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

FORM 10-Q

(Mark one)

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

For the quarterly period ended June 30, 2022

☐ **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 August 1, 2022 there were 17,426,034 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended June 30, 2022

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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 or supplemental new drug applications to the U.S. Food and Drug Administration (the "FDA"), pipeline or potential markets for our products, selling and marketing strategies and associated costs to support the sales of Purified Cortrophin® Gel (Repository Corticotropin Injection USP) ("Cortrophin Gel"), impact of accounting principles, litigation expenses, liquidity and capital resources, the impact of the novel coronavirus ("COVID-19") global pandemic on our business, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words, and the use of future dates. Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including those discussed in the "Risk Factors" section in Part I, Item 1A. of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and the following factors:

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

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2021, including the factors described in "Item 1A. Risk Factors." Other risks may be described from time to time in our filings made under

the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

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

NOTE REGARDING TRADEMARKS

Apexicon®, Cortenema®, Purified Cortrophin® Gel, Cortrophin-Zinc®, Inderal® LA, Inderal® XL, InnoPran XL®, Lithobid®, Reglan®, Vancocin®, and Veregen® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries. Atacand® and Atacand HCT® are the property of AstraZeneca AB and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Arimidex® and Casodex® are the property of AstraZeneca UK Limited and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Oxistat® is the property of Fougera Pharmaceuticals Inc. and licensed to ANI Pharmaceuticals, Inc. for U.S. sales of Oxistat® Lotion. Pandel® is property of Taisho Pharmaceutical Co, Ltd. and licensed to ANI Pharmaceuticals for U.S. sales of Pandel® creme.

Part I — FINANCIAL INFORMATION

Item 1. Financial Statements

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

	June 30, 2022	*December 31, 2021*
Assets		
Current Assets		
Cash and cash equivalents	$ 63,385	$ 100,300
Accounts receivable, net of $150,428 and $105,260 of adjustments for chargebacks and other allowances at June 30, 2022 and December 31, 2021, respectively	150,410	128,526
Inventories, net	92,545	81,693
Prepaid income taxes	2,013	3,667
Assets held for sale	8,020	—
Prepaid expenses and other current assets	6,026	7,589
Total Current Assets	322,399	321,775
Non-current Assets		
Property and equipment	71,042	75,627
Accumulated depreciation	(27,271)	(22,956)
Property and equipment, net	43,771	52,671
Restricted cash	5,001	5,001
Deferred tax assets, net of deferred tax liabilities and valuation allowance	76,587	67,936
Intangible assets, net	269,593	294,122
Goodwill	28,221	27,888
Derivatives and other non-current assets	5,762	2,205
Total Assets	$ 751,334	$ 771,598
Liabilities, Mezzanine Equity, and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	27,641	22,967
Accrued royalties	6,295	6,225
Accrued compensation and related expenses	5,682	8,522
Accrued government rebates	9,440	5,492
Returned goods reserve	34,899	35,831
Accrued expenses and other	11,505	7,650
Total Current Liabilities	96,312	87,537
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	286,095	286,520
Non-current contingent consideration	30,958	31,000
Derivatives and other non-current liabilities	1,011	7,801
Total Liabilities	$ 414,376	$ 412,858
Commitments and Contingencies (Note 13)		
Mezzanine Equity		
Convertible Preferred Stock, Series A, $0.0001 par value, 1,666,667 shares authorized; 25,000 shares issued and outstanding at June 30, 2022 and December 31, 2021	24,850	24,850
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 17,566,363 shares issued and 17,427,252 outstanding at June 30, 2022; 16,912,401 shares issued and 16,829,739 shares outstanding at December 31, 2021	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	—	—
Treasury stock, 139,112 shares of common stock, at cost, at June 30, 2022 and 82,662 shares of common stock, at cost, at December 31, 2021	(4,736)	(3,135)
Additional paid-in capital	395,043	387,844
Accumulated deficit	(83,630)	(47,765)
Accumulated other comprehensive income/(loss), net of tax	5,430	(3,055)
Total Stockholders' Equity	312,108	333,890
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 751,334	$ 771,598

