paid the third quarterly payment of $1.9 million, with $1.9 million due at December 31, 2024. The present value of the remaining 2024 quarterly payments and the present value of estimated royalties payable to EyePoint Parent for years 2025 to 2028 will continue to be revalued at an appropriate discount rate for the Company at each reporting date until they are settled. The fair value of the remaining future payments as of September 30, 2024 was approximately $23.1 million.

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

(in thousands) **Description**	**Fair Value at September 30, 2024**	**Level 1**	**Level 2**	**Level 3**
Assets				
Money Market Fund	$ 83,304	$ 83,304	$ —	$ —
Interest rate swap	$ 3,556	$ —	$ 3,556	$ —
CG Oncology - Investment in equity securities	$ 8,298	$ 8,298	$ —	$ —
Liabilities				
Contingent consideration, Novitium	$ 12,758	$ —	$ —	$ 12,758
Contingent Value Rights, Alimera	$ 8,700	$ —	$ —	$ 8,700
Accrued licensor payment	$ 23,125	$ —	$ —	$ 23,125

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 nine months ended September 30, 2024 and 2023.

17. 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Scitus Pharma Services	$ 1,155	$ 1,322	$ 2,236	$ 3,227
SS Pharma LLC	—	2,480	1,245	6,059
SThree Chemicals Pvt Ltd	4,214	—	5,283	—
Esjay Pharma LLC	79	—	79	—
	$ 5,448	$ 3,802	$ 8,843	$ 9,286

As of September 30, 2024, the outstanding balances due to Scitus, SThree, and Esjay were $0.4 million, $1.6 million, and $14 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. 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. 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.

18. 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, and the products acquired as part of the Merger with Alimera, ILUVIEN and YUTIQ, as of and from September 16, 2024 through the end of the quarter.

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, and transaction and integration expenses related to the acquisition of Alimera.

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:

(in thousands)	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Net Revenues				
Generics, Established Brands, and Other	$ 91,906	$ 102,095	$ 281,246	$ 284,794
Rare Disease	56,426	29,734	142,556	70,368
Total net revenues	$ 148,332	$ 131,829	$ 423,802	$ 355,162
Segment earnings before interest, taxes, depreciation and amortization ("EBITDA") and reconciliation to income before income taxes				
Generics, Established Brands, and Other	$ 33,588	$ 41,234	$ 110,528	$ 120,070
Rare Disease	6,626	4,044	14,826	6,937
Depreciation and amortization	(15,748)	(15,207)	(45,131)	(44,597)
Corporate and other unallocated expenses[1]	(44,985)	(12,123)	(75,261)	(42,165)
Total operating (loss) income	(20,519)	17,948	4,962	40,245
Unrealized gain on investment in equity securities	1,355	—	8,298	—
Interest expense, net	(2,331)	(6,398)	(11,587)	(21,194)
Other expense, net [2]	(10,003)	(39)	(10,123)	(126)
(Loss) Income Before Income Tax (Benefit) Expense	$ (31,498)	$ 11,511	$ (8,450)	$ 18,925

(1) Includes expenses not directly allocated or attributable to a reporting segment, including certain management, legal, accounting, human resources, insurance, and information technology expenses, transaction and integration expenses related to the acquisition of Alimera, severance and equity payouts, 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, which occurred in the first quarter of 2024.

(2) The loss on extinguishment of approximately $7.5 million, which occurred in the third quarter of 2024 is included in Other expense, net above. Refer to Note 4 "Restructuring Canada Operations" to the Notes to Condensed Consolidated Financial Statements for further information.

Geographic Information

The following depicts the Company's total revenue according to geographic location. The Company has ceased operations at the Oakville, Ontario, Canada location as of March 31, 2023. The revenue from Alimera is also included in the three and nine months ended September 30, 2024 in the table below. The majority of the assets of the Company are located in the United States.

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

(in thousands) Location of Operations	Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
United States	$ 147,116	$ 131,829	$ 422,586	$ 354,597
International	1,216	—	1,216	565
Total Revenue	$ 148,332	$ 131,829	$ 423,802	$ 355,162

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 "Restructuring Canada Operations" to the Notes to Condensed Consolidated Financial Statements. The table below includes Alimera property, plant and equipment, net, as of September 30, 2024. The Company's property, plant and equipment are as follows:

(in thousands)	September 30, 2024	December 31, 2023
United States	$ 54,637	$ 43,163
International	2,067	1,430
Total property and equipment, net	$ 56,704	$ 44,593

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 committed to its mission of "Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high quality therapeutics. Our Company is focused on delivering sustainable growth through its Rare Disease business, which markets novel products in the areas of ophthalmology, rheumatology, nephrology, neurology, and pulmonology; its Generics business, which leverages R&D expertise, operational excellence, and U.S.-based manufacturing; and its Established Brands business.

On September 16, 2024, the Company completed its previously announced acquisition of Alimera Sciences, Inc., a Delaware corporation ("Alimera") pursuant to the terms of the Agreement and Plan of Merger, dated as of June 21, 2024 (the "Merger Agreement"), by and among the Company, Alimera and ANIP Merger Sub INC., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"). Pursuant to the Merger Agreement, Merger Sub merged with and into Alimera, with Alimera surviving the merger as a wholly-owned subsidiary of the Company (the "Merger"). In connection with the Merger, the Company added two growing and durable assets, ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg, which has received marketing authorization and reimbursement in the United States ("U.S.") and 24 countries for the treatment of diabetic macular edema ("DME") and YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg, available in the U.S. for the treatment and prevention of non-infectious uveitis affecting the posterior segment of the eye ("NIU-PS").

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 "Restructuring Canada Operations" to the Notes to Condensed Consolidated Financial Statements).

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

The Alimera Acquisition 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. ILUVIEN and YUTIQ are durable assets with high barriers to genericization which the Company believes have a clear role for patients in need of alternative therapeutic options. ANI sees the potential to unlock significant additional growth for both ILUVIEN and YUTIQ through commercial synergies and execution.

We have spent significant time, effort and resources in establishing our Rare Disease platform. Throughout 2023 and 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. We plan to continue to invest in 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. 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. On January 24, 2022, we announced the commercial launch of Cortrophin Gel in the U.S. as our foundational Rare Disease asset.

During the first quarter of 2024, ANI launched a targeted ophthalmology-focused sales force for Cortrophin Gel. The team has continued to gain momentum in ophthalmology, driving significant growth in the number of new patient starts in the second quarter and third quarter to date. Importantly, the addition of Alimera expands the reach of the ophthalmology sales team and believes there will be significant overlap between high potential prescribers of Cortrophin Gel, ILUVIEN and YUTIQ.

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 recently completed 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, and Veregen. 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

Acquisition of Alimera Sciences, Inc.

On September 16, 2024, the Company completed our previously announced merger with Alimera (the "Closing"). At the effective time of the Merger (the "Effective Time"), each share of common stock, par value $0.01 per share, of Alimera (the "Alimera Common Stock") outstanding immediately prior to the Effective Time including each Alimera RSA, Alimera PSU, Alimera RSU, and Alimera Warrant (as defined below), but excluding any treasury shares or shares owned by the Company, Merger Subs or any other subsidiary of the Company or Alimera), was canceled and ceased to exist and was converted into the right to receive (i) $5.50 in cash ("Closing Cash Consideration"), and (ii) 1 contingent value right (a "CVR"), which represents the right to receive the milestone payments (as defined below) subject to the terms and conditions set forth in the CVR Agreement entered into on September 16, 2024 (clauses (i) and (ii) collectively, the "Merger Consideration"). The Company also repaid $72.5 million of Alimera debt.

Each CVR entitles the holder to receive milestone payments for 2026 and 2027. The milestone payments for each CVR equals 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 applicable Alimera Options).

In addition to the amounts payable to the holders thereof in connection with the Closing, all of the outstanding awards of restricted stock with respect to shares of Alimera Common Stock (each, an "Alimera RSA"), each Alimera Performance Stock Unit ("Alimera PSU"), each Alimera Restricted Stock Unit ("Alimera RSU") and each Alimera Warrant that were outstanding immediately prior to the Effective Time were automatically canceled and converted into the right to receive one (1) CVR per share of Alimera Common Stock then underlying the applicable instrument.

Each stock option previously granted by Alimera to purchase Alimera Common Stock (each, an "Alimera Option") that was outstanding and unexercised as of the Effective Time and which had a per share exercise price that was less than the Closing Cash Consideration was, in addition to the amounts payable to the holders thereof in connection with the Closing, automatically canceled and converted into the right to receive one (1) CVR per share of Alimera Common Stock then underlying such Alimera Option. No other Alimera Options were cancelled and converted into the right to receive a CVR, provided that each Alimera Option with a per share exercise price greater than or equal to the Closing Cash Consideration but less than the Total Consideration (as defined in the Merger Agreement) may receive a payment in connection with the payout of the CVRs (if any).

During the three and nine months ended September 30, 2024, the Company incurred approximately $8.8 million and $12.2 million, respectively, in transaction costs related to the Merger Agreement, all of which were expensed. See Note 3 "Business Combination" to the Notes to Condensed Consolidated Financial Statements for further information on the acquisition.

New Capital Structure

On August 13, 2024, we completed an offering of $316.25 million aggregate principal amount of 2.25% convertible senior notes due September 1, 2029. The Company utilized a majority of the net proceeds as well as cash from its balance sheet to repay in full its existing senior secured term loan facility with total unpaid principal of $292.5 million. The initial conversion price of the convertible notes is $74.11 per share. Concurrent with the convertible senior notes offering, the Company used $40.6 million of the net proceeds to enter into capped call transactions. The cap price of the capped call transactions is initially $114.02 per share, which represents a premium of 100% over the last reported sale price of the Company's common stock on August 7, 2024. The capped call transactions are expected generally to reduce the potential dilution to ANI's common stock upon any conversion of the notes up to the cap price of $114.02.

To fund the Alimera Acquisition, the Company entered into a new senior secured credit agreement consisting of a $325.0 million delayed draw term loan facility and $75.0 revolving credit facility on August 13, 2024. On September 16, 2024 the Company drew the full $325.0 million term loan; the $75.0 million revolving credit facility remains available to borrow. Refer to the Liquidity and Capital Resources section below for further information related to the debt agreements.