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

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

	Three Months Ended June 30,		*Six Months Ended June 30,*	
	2022	*2021*	*2022*	*2021*
Net Revenues	$ 73,855	$ 48,625	$ 138,332	$ 103,146
Operating Expenses				
Cost of sales (excluding depreciation and amortization)	35,294	22,314	69,565	42,299
Research and development	4,165	2,805	9,439	5,773
Selling, general, and administrative	31,958	18,820	60,775	36,407
Depreciation and amortization	13,764	11,324	28,321	22,222
Contingent consideration fair value adjustment	(1,095)	—	(342)	—
Legal settlement expense	—	8,400	—	8,400
Purified Cortrophin Gel pre-launch charges	—	515	—	553
Restructuring activities	2,570	—	2,570	—
Intangible asset impairment charge	112	—	112	—
Total Operating Expenses	86,768	64,178	170,440	115,654
Operating Loss	(12,913)	(15,553)	(32,108)	(12,508)
Other Expense, net				
Interest expense, net	(6,669)	(2,531)	(13,282)	(4,985)
Other income/(expense), net	764	(67)	675	(582)
Loss Before Benefit for Income Taxes	(18,818)	(18,151)	(44,715)	(18,075)
Benefit for income taxes	3,895	4,045	9,662	4,055
Net Loss	$ (14,923)	$ (14,106)	$ (35,053)	$ (14,020)
Dividends on Series A Convertible Preferred Stock	(407)	—	(812)	—
Net Loss Available to Common Shareholders	$ (15,330)	$ (14,106)	$ (35,865)	$ (14,020)
Basic and Diluted Loss Per Share:				
Basic Loss Per Share	$ (0.94)	$ (1.17)	$ (2.21)	$ (1.16)
Diluted Loss Per Share	$ (0.94)	$ (1.17)	$ (2.21)	$ (1.16)
Basic Weighted-Average Shares Outstanding	16,272	12,085	16,205	12,045
Diluted Weighted-Average Shares Outstanding	16,272	12,085	16,205	12,045

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

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

	Three Months Ended June 30,		***Six Months Ended June 30,***	
	2022	***2021***	***2022***	***2021***
Net loss	$ (14,923)	$ (14,106)	$ (35,053)	$ (14,020)
Other comprehensive income/(loss), net of tax:				
Gains/(losses) on interest rate swap, net of tax	2,718	(401)	8,485	6,004
Total other comprehensive income/(loss), net of tax	2,718	(401)	8,485	6,004
Total comprehensive loss, net of tax	$ (12,205)	$ (14,507)	$ (26,568)	$ (8,016)

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Mezzanine Equity and Stockholders' Equity
For the Three Months Ended June 30, 2022 and 2021
(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 Gain/(Loss), Net of Tax	Accumulated Deficit	Total Mezzanine Equity and Stockholders' Equity
Balance, March 31, 2021	$ —	—	$ 1	12,830	$ —	$ 216,223	86	$ (2,594)	$ (5,032)	$ (4,886)	$ 203,712
Stock-based Compensation Expense	—	—	—	—	—	2,844	—	—	—	—	2,844
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	15	(468)	—	—	(468
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	12	—	337	—	—	—	—	337
Issuance of Restricted Stock Awards	—	—	—	19	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(35)	—	(1)	(21)	—	—	—	(1
Other Comprehensive Income	—	—	—	—	—	—	—	—	(401)	—	(401
Net Loss	—	—	—	—	—	—	—	—	—	(14,106)	(14,106
Balance, June 30, 2021	$ —	—	$ 1	12,826	$ —	$ 219,403	80	$ (3,062)	$ (5,433)	$ (18,992)	$ 191,917
Balance, March 31, 2022	$ 24,850	25	$ 1	17,374	$ —	$ 391,084	123	$ (4,253)	$ 2,712	$ (68,300)	$ 346,094
Stock-based Compensation Expense	—	—	—	—	—	3,756	—	—	—	—	3,756
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	16	(483)	—	—	(483
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	8	—	203	—	—	—	—	203
Issuance of Restricted Stock Awards	—	—	—	208	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(407)	(407
Restricted Stock Awards Forfeitures	—	—	—	(24)	—	—	—	—	—	—	—
Other Comprehensive Income	—	—	—	—	—	—	—	—	2,718	—	2,718
Net Loss	—	—	—	—	—	—	—	—	—	(14,923)	(14,923
Balance, June 30, 2022	$ 24,850	25	$ 1	17,566	$ —	$ 395,043	139	$ (4,736)	$ 5,430	$ (83,630)	$ 336,958