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 third 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 September 30,		Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**	**2024**	**2023**
Net Revenues	$ 148,332	$ 131,829	$ 423,802	$ 355,162
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	63,075	48,101	169,930	128,093
Research and development	10,128	11,121	27,935	24,419
Selling, general, and administrative	79,075	42,007	179,917	117,235
Depreciation and amortization	15,748	15,207	45,131	44,597
Contingent consideration fair value adjustment	825	(2,555)	1,274	(559)
Restructuring activities	—	—	—	1,132
Gain on sale of building	—	—	(5,347)	—
Operating (loss) income	(20,519)	17,948	4,962	40,245
Unrealized gain on investment in equity securities	1,355	—	8,298	—
Interest expense, net	(2,331)	(6,398)	(11,587)	(21,194)
Other expense, net	(2,535)	(39)	(2,655)	(126)
Loss on extinguishment of debt	(7,468)	—	(7,468)	—
(Loss) Income Before Income Tax (Benefit) Expense	(31,498)	11,511	(8,450)	18,925
Income tax (benefit) expense	(7,332)	1,571	(204)	1,301
Net (Loss) Income	$ (24,166)	$ 9,940	$ (8,246)	$ 17,624

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Net Revenues	100 %	100 %	100 %	100 %
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	42.5 %	36.5 %	40.1 %	36.1 %
Research and development	6.8 %	8.4 %	6.6 %	6.9 %
Selling, general, and administrative	53.3 %	31.9 %	42.5 %	33.0 %
Depreciation and amortization	10.6 %	11.5 %	10.6 %	12.6 %
Contingent consideration fair value adjustment	0.6 %	(1.9)%	0.3 %	(0.2)%
Restructuring activities	— %	— %	— %	0.3 %
Gain on sale of building	— %	— %	(1.3)%	— %
Operating (loss) income	(13.8)%	13.6 %	1.2 %	11.3 %
Unrealized gain on investment in equity securities	0.9 %	— %	2.0 %	— %
Interest expense, net	(1.6)%	(4.9)%	(2.7)%	(6.0)%
Other expense, net	(1.7)%	— %	(0.6)%	— %
Loss on extinguishment of debt	(5.0)%	— %	(1.8)%	— %
(Loss) Income Before Income Tax (Benefit) Expense	(21.2)%	8.7 %	(1.9)%	5.3 %
Income tax (benefit) expense	(4.9)%	1.2 %	— %	0.4 %
Net (Loss) Income	(16.3)%	7.5 %	(1.9)%	4.9 %

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

Net Revenues

(in thousands)	Three Months Ended September 30, 2024	2023	Change	% Change
Rare Disease Segment				
Cortrophin Gel	$ 52,555	$ 29,734	$ 22,821	76.8 %
ILUVIEN and YUTIQ	3,871	—	3,871	100.0 %
Rare Disease segment total net revenues	$ 56,426	$ 29,734	$ 26,692	89.8 %
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 78,223	$ 70,593	$ 7,630	10.8 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	13,683	31,502	(17,819)	(56.6)%
Generics, established brands, and other segment total net revenues	$ 91,906	$ 102,095	$ (10,189)	(10.0)%
Total net revenues	$ 148,332	$ 131,829	$ 16,503	12.5 %

We derive substantially all of our revenues from sales of rare disease, generic, 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 September 30, 2024 were $148.3 million compared to $131.8 million for the same period in 2023, an increase of 12.5%, primarily as a result of the following factors:

- Net revenues of rare disease pharmaceutical products, which include Cortrophin Gel and a partial month contribution from ILUVIEN and YUTIQ, were $56.4 million during the three months ended September 30, 2024, an increase of $26.7 million from $29.7 million for the same period in 2023. This increase was driven by increased volume in this third year of launch of Cortrophin Gel (product was launched in late January 2022), and a partial month of sales from ILUVIEN and YUTIQ, as a result of the acquisition of Alimera on September 16, 2024.

- Net revenues for generic pharmaceutical products were $78.2 million during the three months ended September 30, 2024, an increase of 10.8% compared to $70.6 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 Baclofen, Candesartan, Colestipol, Estradiol, Fludrocortisone, L-Glutamine, Pentoxifylline, and various other products tempered by a decrease in revenues of Thyroid, Dapsone, Famotidine, and MAS-ER, among others.

- Net revenues for branded pharmaceutical products, royalties, and other pharmaceutical services were $13.7 million during the three months ended September 30, 2024, a decrease of 56.6% compared to $31.5 million for the same period in 2023, driven by a net decrease in volume. During the three months ended September 30, 2023, we benefited from supplying incremental volume in markets that were experiencing supply chain disruptions for competing products.

Cost of Sales (Excluding Depreciation and Amortization)

	Three Months Ended September 30,			
(in thousands)	2024	2023	Change	% Change
Cost of sales (excluding depreciation and amortization)	$ 63,075	$ 48,101	$ 14,974	31.1 %

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

For the three months ended September 30, 2024, cost of sales increased to $63.1 million from $48.1 million for the same period in 2023, an increase of $15.0 million, or 31.1%. The increase is primarily due to significant net growth in sales volumes of pharmaceutical products, significant growth of royalty bearing products, including Cortrophin Gel, and the amortization of the inventory step-up related to the acquisition of Alimera of approximately $3.2 million.

Cost of sales, as a percentage of net revenues, increased to 42.5% from 36.5% for the three months ended September 30, 2024, compared to the same period in 2023, primarily due to a shift in product mix year over year, increase in sales of products that bear a royalty payable, and the amortization of Alimera inventory step-up.

During the three months ended September 30, 2024 and September 30, 2023, no single vendor represented more than 10% of our raw material inventory purchases.

Other Operating Expenses, net

	Three Months Ended September 30,			
(in thousands)	2024	2023	Change	% Change
Research and development	$ 10,128	$ 11,121	$ (993)	(8.9)%
Selling, general, and administrative	79,075	42,007	37,068	88.2 %
Depreciation and amortization	15,748	15,207	541	3.6 %
Contingent consideration fair value adjustment	825	(2,555)	3,380	(132.3)%
Total other operating expenses, net	$ 105,776	$ 65,780	$ 39,996	60.8 %

For the three months ended September 30, 2024, other operating expenses, net increased to $105.8 million from $65.8 million for the same period in 2023, an increase of $40.0 million, or 60.8%, primarily as a result of the following factors:

- Research and development expenses decreased from $11.1 million to $10.1 million, a nominal decrease of approximately $1.0 million or 8.9% when comparing the three months ended September 30, 2024 to the same period in 2023.
- Selling, general, and administrative expenses increased from $42.0 million to $79.1 million, an increase of $37.1 million, or 88.2%, due to increased employment related costs, investment in Rare Disease sales and marketing infrastructure and activities, legal expenses, transaction and integration expenses incurred in connection with the acquisition of Alimera of approximately $10 million, severance expense of approximately $5.3 million and the settlement of all outstanding equity awards held by Alimera employees of approximately $9.2 million, and an overall increase in activities to support revenue growth.
- Depreciation and amortization expense was $15.7 million for the three months ended September 30, 2024, compared to $15.2 million for the same period in 2023.

- We recognized a loss of $0.8 million and gain of $2.6 million in the three months ended September 30, 2024 and 2023, respectively, for the contingent consideration fair value adjustment. The change in the fair value adjustment during the three months ended September 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 decrease in discount rates. Additionally, the fair value measurement adjustment in the three months ended September 30, 2024 is related to only the third milestone, whereas the fair value adjustment at September 30, 2023 related to all three milestones.

Other Expense, net

	Three Months Ended September 30,			
(in thousands)	2024	2023	Change	% Change
Unrealized gain on investment in equity securities	$ 1,355	$ —	$ 1,355	(100.0)%
Interest expense, net	(2,331)	(6,398)	4,067	(63.6)%
Other expense, net	(2,535)	(39)	(2,496)	6400.0 %
Loss on extinguishment of debt	(7,468)	—	(7,468)	100.0 %
Total other expense, net	$ (10,979)	$ (6,437)	$ (4,542)	70.6 %

For the three months ended September 30, 2024, we recognized total other expense of $11.0 million as compared to total other expense of $6.4 million for the same period in 2023, an increase of $4.5 million.

- We recorded an unrealized gain on our investment in equity securities held in CG Oncology of approximately $1.4 million is due to the mark to market to fair value of equity securities as of the balance sheet date. There was no comparable gain on investment in the three months ended September 30, 2023.

- Interest expense, net for the three months ended September 30, 2024 consists primarily of interest expense on borrowings under our Term Facility of approximately $4.0 million and amortization of deferred debt issuance costs of approximately $0.3 million, and interest expense on the New Credit Facility of approximately $1.1 million and Convertible Senior Notes of approximately $1.0 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 $1.7 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 average cash balances during the current period, interest income realized on our interest rate swaps, and the inclusion of approximately only one and a half months of Term Facility interest in the current three months ended September 30, 2024 as compared to three full months in September 30, 2023 due to the timing of the extinguishment of the Term Facility (August 13, 2024) and the draw down of the New Credit Facility (September 16, 2024).

- Other expense, net, increased to approximately $2.5 million, primarily due to the fees paid to JPMorgan Chase Bank, N.A. and Blackstone Credit & Insurance of $2.8 million pursuant to the terms of the debt commitment letter, dated June 21, 2024, entered into in connection with the acquisition of Alimera, offset by other income.
- We recorded a loss on debt extinguishment of approximately $7.5 million, comprised of the write-off unamortized deferred financing fees related to the Credit Facility. On August 13, 2024, the Company entered into the 2.25% Convertible Senior Notes due 2029 (as described in Note 7 “2.25% Convertible Senior Notes” to the Notes to Condensed Consolidated Financial Statements). The proceeds of the Convertible Senior Notes were used to repay the Truist Credit Facility in its entirety, approximately $294.0 million, comprised of $292.5 million of unpaid principal, $1.2 million in accrued and unpaid interest, and $0.3 million of legal fees. There was no comparable transaction in the three months ended September 30, 2023.

Income Tax (Benefit) Expense

(in thousands)	Three Months Ended September 30, 2024	2023	Change	% Change
Income tax (benefit) expense	$ (7,332)	$ 1,571	$ (8,903)	(566.7)%

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 September 30, 2024, we recognized an income tax benefit of approximately $7.3 million. The Company's effective tax rate was 23.3% after discrete items for the three months ended September 30, 2024. The effective tax rate differed from the federal statutory rate of 21% primarily due to state taxes, treatment of discrete items (including stock based compensation), and non-deductible expenses related to the completed acquisition of Alimera which were treated as a discrete item during the quarter which affects the estimated tax rate.

For the three months ended September 30, 2023, we recognized an income tax expense of $1.6 million. The income tax expense resulted from applying an estimated annual worldwide effective tax rate of 13.6% to pre-tax consolidated income of $11.5 million reported during the period. 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 stock based compensation.

RESULTS OF OPERATIONS FOR THE NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023

Net Revenues

(in thousands)	Nine Months Ended September 30, 2024	2023	Change	% Change
Rare Disease Segment				
Cortrophin Gel	138,685	70,368	68,317	97.1 %
ILUVIEN and YUTIQ	3,871	—	3,871	100.0 %
Rare Disease segment total net revenues	$ 142,556	$ 70,368	$ 72,188	102.6 %
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 222,404	$ 197,623	$ 24,781	12.5 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	58,842	87,171	(28,329)	(32.5)%
Generics, established brands, and other segment total net revenues	$ 281,246	$ 284,794	$ (3,548)	(1.2)%
Total net revenues	$ 423,802	$ 355,162	$ 68,640	19.3 %

Net revenues for the nine months ended September 30, 2024 were $423.8 million compared to $355.2 million for the same period in 2023, an increase of 19.3%, primarily as a result of the following factors:

- Net revenues of rare disease pharmaceutical products, which include Cortrophin Gel and a partial month of contribution from ILUVIEN and YUTIQ, were $142.6 million during the nine months ended September 30, 2024, an increase of $72.2 million from $70.4 million for the same period in 2023. This increase was driven by increased volume in this third year of launch of Cortrophin Gel (product was launched in late January 2022), and a partial month of sales from ILUVIEN and YUTIQ, as a result of the acquisition of Alimera on September 16, 2024.

- Net revenues for generic pharmaceutical products were $222.4 million during the nine months ended September 30, 2024, an increase of 12.5% compared to $197.6 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 Baclofen, Candesartan, Colestipol, Estradiol,Lacosamide, Nitrofurantoin, Pentoxifylline, Pirfenidone, Prednisone, Vancomycin, and various other products tempered by a decrease in revenues of Dapsone, Famotidine, Meloxicam, Nebivolol, Paliperidone, Prochlorperazine, Thyroid, and Vancomycin OS among others.

- Net revenues for branded pharmaceutical products, royalties, and other pharmaceutical services were $58.8 million during the nine months ended September 30, 2024, a decrease of 32.5% compared to $87.2 million for the same period in 2023, driven by a net decrease in volume. During portions of the prior year and 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 and third quarter of 2024.

Cost of Sales (Excluding Depreciation and Amortization)

	Nine Months Ended September 30,			
(in thousands)	2024	2023	Change	% Change
Cost of sales (excluding depreciation and amortization)	$ 169,930	$ 128,093	$ 41,837	32.7 %

For the nine months ended September 30, 2024, cost of sales increased to $169.9 million from $128.1 million for the same period in 2023, an increase of $41.8 million, or 32.7%. The increase is primarily due to significant net growth in sales volumes of pharmaceutical products, significant growth of royalty bearing products, including Cortrophin Gel, and the amortization of the inventory step-up related to the acquisition of Alimera of approximately $3.2 million.

Cost of sales, as a percentage of net revenues, increased to 40.1% from 36.1% for the nine months ended September 30, 2024, compared to the same period in 2023, primarily due to a shift in product mix year over year, and increase in sales of products that bear a royalty payable.

During the nine months ended September 30, 2024, approximately 17% of our raw material purchases were from one supplier. During the nine months ended September 30, 2023, no single vendor represented more than 10% of our raw material inventory purchases.

Other Operating Expenses, net

	Nine Months Ended September 30,			
(in thousands)	2024	2023	Change	% Change
Research and development	$ 27,935	$ 24,419	$ 3,516	14.4 %
Selling, general, and administrative	179,917	117,235	62,682	53.5 %
Depreciation and amortization	45,131	44,597	534	1.2 %
Contingent consideration fair value adjustment	1,274	(559)	1,833	(327.9)%
Restructuring activities	—	1,132	(1,132)	(100.0)%
Gain on sale of building	(5,347)	—	(5,347)	100.0 %
Total other operating expenses	$ 248,910	$ 186,824	$ 62,086	33.2 %

For the nine months ended September 30, 2024, other operating expenses, net increased to $248.9 million from $186.8 million for the same period in 2023, an increase of $62.1 million, or 33.2%, primarily as a result of the following factors:

- Research and development expenses increased from $24.4 million to $27.9 million, an increase of $3.5 million or 14.4%, primarily due to a higher level of activity associated with ongoing and new projects in the nine months ended September 30, 2024.
- Selling, general, and administrative expenses increased from $117.2 million to $179.9 million, an increase of $62.7 million, or 53.5%, due to increased employment related costs, investment in Rare Disease sales and marketing infrastructure and activities, legal expenses, transaction and integration expenses related to the acquisition of Alimera of approximately $13.5 million, severance expense of approximately $5.3 million and the settlement of all outstanding equity awards held by Alimera employees of approximately $9.2 million, and an overall increase in activities to support revenue growth.
- Depreciation and amortization expense was $45.1 million for the nine months ended September 30, 2024, compared to $44.6 million for the same period in 2023.

- We recognized a loss of $1.3 million and a gain of $0.6 million in the nine months ended September 30, 2024 and 2023, respectively, for the contingent consideration fair value adjustment. The change in the fair value adjustment during the nine months ended September 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 nine months ended September 30, 2024 is related to only the third milestone, whereas the fair value adjustment at September 30, 2023 related to all three milestones.

- We recognized restructuring activities expenses of $1.1 million in the nine months ended September 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 nine months ended September 30, 2024.

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

Other Expense, net

	Nine Months Ended September 30,			
(in thousands)	2024	2023	Change	% Change
Unrealized gain on investment in equity securities	$ 8,298	$ —	$ 8,298	100.0 %
Interest expense, net	(11,587)	(21,194)	9,607	(45.3)%
Other expense, net	(2,655)	(126)	(2,529)	2007.1 %
Loss on extinguishment of debt	(7,468)	—	(7,468)	100.0 %
Total other expense, net	$ (13,412)	$ (21,320)	$ 7,908	(37.1)%

For the nine months ended September 30, 2024, we recognized total other expense, net of $13.4 million as compared to total other expense of $21.3 million for the same period in 2023, a decrease of $7.9 million.

- The unrealized gain on investment in equity securities of approximately $8.3 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 nine months ended September 30, 2023.

- Interest expense, net for the nine months ended September 30, 2024 consists primarily of interest expense on borrowings under our Term Facility of approximately $21.0 million and amortization of deferred debt issuance costs of approximately $1.5 million, and interest expense on the New Credit Facility of approximately $1.1 million and Convertible Senior Notes of approximately $1.0 million, offset by dividend income earned on our money market funds and interest earned on our cash balances of approximately $8.0 million, the effects of the interest rate swap of approximately $4.9 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 average cash balances during the current period, interest income realized on our interest rate swaps, and the inclusion of approximately seven and a half months of Term Facility interest in the current nine months ended September 30, 2024 as compared to nine full months in September 30, 2023 due to the timing of the extinguishment of the Term Facility (August 13, 2024) and the draw down of the New Credit Facility (September 16, 2024).

- Other expense, net, increased to approximately $2.7 million, primarily due to the fees paid to JPMorgan Chase Bank, N.A. and Blackstone Credit & Insurance of $2.8 million pursuant to the terms of the debt commitment letter, dated June 21, 2024, entered into in connection with the acquisition of Alimera, offset by other income.
- We recorded a loss on debt extinguishment of approximately $7.5 million, comprised of the write-off unamortized deferred financing fees related to the Credit Facility. On August 13, 2024, the Company entered into the 2.25% Convertible Senior Notes due 2029 (as described in Note 7 “2.25% Convertible Senior Notes” to the Notes to Condensed Consolidated Financial Statements). The proceeds of the Convertible Senior Notes were used to repay the infrastructure Credit Facility in its entirety, approximately $294.0 million, comprised of $292.5 million of unpaid principal, $1.2 million in accrued and unpaid interest, and $0.3 million of legal fees. There was no comparable transaction in the nine months ended September 30, 2023.

Income Tax (Benefit) Expense

(in thousands)	Nine Months Ended September 30, 2024	2023	Change	% Change
Income tax (benefit) expense	$ (204)	$ 1,301	$ (1,505)	(115.7)%

For the nine months ended September 30, 2024, we recognized an income tax benefit of $0.2 million. The Company's effective tax rate was 2.4% after discrete items for the nine months ended September 30, 2024. The effective tax rate differed from the federal statutory rate of 21% primarily due to state taxes, treatment of discrete items (including 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 completed acquisition of Alimera.

For the nine months ended September 30, 2023, we recognized an income tax expense of $1.3 million. The income tax expense resulted from applying an estimated annual worldwide effective tax rate of 6.9% to pre-tax consolidated income of $18.9 million reported during the period. 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 stock based compensation.

LIQUIDITY AND CAPITAL RESOURCES

Term Loan A

On August 13, 2024, the Company, as lead borrower, entered into a delayed-draw credit agreement (the "New Credit Agreement") with JPMorgan Chase Bank, N.A., and other financial institutions (together, the "Lenders"), which provides for aggregate principal commitments consisting of (i) a senior secured term loan facility in an aggregate principal amount of $325.0 million (the "Term Loan A" or "TLA"), and (ii) a senior secured revolving credit facility in an aggregate commitment amount of $75.0 million, which may be used for revolving credit loans, swingline loans and letters of credit (the "TLA Revolver" and together with the TLA, the "New Credit Facility").

The facilities are secured by a lien on substantially all of the personal property owned by the Company and its material wholly-owned domestic subsidiaries and is guaranteed by all of the Company's material wholly-owned domestic subsidiaries. The New Credit Facility matures on the date that is five years following the closing date of the New Credit Agreement, provided that if any of the Notes (defined below) remain outstanding on the date that is 91 days prior to the maturity date of the Notes, the New Credit Facility will mature on such date unless certain terms are met.

At the Company's option, loans under the New Credit Facility accrue interest at a per annum rate equal to (i) the alternate base rate or (ii) the adjusted term SOFR rate for an interest period of one, three or six months, plus a spread depending on the Company's first lien net leverage ratio, between 1.25% and 2.00% in the case of ABR loans and between 2.25% and 3.00% in the case of adjusted term SOFR rate loans. A commitment fee accrues on the unutilized commitments under the TLA Revolver and, from and after the date that is two months after the closing date of the New Credit Agreement, the TLA at a per annum rate equal between 0.25% and 0.40% depending on the Company's first lien net leverage ratio.

The New Credit Agreement contains usual and customary representations and warranties of the parties for credit facilities of this type, subject to customary exceptions and materiality standards. In addition, the Company is required to maintain a first lien net leverage ratio not to exceed 3.00:1.00 (provided, that the lead borrower under the New Credit Agreement may elect to increase the ratio to 3.50:1.00 for four consecutive fiscal quarters following the consummation of a material acquisition) and a minimum interest coverage ratio of 3.00 to 1.00.