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Mezzanine Equity and Stockholders' Equity
For the Six Months Ended June 30, 2022 and 2021
(in thousands)
(unaudited)

	Mezzanine Equity Series A Convertible Preferred Stock	Mezzanine Equity Series A Convertible Preferred Stock Shares	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Other Comprehensive (Loss)/Gain, Net of Tax	Accumulated Deficit	Total Mezzanine Equity and Stockholders' Equity
Balance, December 31, 2020	$ —	—	$ 1	12,430	$ —	$ 214,354	76	$ (2,246)	$ (11,437)	$ (4,972)	$ 195,700
Stock-based Compensation Expense	—	—	—	—	—	4,713	—	—	—	—	4,713
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	25	(816)	—	—	(816)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	12	—	337	—	—	—	—	337
Issuance of Restricted Stock Awards	—	—	—	457	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(73)	—	(1)	(21)	—	—	—	(1)
Other comprehensive income	—	—	—	—	—	—	—	—	6,004	—	6,004
Net Loss	—	—	—	—	—	—	—	—	—	(14,020)	(14,020)
Balance, June 30, 2021	$ —	—	$ 1	12,826	$ —	$ 219,403	80	$ (3,062)	$ (5,433)	$ (18,992)	$ 191,917
Balance, December 31, 2021	$ 24,850	25	$ 1	16,913	$ —	$ 387,844	83	$ (3,135)	$ (3,055)	$ (47,765)	$ 358,740
Stock-based Compensation Expense	—	—	—	—	—	6,993	—	—	—	—	6,993
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	56	(1,601)	—	—	(1,601)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	8	—	206	—	—	—	—	206
Issuance of Restricted Stock Awards	—	—	—	669	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(24)	—	—	—	—	—	—	—
Dividends on Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(812)	(812)
Other comprehensive income	—	—	—	—	—	—	—	—	8,485	—	8,485
Net Loss	—	—	—	—	—	—	—	—	—	(35,053)	(35,053)
Balance, June 30, 2022	$ 24,850	25	$ 1	17,566	$ —	$ 395,043	139	$ (4,736)	$ 5,430	$ (83,630)	$ 336,958