The New Credit Agreement also contains certain customary covenants including but not limited to restrictions on the amount of debt the Company and its restricted subsidiaries may incur and payments the Company and its restricted subsidiaries may make, and events of default, as well as, in the event of an occurrence of an event of default, customary remedies for the Lenders, including the acceleration of any amounts outstanding under the New Credit Agreement.

On September 16, 2024 (the "Closing Date") the Company drew the full $325.0 million of Term Loan A principal on September 16, 2024, with proceeds used to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the transaction. As of September 30, 2024, the TLA Revolver remains undrawn, and $75.0 million is available for borrowing, subject to certain conditions. The TLA and the TLA Revolver mature on September 16, 2029. The New Credit Facility contains certain contingent acceleration clauses, none of which have been triggered as of September 30, 2024. The cash interest rate and effective rate under the Term Loan A was approximately 7.95% at September 30, 2024.

2.25% Convertible Senior Notes Due 2029

On August 07, 2024, the Company entered into a purchase agreement (the "Purchase Agreement") with the initial purchasers (the "Initial Purchasers") relating to the issuance of the $275.0 million aggregate principal amount of the Company's Convertible Senior Notes due 2029 (the "Notes"). Pursuant to the terms of the Purchase Agreement, the Company granted the Initial Purchasers an option to purchase up to an additional $41.25 million aggregate principal amount of Notes (the "Option") for settlement at any time during the thirteen days beginning on, and including, August 7, 2024, which Option was excercised in full on August 8, 2024.

On August 13, 2024 (the "Closing Date" or "Issue Date"), the Company completed an offering of $316.25 million aggregate principal amount of Notes. The Notes were issued pursuant to an indenture (the "Indenture") dated as of Augsut 13, 2024 between the Company and U.S. Bank Trust Company, National Association ("Trustee"). The Notes are due September 1, 2029, unless earlier repurchased, redeemed, or converted. The Notes will accrue interest at a rate of 2.25% per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2025. After deducting the initial purchasers' discounts and commissions of approximately $9.5 million, but before deducting the Company's offering expenses, the net proceeds to the Company from the offering of the Notes was approximately $306.8 million. After payment of the cost of entering into the Capped Call Transactions (as defined below), the Company used the remainder of the net proceeds from the Notes offering, together with cash on hand, to repay the Company's existing senior secured credit agreement, dated as of November 19, 2021, by and among the Company, certain of the Company's subsidiaries, as guarantors, Truist Bank, as administrative agent and other parties thereto, as amended, supplemented or otherwise modified from time to time (as amended, the "Credit Agreement").

The Notes are the Company's senior, unsecured obligations and are (i) equal in right of payment with the Company's existing and future senior, unsecured indebtedness; (ii) senior in right of payment to the Company's existing and future indebtedness that is expressly subordinated to the Notes; (iii) effectively subordinated to the Company's existing and future secured indebtedness, to the extent of the value of the collateral securing that indebtedness; and (iv) structurally subordinated to all existing and future indebtedness and other liabilities, including trade payables, and (to the extent the Company is not a holder thereof) preferred equity, if any, of the Company's subsidiaries.

Prior to the close of business on the business day immediately preceding June 1, 2029, holders of the Notes will have the right to convert their Notes only upon the occurrence of certain events as set forth in the Indenture. All or any portion of the Notes may be converted prior to June 1, 2029 at the holders' option upon the occurrence of any of the following: (i) during any calendar quarter (and only during such calendar quarter) commencing after the calendar quarter ending on September 30, 2024, if the last reported sale price per share of the Company's common stock exceeds 130% of the conversion price of the Notes for each of at least 20 trading days, whether or not consecutive, during the 30 consecutive trading days ending on, and including, the last trading day of the immediately preceding calendar quarter; (ii) during the five consecutive business days immediately after any ten consecutive trading day period (such ten consecutive trading day period, the "measurement period") in which the trading price per $1,000 principal amount of Notes for each trading day of the measurement period was less than 98% of the product of the last reported sale price per share of the Company's common stock on such trading day and the conversion rate of the Notes on such trading day; (iii) upon the occurrence of certain corporate events or distributions on the Company's common stock, as described in the Indenture; or (iv) if the Company calls such Notes for redemption.

On or after June 1, 2029 until the close of business on the second scheduled trading day immediately before the maturity date of the Notes, holders may convert all or any portion of their Notes at any time at their election. The initial conversion rate for the Notes is 13.4929 shares of the Company's common stock per $1,000 principal amount of Notes, which represents an initial conversion price of approximately $74.11 per share of the Company's common stock. The conversion rate and conversion price will be subject to customary adjustments upon the occurrence of certain events. In addition, if certain corporate events that constitute a "Make-Whole Fundamental Change" (as defined in the Indenture) occur, then the conversion rate will, in certain circumstances, be increased for holders that convert their Notes in connection with such Make-Whole Fundamental Change, as described in the Indenture.

Upon conversion of the Notes, the Company will pay cash up to the aggregate principal amount of the Notes to be converted and pay or deliver, as the case may be, cash, shares of the Company's common stock or a combination of cash and shares of the Company's common stock, at the Company's election, in respect of the remainder, if any, of the Company's conversion obligation.

Capped Call Transactions

In connection with the offering of Notes, on August 7, 2024 and August 8, 2024, the Company entered into capped call transactions with certain financial institutions ("Capped Calls"). The Capped Calls each have an initial strike price of $114.02, which represents a premium of 100% over the last reported sale price of the Company's common stock on August 7, 2024. The Company used approximately $40.6 million of the net proceeds from the offering of the Notes to pay premiums on the Capped Calls.

The Capped Calls are expected to generally to reduce potential dilution to the Company's common stock upon any conversion of the Notes and/or offset any cash payments the Company is required to make in excess of the principal amount of converted Notes, as the case may be, with such reductions and/or offset subject to a cap, based on the cap price of the Capped Calls. The Capped Calls cover, subject to anti-dilution adjustments, approximately 4.3 million shares of the Company's common stock.

The Capped Calls will expire upon the maturity of the Notes. The Capped Calls are separate transactions entered into by the Company with the financial institution counterparties thereto, the Capped Calls are not part of the terms of the Notes and the Capped Calls do not change the holders' rights under the Notes. The Capped Calls do not meet the criteria for separate accounting as a derivative as they meet the criteria for equity classification, and the capped call transaction premiums are recorded as a reduction to Additional Paid-In Capital within Shareholders' Equity, net of deferred income taxes.

Debt Extinguishment

On November 19, 2021, the Company, as borrower, entered into a credit agreement (the "Credit Agreement") with Truist Bank and other lenders, which provided 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 was secured by substantially all our assets and the assets of our domestic subsidiaries. On August 13, 2024, the Company entered into the 2.25% Convertible Senior Notes due 2029. The proceeds of the Convertible Senior Notes were used to repay the Credit Facility in its entirety, approximately $294.0 million, comprised of $292.5 million of unpaid principal, $1.2 million in accrued and unpaid interest, and $0.3 million of legal fees. In connection with the issuance of the Convertible Senior Notes, the Company recorded a loss on debt extinguishment in the unaudited interim consolidated statement of operations for the three and nine months ended September 30, 2024, amounting to approximately $7.5 million, comprised of the write-off unamortized deferred financing fees related to the Credit Facility as of August 13, 2024.

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.

Accrued Licensor Payments

On May 17, 2023, Alimera entered into a product rights agreement with EyePoint Parent which granted Alimera an exclusive and sublicensable right and license under EyePoint Parent's and its affiliates' interest in certain of EyePoint Parent's and its affiliates' intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa, where the Company already has such rights pursuant to the New Collaboration Agreement, and except for China, Hong Kong, Macau, Taiwan, Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, South Korea, Thailand and Vietnam, where Ocumension holds a license from EyePoint Parent. Pursuant to the agreement, Alimera paid EyePoint Parent an upfront payment of $75.0 million and has also made three quarterly guaranteed payments to EyePoint Parent totaling $5.6 million during 2024, with one remaining payment of $1.9 due at December 31, 2024.

The Company will also pay royalties to EyePoint Parent from 2025 to 2028 at a percentage of mid-to-low double digits of annual U.S. net sales of certain products (including YUTIQ and ILUVIEN) in excess of certain thresholds, beginning at $70.0 million in 2025, increasing annually thereafter. Upon making the quarterly payments in the aggregate amount of $7.5 million in 2024, the licenses and rights granted to the Company will automatically become perpetual and irrevocable.

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue and corresponding collections from customers, our New Credit Facility, under which $75.0 million remains available for borrowing as of September 30, 2024, and the completed offering of $316.3 million of Convertible Senior Notes, 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:

	Nine Months Ended September 30,	
(in thousands)	**2024**	**2023**
Operating Activities	$ 48,157	$ 74,219
Investing Activities	$ (394,038)	$ (13,732)
Financing Activities	$ 269,852	$ 79,357

Net Cash Provided by Operations

Net cash provided by operating activities was $48.2 million for the nine months ended September 30, 2024, compared to net cash provided by operating activities of $74.2 million during the same period in 2023, a decrease of $26.1 million. The decrease in cash provided by operating activities resulted from an increase in non-cash items such as stock-based compensation, depreciation and amortization, amortization of inventory step up, 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 Used in Investing Activities

Net cash used in by investing activities for the nine months ended September 30, 2024 was $394.0 million, principally due to the acquisition of Alimera of approximately $393.1 million and capital expenditures of approximately $13.8 million, offset by proceeds received from the sale of the Oakville, Ontario manufacturing site in March 2024 of approximately $13.5 million. Net cash used in investing activities for the nine months ended September 30, 2023 was $13.7 million, principally due to acquisitions of ANDAs from the estates of Akorn Holding Company and Slayback Pharma Limited Liability Company totaling for $7.1 million and $6.6 million of capital expenditures.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 was $269.9 million, principally resulting from proceeds from the New Credit Facility of $325.0 million, proceeds from the offering of the Convertible Senior Notes of $316.3 million, offset by the repayment of the Truist Credit Facility of $292.5 million, purchase of the capped calls of $40.6 million, payments of debt issuance costs related to the Convertible Senior Notes and New Credit Facility of $15.4 million, $12.5 million paid to the Company Members of Novitium, and $10.6 million of treasury stock purchase, and other items. Net cash provided by financing activities for the nine months ended September 30, 2023 was $79.4 million, principally due to $80.6 million in proceeds received from the May 2023 public offering and $7.0 million from proceeds from stock option exercises and ESPP purchases, offset by purchases of $4.8 million of treasury stock related to restricted stock vests, $2.3 million maturity payments on the Term Facility, and $1.2 million convertible preferred stock dividends paid.

CRITICAL ACCOUNTING ESTIMATES

Except for updates to accounting policies as a result of the acquisition of Alimera, as described in Note 1, *Description of Business and Summary of Significant Accounting Policies,* of the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q to the accompanying consolidated financial statements, our critical accounting policies and estimates have not changed since December 31, 2023. Our critical accounting estimates were 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.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Market risks include interest rate risk, equity risk, foreign currency exchange rate risk, commodity price risk, and other relevant market rate or price risks. Of these risks, interest rate risk, equity risk, and foreign currency exchange rate risk could have a significant impact on our results of operations. In connection with our recent acquisition of Alimera, we have materially increased our international operations, exposing us to increased risk of foreign currency exchange fluctuations as compared to prior periods. In particular, we are now exposed to foreign currency fluctuations in British Pounds and Euros in addition to the Indian rupee. There have been no other 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 September 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

On September 16, 2024, we completed the acquisition of Alimera. We are currently in the process of evaluating and integrating the acquired operations, processes, and internal controls. See Note 3 of the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q for additional information on this acquisition. There were no other changes in our internal control over financial reporting, during the quarter ended September 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 15, *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 Quarterly Report on Form 10-Q, please carefully consider the factors described under the heading "Risk Factors" in our 2023 Form 10-K in Part I, Item 1A and in our Quarterly Report on Form 10-Q for the period ended June 30, 2024 in Part II, 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, including as related to the 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 our Business

Several of the products we have acquired cannot be manufactured in our facilities and are manufactured, packaged and/or distributed by third parties, which we cannot control. If we are unable to secure or maintain qualified contract manufacturers for those products, a contract manufacturer or distributor fails to comply with federal, state, and local laws and regulations, or third-party manufacturers or distributors sustain delays in production and distribution of our products, our business, financial position, and operating results could be materially, adversely affected.

We have acquired, and may continue to acquire, a variety of products that we seek to commercialize. Some of these products, including injectables, softgel capsules, and Purified Cortrophin Gel, as well as the products we acquired following the acquisition of Alimera, are products that we cannot currently manufacture in our facilities. As a result, we may seek partners to contract manufacture the products on our behalf, and we rely on third parties to manufacture, package and/or distribute many of our products. Like our Company, these companies must comply with cGMPs and other federal, state, and local laws and regulations regarding pharmaceutical manufacturing. Noncompliance by those companies may result in warning letters, fines, product recalls, and partial or total suspension of production and distribution. If we are unable to find qualified contract manufacturers or distributors or if a contract manufacturer or distributor fails to comply with federal, state, and local laws and regulations, we may be unable to commercialize these products, which could have a material adverse effect on our business, financial position, and operating results, including an impairment of the acquired product.

We expect our reliance on third party manufacturers to continue to increase in the future as we receive approvals for new products to be manufactured through our collaborative arrangements, and as we seek additional growth opportunities outside of the capabilities of our current manufacturing facilities, including following the acquisition of Alimera. If we are unable to secure third-party manufacturers for these products on commercially acceptable terms, we may not be able to market and distribute such products at a profit.

In addition, manufacturers and distributors of our products may sometimes encounter difficulties in production and distribution. These problems include failure to meet target production costs and yields, failure to meet product release specifications, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Adverse weather conditions and natural disasters may also affect our manufacturers' and distributors' supply chains, which could negatively impact our ability to source materials and components to make our products and, in more severe cases, such as hurricanes, earthquakes, floods, droughts, tornadoes or blizzards, eliminate the availability, or significantly increase the cost, of the components to make our products, sometimes for prolonged periods of time. The response of federal, state and local governmental bodies and agencies to climate change through regulations, mandates, reporting and disclosure requirements, taxes or levies could materially increase our or our manufacturers' cost to operate or obtain product components at a reasonable price, resulting in a material adverse effect on our financial results.

Any of these situations could materially and adversely harm our business and financial condition. We cannot assure you that any product quality issues relating to the manufacture and/or distribution of our product candidate or any future product candidates will not occur in the future. Any delays or difficulties with third-party manufacturers and/or distributors could adversely affect the marketing and distribution of these products, or future products, which could have a material adverse effect on our business, financial position, and operating results.

We may fail to realize the benefits expected from our acquisition of Alimera and 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.

On September 16, 2024, we completed our previously announced acquisition (the "Merger") of Alimera Sciences, Inc., a Delaware corporation ("Alimera") pursuant to the terms of the Agreement and Plan of Merger, dated as of June 21, 2024 (the "Merger Agreement"), by and among the Company, Alimera and ANIP Merger Sub INC., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"). The anticipated benefits we expect from this acquisition include, among other things, benefits relating to enhanced revenues, a strengthened market position for the combined company and operating efficiencies and these benefits are, necessarily, based on projections and assumptions about the combined businesses of our Company and Alimera, which may not materialize as expected or which may prove to be inaccurate. The value of our common stock could be adversely affected if we are unable to realize the anticipated benefits from the Merger on a timely basis or at all. Achieving the benefits of the Merger will depend, in part, on our ability to continue to integrate the business, operations and products of Alimera successfully and efficiently with our business.

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 timely 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 has materially increased 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, 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;
- unanticipated write-offs or charges. In connection with the Merger we recorded goodwill in the fair value amount of the acquisition. 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;
- our expansion into international operations as a result of the Merger (as discussed below);
- incurrence of significant costs in connection with consummating the Merger and integrating the operations of Alimera into our business;
- the potential for securities class action lawsuits and derivative lawsuits that may be brought as a result of the Merger, including costs associated with defending such lawsuits; and
- our failure to identify or accurately assess the magnitude of certain liabilities we assumed in the Merger could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, unexpected increases in taxes due, a loss of anticipated tax benefits or other known and unknown liabilities which could result in adverse effects on our business, operating results or financial condition.

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.

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

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. These fees and costs have been, and will continue to be for some time, substantial, and additional unanticipated costs may be incurred in our integration of Alimera. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. To the extent these acquisition and integration expenses are higher than anticipated, we may experience liquidity or cash flow issues.

We have incurred substantial debt in order to satisfy our obligations in connection with the Merger.

We financed the cash portion of the Merger with borrowings of $325.0 million under that certain senior secured credit agreement entered into on August 13, 2024 with JPMorgan Chase Bank, N.A. as administrative agent and other financial institutions. In order to service the debt we incurred under the Merger, we 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.

In connection with the Merger, we recorded goodwill 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 the Merger, we recorded 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, if goodwill recorded in connection with the Merger becomes impaired, our earnings could be significantly and adversely affected.

The Merger may become the target of derivative lawsuits that could result in substantial costs in connection with the Merger.

We may incur significant, non-recurring costs in connection with consummating the Merger and integrating the operations of Alimera into our business operations. Derivative lawsuits are often brought against public companies that have entered into merger agreements and have consummated acquisitions. The outcome of any litigation is uncertain, but regardless of the outcome of any such lawsuits, we may incur significant fees and expenses relating to legal services (including any costs that would be incurred in defending against any potential derivative lawsuits in connection with the Merger if any such proceedings are brought), accounting and other fees and costs, associated with consummating the Merger.

If we fail to successfully manage our international operations, our business, operating results and financial condition could suffer.

Alimera had, and we have acquired, direct operations and are marketing 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 of the closing of the Merger, the percentage of our revenues generated outside of the United States increased materially, and our new international operations require significant management attention and financial resources.

There is a high level of regulation in all markets where the products we acquired from Alimera have been 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 relied on distributors in many countries to provide adequate levels of experience and expertise on its behalf, and we will now rely on those distributors. We 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, within the Middle East, 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 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 exposes 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. 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.

The Merger magnifies the operational risks that we face.

Alimera was subject to many of the same operational risks as our business prior to the Merger, which are described in our 2023 Form 10-K and in our Quarterly Report on Form 10-Q for the period ended June 30, 2024. Given the substantial size of Alimera and associated complexities, many of the risk factors that we faced prior to the Merger will only become more magnified and substantial and the expanded business will only pose additional challenges for management, including those that relate to management and monitoring of new operations.

As a result of the consummation of the Merger, we 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 consummation of the Merger, we now have certain additional requirements that we 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 historically has reimbursement or by a new price in a country where we obtain reimbursement approval in the future.

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 also need to maintain current 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 did not and we do not currently have rights in China and certain other parts of Asia. As a result of the Merger, in order to market our products in foreign jurisdictions, we are 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, 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.

As a result of the consummation 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 did not have in-house manufacturing capability and depended entirely on single source third-party manufacturers for the manufacture of its products; following the consummation of the Merger, we rely on these third-party manufacturers for the manufacture of the products we acquired from Alimera, 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 relied, and we now rely, 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 relied, and we now rely, 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. 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 our ability to fulfill demand for YUTIQ could be materially impaired. Additionally, we may experience lengthy delays if we need to change a third-party supplier or manufacturer, including for YUTIQ, which could have a material impact on business and results of operations. Further, suppliers and manufacturers for the products we acquired from Alimera rely on additional third parties for the manufacture of component parts. Any inability of these 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 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 September 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
July 1 - July 31, 2024	1,743	$ 61.35	—	$ —
August 1 - August 31, 2024	2,953	$ 60.95	—	$ —
September 1 - September 30, 2024	6,653	$ 59.21	—	$ —
Total	11,349	$ 59.99	—	

(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

(c) 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.

On August 23, 2024 Krista Davis, Senior Vice President and Chief Human Resources Officer of the Company, adopted a Rule 10b5-1 trading plan for the period commencing three months from such date and ending on November 3, 2025 for sale of up to 5,866 shares of common stock of the Company.

On September 17, 2024, Meredith Cook, Senior Vice President, General Counsel and Corporate Secretary of the Company, adopted a Rule 10b5-1 trading plan for the period commencing three months from such date and ending on December 31, 2025 for sale of up to 4,800 shares of common stock of the Company.

On August 14, 2024, Muthusamy Shanmugam, Head of Research and Development and COO of New Jersey Operations of the Company, terminated his existing Rule 10b5-1 trading plan. Subsequently, on September 19, 2024, Muthusamy Shanmugam, adopted a Rule 10b5-1 trading plan for the period commencing three months from such date and ending on May 30, 2025 for sale of up to 200,000 shares of common stock of the Company.