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Six Months Ended June 30, 2022	2021
Cash Flows From Operating Activities		
Net loss	$ (35,053)	$ (14,020)
Adjustments to reconcile net loss to net cash and cash equivalents (used in)/provided by operating activities:		
Stock-based compensation	6,993	4,713
Deferred taxes	(11,378)	(6,676)
Depreciation and amortization	28,731	22,222
Non-cash interest	1,969	1,141
Contingent consideration fair value adjustment	(342)	—
Asset impairment charges	575	—
Gain on sale of ANDAs	(750)	—
Changes in operating assets and liabilities:		
Accounts receivable, net	(21,884)	3,145
Inventories, net	(10,852)	2,823
Prepaid expenses and other current assets	1,563	1,202
Accounts payable	4,047	1,688
Accrued royalties	70	(1,719)
Current income taxes payable, net	1,654	(6,281)
Accrued government rebates	3,948	914
Returned goods reserve	(903)	4,754
Accrued expenses, accrued compensation, and other	1,186	7,003
Net Cash and Cash Equivalents (Used in)/Provided by Operating Activities	(30,426)	20,909
Cash Flows From Investing Activities		
Acquisition of Novitium Pharma LLC, net of cash acquired	(33)	—
Acquisition of product rights, IPR&D, and other related assets	(229)	(21,057)
Acquisition of property and equipment, net	(3,270)	(1,630)
Proceeds from the sale of long-lived assets	750	—
Net Cash and Cash Equivalents Used in Investing Activities	(2,782)	(22,687)
Cash Flows From Financing Activities		
Payments on borrowings under credit agreements	(1,500)	(5,206)
Borrowings under Prior Revolver agreement	—	24,000
Series A convertible preferred stock dividends paid	(812)	—
Proceeds from stock option exercises and ESPP purchases	206	336
Payments of debt issuance costs	—	(141)
Treasury stock purchases for restricted stock vests	(1,601)	(816)
Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities	(3,707)	18,173
Net Change in Cash and Cash Equivalents	(36,915)	16,395
Cash and cash equivalents, beginning of period	105,301	12,867
Cash and cash equivalents, end of period	$ 68,386	$ 29,262
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	$ 100,300	$ 7,864
Restricted cash	5,001	5,003
Cash, cash equivalents, and restricted cash, beginning of period	$ 105,301	$ 12,867
Reconciliation of cash, cash equivalents, and restricted cash, end of period		
Cash and cash equivalents	$ 63,385	$ 24,261
Restricted cash	5,001	5,001
Cash, cash equivalents, and restricted cash, end of period	$ 68,386	$ 29,262
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 11,400	$ 3,953
Cash paid for income taxes	$ 124	$ 8,360
Supplemental non-cash investing and financing activities:		
Debt issuance costs in accrued expenses	$ —	$ 81
Property and equipment purchased and included in accounts payable	$ 779	$ 119

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

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by building a successful Purified Cortrophin Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our manufacturing capabilities. Our four pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, one is located in East Windsor, New Jersey, and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. On June 2, 2022, we announced that we intend to cease operations at our Oakville, Ontario, Canada manufacturing plant by first quarter 2023. This action is part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. We will transition the majority of products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites, and we are seeking to find potential buyers for the Oakville site.

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

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"). Certain prior period information has been reclassified to conform to the current period presentation. In our opinion, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly our financial position, results of operations, comprehensive income, and cash flows. The consolidated balance sheet at December 31, 2021 has been derived from audited financial statements as of that date. The unaudited interim condensed consolidated results of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the U.S. Securities and Exchange Commission (the "SEC"). We believe that the disclosures provided herein are adequate to make the information presented not misleading when these unaudited interim condensed consolidated financial statements are read in conjunction with the audited financial statements and notes previously distributed in our Annual Report on Form 10-K for the year ended December 31, 2021.

Principles of Consolidation

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

Foreign Currency

We have subsidiaries located in Canada and India. The Canada-based subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar. The Indian-based subsidiary generally conducts its transactions in Indian rupees, which is also its functional currency. The results of any non-U.S. dollar transactions and balances are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. Our gain or loss on transactions denominated in foreign currencies and the translation impact of local currencies to U.S. dollars was immaterial for the three and six months ended June 30, 2022 and 2021. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

Use of Estimates

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

Restructuring Activities

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

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

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

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

We recognize revenue using the following steps:

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

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

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

	Three Months Ended		Six Months Ended	
Products and Services (in thousands)	**June 30, 2022**	**June 30, 2021**	**June 30, 2022**	**June 30, 2021**
Sales of generic pharmaceutical products	$ 49,863	$ 34,199	$ 98,970	$ 66,812
Sales of established brand pharmaceutical products	8,463	11,038	16,915	18,555
Sales of rare disease pharmaceutical products	10,202	—	11,494	—
Sales of contract manufactured products	4,389	2,322	7,293	4,895
Royalties from licensing agreements	194	—	2,097	11,210
Product development services	531	97	1,097	255
Other	213	969	466	1,419
Total net revenues	$ 73,855	$ 48,625	$ 138,332	$ 103,146