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
4.1	Indenture, dated as of August 13, 2024, between ANI Pharmaceuticals, Inc. and U.S. Bank Trust Company, National Association, as trustee (incorporated by reference to Exhibit 4.1 on the Current Report on Form 8-K filed with the SEC on August 13, 2024).
4.2	Form of certificate representing the 2.25% Convertible Senior Notes due 2029 (included as Exhibit A to Exhibit 4.1) (incorporated by reference to Exhibit 4.2 on the Current Report on Form 8-K filed with the SEC on August 13, 2024).
10.1	Form of Capped Call Transaction Confirmation (incorporated by reference to Exhibit 10.1 on the Current Report on Form 8-K filed with the SEC on August 13, 2024).
10.2†	Credit Agreement, dated as of August 13, 2024, among ANI Pharmaceuticals, Inc., ANIP Acquisition Company, the guarantors party thereto., JPMorgan Chase Bank, N.A., as administrative agent, and other financial institutions as lenders (incorporated by reference to Exhibit 10.2 on the Current Report on Form 8-K filed with the SEC on August 13, 2024).
10.3	Contingent Value Rights Agreement dated September 16, 2024, by and between ANI Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company (included as Exhibit 10.1 on the Current Report on Form 8-K filed with the SEC on September 20, 2024).
10.4	ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan Sub-Plan for U.K. Employees
10.5	ANI Pharmaceuticals, Inc Amended and Restated 2022 Stock Incentive Plan Notice of Restricted Stock Grant
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.
† Certain schedules and certain exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished supplementally to the SEC upon request; provided, however, that the parties may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any document so furnished.

SIGNATURES

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

ANI Pharmaceuticals, Inc. (Registrant)

Date: November 8, 2024

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

Date: November 8, 2024

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

Exhibit 10.4

ANI PHARMACEUTICALS, INC. (THE "COMPANY")

THE COMPANY'S AMENDED AND RESTATED 2022 STOCK INCENTIVE PLAN (THE "PLAN")

SUB-PLAN FOR U.K. EMPLOYEES (THE "SUB-PLAN")

This Sub-Plan is a sub-plan of the Plan (as amended) and has been created and approved in accordance with the provisions of Section 3.2(e) of the Plan. Terms defined in the Plan shall have the same meanings in this Sub-Plan unless otherwise defined in this Sub-Plan.

SECTION 1 Definitions. As used in this Sub-Plan, the following terms shall have the meanings set forth below.

(a) "Eligible Participant" means any employees of the Employer (or its Subsidiaries) as determined by the Board.

(b) "Employer" means the Company or any of its Subsidiaries, as applicable.

(c) "FPO" means the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 of the United Kingdom (as may be amended from time to time).

(d) "FSMA" means the Financial Services and Markets Act 2000 of the United Kingdom (as may be amended from time to time).

(e) "Group" has the meaning given to that term under FSMA.

(f) "Incapacity" means any Participant that is, in the reasonable opinion of a medical practitioner, physically or mentally incapable of performing his or her duties and may remain so for more than three months and the medical practitioner has given a medical opinion to the Employer to that effect; and

(g) "U.K. Employee" means an Eligible Participant who is employed by the Employer which is a member of the Company's Group and who is resident in the United Kingdom.

SECTION 2 Purpose.

(a) The purpose of this Sub-Plan is primarily to establish a sub-plan under the auspices of the Plan that will apply to Incentive Awards to be made to U.K. Employees. As a result:

(i) all Incentive Awards to U.K. Employees shall be made under this Sub-Plan;

(ii) no Incentive Awards shall be made under this Sub-Plan to any person other than a U.K. Employee, and this Sub-Plan shall not apply to any Awards made under the Plan to any such other person; and

(iii) Sections 5, 6, 7, 8, 9, 10 and 11 of the Plan shall be deemed amended accordingly insofar as it applies to this Sub-Plan.

(b) The provisions of the Sub-Plan vary from those applicable under the Plan so as to:

(i) enable the Sub-Plan (and any Incentive Awards made or proposed to be made under the Sub-Plan, and communications concerning those Incentive Awards) to take advantage of certain exemptions available in the United Kingdom from certain prohibitions and restrictions which might otherwise apply to such Incentive Awards and communications in the United Kingdom under the regulatory regime established under FSMA; and

(ii) take account of United Kingdom tax treatment of the Incentive Awards.

(c) No Incentive Award shall be made under this Sub-Plan unless such Incentive Award relates to a type of investment set out or referred to in Article 60(1) of the FPO.

SECTION 3 Interaction with the Plan.

(a) This Sub-Plan should be read in conjunction with the Plan and is subject to the terms and conditions of the Plan except to the extent that the terms and conditions of the Plan differ from or conflict with the terms set out in this Sub-Plan, in which event, the terms set out in this Sub-Plan shall prevail.

(b) Subject to the other provisions of this Sub-Plan, the provisions of the Plan will apply to this Sub-Plan as if references therein to the Plan were references to this Sub-Plan.

(c) The term "disability" as used Section 12 of the Plan shall be replaced by the term "Incapacity" as defined in this Sub-Plan.

(d) The first sentence in Section 15.1 of the Plan shall read, for the purposes of this Sub-Plan, as follows: "The right to dismiss any Eligible Participant is specifically reserved to the Employer".

SECTION 4 Taxes.

(a) Section 13 of the Plan shall be supplemented by this Section 4.

(b) All Awards under this Sub-Plan shall be subject to applicable United Kingdom taxes, national insurance contributions and/or other levies. As a condition to the issuance, vesting, exercise or settlement of any Award, the Participant shall be required to pay to the Employer or such other applicable member of the Company's Group, or make other arrangements satisfactory to the Employer or such other applicable member of the Company's Group to provide for the payment of, any national, federal, state or local or other taxes, social

security, employee's United Kingdom national insurance contributions and other levies ("U.K. Employment Taxes") that the Employer or such other applicable member of the Company's Group is required to withhold, or in respect of which the Employer or such other applicable member of the Company's Group is required to account to any tax authority including HM Revenue & Customs ("HMRC"), with respect to any income or gains arising or deemed to arise to the Participant in connection with any Award (including for the avoidance of doubt in connection with the exercise of any vesting of any Award). For the purposes of this Sub-Plan the person so required to account for such U.K. Employment Taxes shall be referred to as the "Responsible Person". The Company, any Responsible Person and any other member of the Company's Group are each authorised to withhold from any Award made, any payment relating to an Award under this Sub-Plan, including any payroll or other payment to a Participant, the amount of required U.K. Employment Taxes due or potentially payable in connection with any transaction involving an Award under this Sub-Plan to the maximum extent permitted by law and regulation. To the extent any amount is withheld by a person who is not the Responsible Person in accordance with this section, such amount shall either be remitted to the Responsible Person on behalf of the Participant, or deemed to have been so remitted where the amount is paid to HMRC or any other relevant tax authority on behalf of such Responsible Person.

SECTION 5 General.

(a) The Sub-Plan, and any Awards granted hereunder, shall be governed, construed and administered in accordance with the laws of the State of Delaware, without reference to its conflict of laws provisions.

(b) The terms and conditions provided in this Sub-Plan are severable and if (despite the provisions of Section 5(a) of this Sub-Plan) any one or more provisions (or the effect of any such provision) are determined to be illegal or otherwise unenforceable under any applicable law, in whole or in part, the remaining provisions shall nevertheless be binding and enforceable.

(c) For the purpose of operating the Sub-Plan, the Company will collect and process information relating to Participants in accordance with the privacy notice which is non-contractual and shall be provided to Eligible Participants in writing from time to time.

Exhibit 10.5

ANI PHARMACEUTICALS, INC.
AMENDED AND RESTATED 2022 STOCK INCENTIVE PLAN

NOTICE OF RESTRICTED STOCK GRANT

ANI Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"), pursuant to its Amended and Restated 2022 Stock Incentive Plan (the "*Plan*"), hereby grants to the individual listed below (the "*Participant*"), this grant of shares of restricted Common Stock as set forth below (the "*Restricted Shares*") that may become vested subject to the conditions set forth in this Notice of Restricted Stock Grant (this "*Notice*"), the Restricted Stock Grant Agreement attached hereto as Attachment A (the "*Grant Agreement*") and the Plan, each of which is incorporated herein by reference and made part hereof. Unless otherwise defined herein, capitalized terms used in this Notice and the Grant Agreement will have the meanings set forth in the Plan.

Participant:	***See E*Trade Account***
Date of Grant:	***See E*Trade Account***
Form of Award:	Restricted Stock Grant
Shares Underlying Award:	[***See E*Trade Account***] Shares of Restricted Stock (the "*Restricted Shares*")
Vesting Schedule:	The Restricted Shares shall vest as set forth in Section 3 of the Grant Agreement, which generally provides for: • On the first anniversary of the Date of Grant 25% of the Restricted Shares shall vest, on the second anniversary of the Date of Grant an additional 25% of the Restricted Shares shall vest, on the third anniversary of the Date of Grant an additional 25% of the Restricted Shares shall vest and on the fourth anniversary of the Date of Grant all of the remaining Restricted Shares shall vest (each such anniversary of the Date of Grant, a "*Vesting Date*"); provided in each case Participant is employed and in good standing through the applicable Vesting Date. • Upon a termination of the Participant's employment with the Company or any of its Subsidiaries as a result of the Participant's death or Disability, any Restricted Shares scheduled to vest on the first Vesting Date following such termination shall immediately vest.

Participant Acceptance:

By accepting this award, the Participant agrees to be bound by the terms and conditions of the Plan, the Grant Agreement and this Notice. The Participant acknowledges delivery of the Plan and the Plan prospectus together with this Notice and the Grant Agreement, as well as the Company's Insider Trading Policy and the Company's Clawback Policy. The Participant accepts as binding, conclusive and final all decisions or interpretations of the Committee upon any questions arising under the Plan, this Notice, the Grant Agreement, or the Clawback Policy.

The Participant confirms acceptance of this award by clicking the "Accept" (or similar wording) button on the award acceptance screen of the Participant's Plan account at www.ETRADE.com. If the Participant wishes to reject this award, the Participant must so notify Sherri Bitter, VP, Human Resources, at sherri.bitter@anipharmaceuticals.com or Krista Davis, Chief Human Resources Officer, at krista.davis@anipharmaceuticals.com no later than sixty (60) days after the Date of Grant. If within such sixty (60) day period the Participant neither affirmatively accepts nor affirmatively rejects this award, the Participant will be deemed to have accepted this award at the end of such sixty (60) day period pursuant to the terms and conditions set forth in this Notice, the Award Agreement, and the Plan.

Attachment A

ANI PHARMACEUTICALS, INC.