	Three Months Ended		Six Months Ended	
Timing of Revenue Recognition (in thousands)	**June 30, 2022**	**June 30, 2021**	**June 30, 2022**	**June 30, 2021**
Performance obligations transferred at a point in time	$ 73,324	$ 48,528	$ 137,235	$ 102,891
Performance obligations transferred over time	531	97	1,097	255
Total	$ 73,855	$ 48,625	$ 138,332	$ 103,146

In the three and six months ended June 30, 2022 and 2021, we did not incur, and therefore did not defer, any material incremental costs to obtain or fulfill contracts. We recognized a decrease of $3.7 million to net revenue from performance obligations satisfied in prior periods during the six months ended June 30, 2022, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. We recognized an increase of $10.3 million to net revenue from performance obligations satisfied in prior periods during the six months ended June 30, 2021, consisting primarily of a final royalty revenue related to

the Kite license agreement pursuant to the Tripartite Agreement as described herein in *Royalties from Licensing Agreements.* We provide technical transfer services to customers, for which services are transferred over time. As of June 30, 2022 and December 31, 2021, we did not have any contract assets related to revenue recognized based on percentage of completion but not yet billed. Our deferred revenue balance as of June 30, 2022, December 31, 2021, and December 31, 2020 was immaterial. For the three and six months ended June 30, 2022, we recognized $0.1 million of revenue that was included in deferred revenue as of December 31, 2021. For the three and six months ended June 30, 2021, we recognized less than $0.1 million of revenue that was included in deferred revenue as of December 31, 2020. Deferred revenue is included in accrued expenses and other in the unaudited interim condensed consolidated balance sheets.

Revenue from Sales of Generic and Branded Pharmaceutical Products

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

Sales of our pharmaceutical products are subject to variable consideration due to chargebacks, government rebates, returns, administrative and other rebates, and cash discounts. Estimates for these elements of variable consideration require significant judgment.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the six months ended June 30, 2022 and 2021, 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, 2020 (1)	$ 88,746	$ 7,826	$ 27,155	$ 8,906	$ 3,839
Accruals/Adjustments	214,125	12,980	21,058	32,207	13,315
Credits Taken Against Reserve	(220,776)	(12,066)	(16,309)	(33,071)	(13,682)
Balance at June 30, 2021 (1)	$ 82,095	$ 8,740	$ 31,904	$ 8,042	$ 3,472
Balance at December 31, 2021 (1)	$ 94,066	$ 5,492	$ 35,831	$ 13,100	$ 4,642
Accruals/Adjustments	320,191	9,356	15,057	20,701	10,494
Credits Taken Against Reserve	(274,714)	(5,408)	(15,989)	(19,283)	(8,938)
Balance at June 30, 2022 (1)	$ 139,543	$ 9,440	$ 34,899	$ 14,518	$ 6,198

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

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consist of agreements in which we manufacture a pharmaceutical product on behalf of a third party. Our performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The contract manufactured products are sold at pre-determined

standalone selling prices and our performance obligations are considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves our dock to be shipped to the customer, as our contract manufactured pharmaceutical products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally fewer than two months. We estimate returns based on historical experience. Historically, we have not had material returns for contract manufactured products.

As of June 30, 2022, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $7.2 million, which consists of firm orders for contract manufactured products. We will recognize revenue for these performance obligations as they are satisfied, which is anticipated within six months.

Royalties from Licensing Agreements

From time to time, we enter into transition agreements with the sellers of products we acquire, under which we license to the seller the right to sell the acquired products. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the sellers. Upon full transition of the products and upon launching the products under our own labels, we recognize revenue for the products as sales of generic or branded pharmaceutical products, as described above. From time to time, we enter into supply and distribution agreements with contract manufacturing customers, under which we license to the contract manufacturing customer the right to sell our products, and we are entitled to a royalty on sales made by the contract manufacturing customer under these arrangements. Therefore, we recognize the revenue associated with sales of the underlying products as royalties. Because these royalties are sales-based, we recognize the revenue when the underlying sales occur, based on sales and gross profit information received from the contract manufacturing customers.