RESTRICTED STOCK GRANT AGREEMENT
(Pursuant to the Amended and Restated 2022 Stock Incentive Plan)

THIS RESTRICTED STOCK GRANT AGREEMENT (this "*Agreement*"), which is attached as Attachment A to a Notice of Grant Agreement (the "*Notice*"), is entered into as of the date set forth on the Notice and is entered into by and between ANI Pharmaceuticals, Inc., a Delaware corporation (the "*Company*"), and the individual identified as the "*Participant*" on the Notice. The parties hereto hereby agree as follows:

1. Grant of Shares. The Company hereby grants to the Participant the number of shares of the Company's Common Stock, $0.0001 par value, that are described as the Restricted Shares on the Notice, subject to the vesting conditions set forth in the Notice and this Agreement.

2. Grant of Restricted Shares. The grant of Restricted Shares contemplated hereby is made pursuant to the Company's Amended and Restated 2022 Stock Incentive Plan (the "*Plan*"), which Plan is incorporated herein by reference. This Agreement constitutes a "Restricted Stock Award" within the meaning of the Plan. Capitalized terms used herein and not otherwise defined have the meanings set forth in the Plan.

3. Vesting.

(a) Subject to any vesting acceleration protections set forth in a written agreement between Participant and the Company (a "*Written Agreement*"), upon the termination of Participant's employment with the Company and all Subsidiaries for any reason (including, subject to Section 3(b), as a result of Participant's death or disability), any then unvested Restricted Shares will be automatically forfeited for no payment or consideration.

(b) Unless otherwise provided in the Notice, on the first anniversary of the Date of Grant 25% of the Restricted Shares shall vest, on the second anniversary of the Date of Grant an additional 25% of the Restricted Shares shall vest, on the third anniversary of the Date of Grant an additional 25% of the Restricted Shares shall vest and on the fourth anniversary of the Date of Grant all of the remaining Restricted Shares shall vest (each such anniversary of the Date of Grant , a "*Vesting Date*"); provided, however, that (i) the vesting acceleration provisions in any applicable Written Agreement shall apply as set forth therein; (ii) vesting may accelerate pursuant to Section 14 of the Plan; and (iii) upon the termination of Participant's employment with the Company and all Subsidiaries as a result of the Participant's death or Disability, any Restricted Shares scheduled to vest on the first Vesting Date following such termination shall immediately vest.

(c) The vesting of the Restricted Shares shall be cumulative, but shall not exceed 100% of the shares of Restricted Shares. If the foregoing schedule would produce fractional shares, the number of shares that vest shall be rounded down to the nearest whole share and the fractional shares will be accumulated so that the resulting whole shares will be included in the number of shares that become vested on the last Vesting Date.

(d) In the event of a Change in Control or Corporate Transaction (as each term is defined in the Plan), Section 14 of the Plan shall apply to the Restricted Shares.

4. Adjustments to the Restricted Shares. If, from time to time, during the Restriction Period (as defined below) there is any change affecting the Company's outstanding Common Stock as a class that is effected without the receipt of consideration by the Company (through merger, consolidation, reorganization, reincorporation, stock dividend, dividend in property other than cash, stock split, liquidating dividend, combination of shares, change in corporation structure or other transaction not involving the receipt of consideration by the Company), then Section 4.3 of the Plan shall apply to the Restricted Shares.

5. Breach of Consulting, Confidentiality or Non-Compete Agreements. Notwithstanding anything in this Agreement to the contrary and in addition to the rights of the Committee under Section 12.4 of the Plan, in the event that the Participant materially breaches the terms of any employment, consulting, confidentiality or non-compete agreement entered into with the Company or any Subsidiary (including an employment, consulting, confidentiality or non-compete agreement made in connection with the grant of the Restricted Shares), whether such breach occurs before or after termination of the Participant's employment with the Company or any Subsidiary, the Committee in its sole discretion may require the Participant to surrender shares of Common Stock received, and to disgorge any profits (however defined by the Committee), made or realized by the Participant in connection with this Agreement or the Restricted Shares granted hereunder, in each case to the extent disgorgement or forfeiture of such amounts is required under a policy of the Company or any successor, or its or their subsidiaries, adopted to comply with applicable requirements of law (including Section 10D of the Securities Exchange Act of 1934, as amended) or of any applicable stock exchange.

6. Rights of Participant. Subject to the provisions of this Agreement, Participant (but not any unapproved transferee) shall, during the term of this Agreement, exercise all rights and privileges of a stockholder of the Company with respect to the Restricted Shares. Participant shall be deemed to be the holder for purposes of receiving any dividends that may be paid with respect to such Restricted Shares and for the purpose of exercising any voting rights relating to such Restricted Shares, even if some or all of such Restricted Shares have not yet vested.

7. Limitations on Transfer. In addition to any other limitation on transfer created by applicable securities laws, during the period before the Restricted Shares vest in accordance with Section 3 (the "*Restriction Period*"), Participant shall not assign, hypothecate, donate, encumber or otherwise dispose of any interest in any of the unvested Restricted Shares.

8. Share Certificates. Reasonably promptly following the Date of Grant, the Company shall reflect ownership thereof in book entry form on the Company's books and records, or, in its discretion cause to be issued to the Participant a certificate in respect of the Restricted Shares. If certificates representing the Restricted Shares are issued, they shall be issued in the name of the Participant, but held in the physical possession of the Company, and the Participant shall execute in blank a stock power in a form provided by the Company, allowing the Company to transfer the shares of Restricted Shares in the event they are forfeited pursuant to the terms of this Grant Agreement. Such certificates shall bear the following (or a similar) legend in addition to any other legends that may be required under federal or state securities laws:

> *"*THE TRANSFERABILITY OF THIS CERTIFICATE AND THE SHARES OF COMMON STOCK REPRESENTED HEREBY ARE SUBJECT TO THE TERMS AND CONDITIONS (INCLUDING FORFEITURE) CONTAINED IN THE ANI PHARMACEUTICALS, INC. AMENDED AND RESTATED 2022 STOCK INCENTIVE PLAN AND A RESTRICTED STOCK GRANT AGREEMENT BETWEEN THE STOCKHOLDER AND ANI

PHARMACEUTICALS, INC. A COPY OF THE PLAN AND THE GRANT AGREEMENT ARE ON FILE WITH ANI PHARMACEUTICALS, INC."

9. Section 83(b) Election. Participant understands that Section 83(a) of the Internal Revenue Code of 1986, as amended (the "*Code*"), taxes as ordinary income the difference between the amount paid for the Restricted Shares and the fair market value of the Restricted Shares as of the date any restrictions on the Restricted Shares lapse. Participant understands that Participant may elect to be taxed at the time the Restricted Shares are awarded, rather than when and as the Restricted Shares vest, by filing an election under Section 83(b) of the Code (an "*83(b) Election*") with the Internal Revenue Service within thirty (30) days from the date of purchase. A copy of an 83(b) Election form that can be used for this purpose can be attained on request from the Company. Even if the fair market value of the Restricted Shares at the time of the execution of this Agreement equals the amount paid for the Restricted Shares, the 83(b) Election must be made to avoid income under Section 83(a) in the future. Participant understands that failure to file such an 83(b) Election in a timely manner may result in adverse tax consequences for Participant. Participant further understands that an additional copy of such 83(b) Election is required to be filed with his or her federal income tax return for the calendar year in which the date of this Agreement falls. Participant further acknowledges and understands that it is Participant's sole obligation and responsibility to timely file such 83(b) Election, and neither the Company nor the Company's legal or financial advisors shall have any obligation or responsibility with respect to such filing. Participant acknowledges that the foregoing is only a summary of the effect of United States federal income taxation with respect to purchase of the Restricted Shares hereunder, and does not purport to be complete. Participant further acknowledges that the Company has directed Participant to seek independent advice regarding the applicable provisions of the Code, the income tax laws of any municipality, state or foreign country in which Participant may reside, and the tax consequences of Participant's death. Participant assumes all responsibility for completing and filing an 83(b) Election and paying all taxes resulting from such election or the lapse of the restrictions on the Restricted Shares.

10. Refusal to Transfer. The Company or its transfer agent shall not be required (a) to transfer on its books any Restricted Shares that shall have been transferred in violation of any of the provisions set forth in this Agreement or (b) to treat as owner of such shares or to accord the right to vote as such owner or to pay dividends to any transferee to whom such Restricted Shares shall have been so transferred.

11. No Employment Rights. This Agreement is not an employment contract and nothing in this Agreement shall affect in any manner whatsoever the right or power of the Company (or any parent or subsidiary of the Company) to terminate Participant's relationship with the Company for any reason at any time, with or without cause and with or without notice.

12. Withholding. All obligations of the Company to deliver shares of Common Stock shall be subject to the rights of the Company to withhold applicable income tax (including U.S. federal, state, and local tax and/or foreign income tax), employment tax (including FICA), payroll tax, social security tax, social insurance, national insurance contributions, payment on account obligations, national and local tax or other amounts ("*Withholding Taxes*").

13. No Entitlement or Claims for Compensation. In connection with the acceptance of the grant of the Restricted Shares under this Grant Agreement, the Participant acknowledges the following:

(a) the Plan is established voluntarily by the Company, the grant of the Restricted Shares under the Plan is made at the discretion of the Committee and the Plan may be modified, amended, suspended or terminated by the Company at any time;

(b) the grant of the Restricted Shares under the Plan is voluntary and occasional and does not create any contractual or other right to receive future grants of equity awards, or benefits in lieu of them, even if equity awards have been granted repeatedly in the past;

(c) all decisions with respect to future grants of awards, if any, will be at the sole discretion of the Committee;

(d) the Participant is voluntarily participating in the Plan;

(e) the grant of Restricted Shares under the Plan are extraordinary items that do not constitute compensation of any kind for services of any kind rendered to the Company or any Subsidiary and which are outside the scope of the Participant's employment contract, if any;

(f) the grant of Restricted Shares under the Plan are not to be considered part of the Participant's normal or expected compensation or salary for any purpose, including, but not limited to, calculating any severance, resignation, termination, payment in lieu of notice, redundancy, end of service payments, bonuses, long-service awards, pension or retirement or welfare benefits or similar payments;

(g) the grant of the Restricted Shares is not intended to replace any pension rights or compensation;

(h) the grant of the Restricted Shares and the Participant's participation in the Plan will not be interpreted to form an employment contract or relationship with the Company or any Subsidiary;

(i) the future value of the shares of Common Stock is unknown and cannot be predicted with certainty. If the Participant vests in the Restricted Shares, the value of the acquired shares of Common Stock may increase or decrease;

(j) the Participant understands that the Company is not responsible for any foreign exchange fluctuation between the United States Dollar and the Participant's local currency that may affect the value of the grant of Restricted Shares; and

(k) in consideration of the grant of the Restricted Shares, the Participant shall have no rights, claim or entitlement to compensation or damages from the forfeiture of the Restricted Shares or diminution in the value of the Restricted Shares as a result of the Participant's termination of employment or service for any reason whatsoever (whether or not in breach of contract or local labor law) or notice to terminate employment or service having been given by either the Participant or the Company, and the Participant irrevocably releases the Company from any such rights, entitlement or claim that may arise. If, notwithstanding the foregoing, any such right or claim is found by a court of competent jurisdiction to have arisen, then, by signing this Agreement, the Participant shall be deemed to have irrevocably waived the Participant's entitlement to pursue such rights or claim.

14. <u>Data Protection and Privacy (For Jurisdictions other than in the European Union or European Economic Area).</u>

(a) The Participant hereby explicitly and unambiguously consents to the collection, use and transfer, in electronic or other form, of the Participant's personal data as described in this Agreement by and among, as applicable, the Participant's employer, the Company and its

Subsidiaries for the exclusive purpose of implementing, administering and managing the Participant's participation in the Plan.

(b) The Participant understands that Participant's employer, the Company and its Subsidiaries, as applicable, hold certain personal information about the Participant regarding the Participant's employment, the nature and amount of the Participant's compensation and the fact and conditions of the Participant's participation in the Plan, including, but not limited to, the Participant's name, home address, telephone number and e-mail address, date of birth, social insurance number or other identification number, salary, nationality, job title, any shares of stock or directorships held in the Company and its Subsidiaries, details of all restricted stock awards or any other entitlement to equity awarded, canceled, exercised, vested, unvested or outstanding in the Participant's favor, for the purpose of implementing, administering and managing the Plan (the "*Data*").

(c) The Participant understands that the Data may be transferred to any third parties assisting in the implementation, administration and management of the Plan, that these recipients may be located in the Participant's country, or elsewhere, and that the recipient's country may have different data privacy laws and protections than the Participant's country. The Participant understands that the Participant may request a list with the names and addresses of any potential recipients of the Data by contacting his or her local human resources representative. The Participant authorizes the recipients to receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing the Participant's participation in the Plan, including any requisite transfer of such Data as may be required to a broker or other third party. The Participant understands that the Data will be held only as long as is necessary to implement, administer and manage Participant's participation in the Plan. The Participant understands that he or she may, at any time, view the Data, request additional information about the storage and processing of the Data, require any necessary amendments to the Data or refuse or withdraw the consents herein, in any case without cost, by contacting in writing the Participant's local human resources representative. The Participant understands, however, that refusing or withdrawing his or her consent may affect the Participant's ability to participate in the Plan. For more information on the consequences of refusal to consent or withdrawal of consent, the Participant understands that the Participant may contact his or her local human resources representative.

15. Miscellaneous.

(a) Notices. Any notice or other communication required or permitted to be delivered to any party under this Agreement shall be in writing and shall be deemed properly delivered, given and received when delivered (by hand, by registered mail, or by courier or express delivery service) to the address or facsimile number set forth beneath the name of such party on the signature page hereto (or to such other address or facsimile number as such party shall have specified in a written notice given to the other parties hereto).

(b) Successors and Assigns. This Agreement shall bind and inure to the benefit of the successors and assigns of the Company and, subject to the restrictions on transfer herein set forth, inure to the benefit of and be binding upon Participant and Participant's heirs, executors, administrators, successors, and assigns. Without limiting the generality of the foregoing, this Agreement shall be assignable by the Company at any time or from time to time, in whole or in part.

(c) Governing Law. This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware.

(d) Further Assurances. The parties agree to execute all such further instruments and to take all such further action as may reasonably be necessary to carry out the intent of this Agreement.

(e) Amendment. This Agreement may not be amended, modified or revoked, in whole or in part, except by an agreement in writing signed by each of the parties hereto.

(f) Severability. In the event that any provision of this Agreement, or the application of any such provision to any person or set of circumstances, shall be determined to be invalid, unlawful, void or unenforceable to any extent, the remainder of this Agreement, and the application of such provision to persons or circumstances other than those as to which it is determined to be invalid, unlawful, void or unenforceable, shall not be impaired or otherwise affected and shall continue to be valid and enforceable to the fullest extent permitted by law.

(g) Counterparts. This Agreement may be executed in two or more counterparts and signature pages may be delivered via facsimile, each of which shall be deemed an original and all of which together shall constitute one instrument.

(h) Country-Specific Terms. Notwithstanding anything to the contrary herein, this Agreement and the grant of Restricted Shares shall be subject to the Country-Specific Terms attached hereto as Addendum A. In addition, if the Participant relocates to one of the countries included in the Country-Specific Terms, the special terms and conditions for such country will apply to the Participant to the extent the Company determines that the application of such terms and conditions is necessary or advisable in order to comply with local law or facilitate the administration of the Plan. The Country-Specific Terms constitute part of this Agreement and are incorporated herein by reference.

ADDENDUM A TO THE RESTRICTED STOCK GRANT AGREEMENT TO EMPLOYEE

COUNTRY-SPECIFIC TERMS
FOR PARTICIPANTS OUTSIDE THE U.S.

These Country-Specific Terms include additional terms and conditions that govern the Restricted Stock Grant Agreement awarded to the Participant under the Plan if the Participant resides in one of the countries listed below. Capitalized terms used but not defined in these Country-Specific Terms are defined in the Plan or the Grant Agreement and have the meanings set forth therein.

U.K.

U.K. Subplan

If the Incentive Award is being made to a U.K. Employee (as such term is defined in such UK Sub-Plan (as defined below)):

(a) the Incentive Award is being made pursuant to the sub-plan for employees resident in the United Kingdom created and approved in accordance with the provisions of Section 3.2(e) of the Plan (the "*UK Sub-Plan*"), and the Plan as amended by the UK Sub-Plan, and the main body of the Grant Agreement shall be deemed amended accordingly;

(b) any references in the main body of the Grant Agreement or Notice to such Incentive Award having been made pursuant to the Plan, or to the participation of the Participant in the Plan, shall be deemed to be references to such Incentive Award having been made pursuant to, and such participation being in, the UK Sub-Plan;

(c) any other reference in the main body of the Grant Agreement or Notice to the Plan shall (as appropriate and unless the context otherwise requires) be deemed to be a reference to the UK Sub-Plan (including the Plan, as amended by and incorporated into the UK Sub-Plan);

(d) any reference in the main body of the Grant Agreement to a specific provision of the Plan shall be deemed to be a reference to such provisions of the Plan as amended by and incorporated into the UK Sub-Plan; and

(e) in the event of any conflict between the terms of the Grant Agreement and the terms of the UK Sub-Plan, the UK Sub-Plan shall prevail.

Termination of Service

The Participant has no right to compensation or damages on account of any loss in respect of an Incentive Award under the Plan and the U.K. Subplan where the loss arises or is claimed to arise in whole or part from: (a) the termination of the Participant's office or employment; or (b) notice to terminate the Participant's office or employment. This exclusion of liability shall apply however, termination of office or employment, or the giving of notice, is caused, and however compensation or damages are claimed. For the purpose of the Plan and the U.K. Subplan, the implied duty of trust and confidence is expressly excluded.

Tax Withholding

The Participant indemnifies the Company for any Withholding Taxes that may be payable with respect to the Restricted Shares (including any shares of Common Stock that are deemed issued).

As a condition to the issuance of Shares under the Incentive Award, the Participant unconditionally and irrevocably agrees, if so required by the Company, to enter into a joint election within section 431(1) of (UK) Income Tax (Earnings and Pensions) Act 2003 ("*ITEPA*") disapplying all restrictions in respect of the acquisition of "restricted securities" (as defined in Section 423 and 424 of ITEPA).

Data Privacy.

Section 14 of the Grant Agreement shall not apply to residents in the United Kingdom and the following shall apply instead:

Data Privacy (For Residents in the United Kingdom).

(a) The Participant hereby acknowledges and understands that the Participant's personal data is collected, retained, used, processed, disclosed and transferred, in electronic or other form, as described in this Grant Agreement by and among, as applicable, the Participant's employer, the Company and its Subsidiaries, and third parties assisting in the implementation, administration and management of the Plan for the exclusive purpose of implementing, administering and managing the Participant's participation in the Plan.

(b) The Participant understands that the Company and its Subsidiaries (including Participant's employer), as applicable, hold certain personal information about him or her regarding the Participant's employment, the nature and amount of the Participant's compensation and the fact and conditions of the Participant's participation in the Plan, including, but not limited to, his or her name, home address, telephone number and e-mail address, date of birth, social insurance number or other identification number, salary, nationality, job title, any equity or directorships held in the Company and details of all restricted stock awards or any other entitlement to equity awarded, canceled, exercised, vested, unvested or outstanding in his or her favor, for the purpose of the implementation, management and administration of the Plan (the "*Data*").

(c) The Participant understands that the Data may be transferred to the Company, its Subsidiaries and any third parties assisting in the implementation, administration and management of the Plan, that these recipients may be located in his or her country, or elsewhere (including countries outside the United Kingdom, such as the United States of America), and that the recipient's country may have a different or lower standard of data privacy rights and protections than his or her country. Where the Data will be transferred outside the Participant's work location, and where there is not a European Commission adequacy decision in place, the transfers will be in accordance with Chapter V of the GDPR. The Participant understands that he or she may request details of the categories of recipients of the Data by contacting the Participant's local human resources representative. The Participant understands that the recipients receive, possess, use, retain and transfer the Data, in electronic or other form, for the purposes of implementing, administering and managing his or her participation in the Plan, including transfers of such Data to a broker or other third party. The Participant understands that the Data will be held only as long as is necessary to implement, administer and manage his or her participation in the Plan in accordance with applicable law. The Participant understands that he or she may, at any time, exercise the rights granted to him/her by the GDPR including the right to: request to access or be provided with a copy of his or her Data, request additional information about the storage and processing of the Data, require any corrections or amendments to the Data in any case without cost and to the extent permitted by law. The above rights can be exercised by contacting in writing his or her local human resources representative. The Participant understands, however,

that processing of his/her Data is necessary and refusing any consent that is sought by the Company or objecting to the processing of his or her Data may affect the Participant's ability to participate in the Plan. For more information on the processing of his or her Data and other personal data, the Participant is referred to the Privacy Notice provided to Participant by Participant's employer.

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: November 8, 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: November 8, 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 September 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: November 8, 2024

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

Dated: November 8, 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.