Pursuant to a 2012 Tripartite Agreement (the “Tripartite Agreement”) between the Company, The Regents of the University of California (“The Regents”), and Cabaret Biotech Ltd., an Israeli corporation (“Cabaret”) (as assignee of Dr. Zelig Eshhar’s rights under the Tripartite Agreement), and subsequent amendments thereto and assignments thereof, we were entitled to receive a percentage of the milestone and sales royalty payments paid to Cabaret by Kite Pharma, Inc. (“Kite”), a subsidiary of Gilead Sciences, Inc., under a license agreement. Under such license agreement, Kite licensed from Dr. Eshhar and Cabaret the patent rights covered by the Tripartite Agreement and agreed to make certain payments to Cabaret based on, among other things, Kite’s sales of Yescarta®. Under the Tripartite Agreement, portions of these payments were to be distributed to The Regents and to us.

Historically, we recorded royalty income related to Yescarta® on an accrual basis utilizing our best estimate of royalties earned based upon information available in the public domain, our understanding of the various agreements governing the royalty, and other information received from time to time from the relevant parties. Generally, cash was received directly from Cabaret once a year. The agreements governing this royalty were subject to multiple actions in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, ANI and Cabaret. In the first quarter of 2021, we became aware that the litigation between Cabaret and Kite was dismissed. In April 2021, Cabaret and the Company settled all amounts due for amounts actually received by Cabaret or Eshhar for the licensing or use of the patent rights governed by the Kite license agreement. As a result, we recognized $11.2 million as royalties from licensing agreements in our net revenues during the three month period ended March 31, 2021. In addition, during the three month period ended March 31, 2021, we agreed to reimburse Cabaret $0.4 million, which has been recorded as other expense, net in the accompanying unaudited interim condensed consolidated statement of operations, related to certain legal expenditures incurred. We received final payment from Cabaret in May 2021. Based upon the events that led to the dismissal of the litigation between Cabaret and Kite, we do not expect to receive any future royalty income related to the Kite license agreement. In conjunction with payment of amounts due to us, all outstanding litigation between the Company and Cabaret was dismissed.

Product Development Services Revenue

We provide product development services to customers, which are performed over time. These are services primarily performed at our facilities in East Windsor, New Jersey and Oakville, Ontario. As we intend to cease operations at the Oakville, Ontario facility by the first quarter of 2023, we expect to transition the product development services at the facility to one of our three U.S.-based manufacturing sites.

The duration of these development projects can be up to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a percentage of completion basis, which results in contract assets on our balance sheet. As of June 30, 2022, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open product development services contracts was $0.3 million. We expect to satisfy these performance obligations within the next nine months.

Credit Concentration

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

During the three and six months ended June 30, 2022 and 2021 we had three customers that accounted for 10% or more of net revenues. As of June 30, 2022, accounts receivable from these customers totaled 83% of accounts receivable, net.

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

	Three Months Ended		Six Months Ended	
	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Customer 1	23 %	34 %	27 %	29 %
Customer 2	19 %	26 %	19 %	22 %
Customer 3	15 %	14 %	14 %	14 %

3. BUSINESS COMBINATION

Summary

On November 19, 2021, we completed our previously announced acquisition of all of the interests of Novitium pursuant to the terms of the Agreement and Plan of Merger (the “Merger Agreement”), dated as of March 8, 2021, for cash consideration, 2,466,654 restricted shares of our common stock valued at $91.2 million based on our closing stock price of $43.54 on the date of closing and discounted for lack of marketability due to restrictions on shares, and up to $46.5 million in additional contingent consideration. Additionally, we agreed to pay certain debts of Novitium in the amount of $8.5 million, which we deemed to be paid in consummation of the transaction closing, and not assumed liabilities, and thus were included as additional cash consideration. This acquisition was accounted for as a business combination. The contingent consideration is based on the achievement of certain milestones, including milestones on gross profit of Novitium portfolio products over a 24-month period, regulatory filings completed during this 24-month period, and a percentage of net profits on certain products that are launched in the future. As of the closing of the acquisition, the contingent consideration had a fair value of $30.8 million. Refer to Note 14 for changes in contingent consideration and changes in fair value. Total consideration including cash, restricted shares and contingent consideration was valued at $206.5 million.

Purchase consideration consisted of the following:

	(in thousands)
Cash consideration	$ 88,109
Repayment of Novitium debts	8,493
Fair value of restricted shares	91,199
Fair value of contingent consideration	30,800
Gross consideration	$ 218,601
Cash acquired	12,076
Net consideration	$ 206,525

The cash consideration was funded in part by borrowings under our new credit facility (Note 5) and through issuance of shares of Series A convertible preferred stock (Note 10). We acquired Novitium due to its proven track record of being a research and development growth engine capable of fueling sustainable growth, to expand our research and development pipeline via niche opportunities, to enhance our contract development and manufacturing organization ("CDMO") business and U.S.-based manufacturing capacity, and to diversify our revenue base.

The preliminary allocation of the fair value of the Novitium acquisition, reflective of certain immaterial measurement period adjustments during the six months ended June 30, 2022, is shown in the table below. The allocation of the fair value will be finalized when all measurement period adjustments, if applicable, are complete.

	(in thousands)
Total Purchase Consideration	$ 218,601
Cash and cash equivalents	12,076
Accounts receivable	27,185
Inventories	14,460
Prepaid expenses and other current assets	1,891
Property and equipment	14,331
Intangible assets	139,200
Goodwill	24,641
Other non-current assets	1,413
Total assets acquired	235,197
Accounts payable	1,560
Accrued expense and other current liabilities	6,035
Accrued compensation and other related expenses	4,909
Accrued government rebates	744
Returned goods reserve	2,202
Other non-current liabilities	1,146
Total liabilities assumed	16,596
Net assets acquired	$ 218,601

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. In connection with the acquisition, we recognized $46.9 million of indefinite-lived in-process research and development intangible assets, $67.4 million of acquired ANDA intangible assets, and $24.9 million of customer relationship intangible assets.

Goodwill is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition, such as the assembled workforce and synergies between the entities. Goodwill established as a result of the acquisition is tax deductible in the U.S.

Novitium operations generated $19.9 million and $39.1 million of revenue during the three and six months ended June 30, 2022, respectively. Novitium recorded a net income of $2.5 million and $2.3 million during the three and six months ended June 30, 2022, respectively.

Restricted Shares

The Novitium acquisition consideration included 2,466,654 restricted shares, which were valued at $91.2 million. These shares contain restrictions on their transfer for periods from three to 24 months following the completion of the acquisition. A Finnerty model was used to value the restricted shares. It includes inputs of not readily observable market data, which are Level 3 inputs. These unobservable inputs include ANI stock volatility with a range of 65% to 71%, and the discounted lack of marketability with a range of 7.5% to 21.5% depending on the length of restriction.

4. RESTRUCTURING

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

For the three and six months ended June 30, 2022, restructuring activities resulted in expenses of $2.6 million and included $1.4 million of severance and other employee benefit costs, $0.9 million of asset-related impairment and accelerated depreciation costs, and $0.3 million of other costs. As of June 30, 2022, $1.3 million of the severance and other employee benefits are unpaid and accrued. These costs are recorded as restructuring activities, an operating item, in the accompanying unaudited interim condensed consolidated statement of operations. Certain of the severance and other employee benefit costs contain a service requirement, and as such, are being accrued over time as they are earned. We expect to incur additional charges of approximately $1.4 million in these costs over the next nine months, and approximately $3.1 to $3.6 million future asset-related accelerated depreciation charges over this period. These costs are part of the Generics, Established Brands, and Other segment.

In conjunction with the planned exit of our Canadian facility, we have determined that the land and building at our Oakville, Ontario, Canada plant will be sold together over the transition period and meet the criteria to be classified as held for sale as of June 30, 2022. The land and building have a net carrying value of $8.0 million, which is presented as assets held for sale on the accompanying unaudited interim condensed consolidated balance sheets. These assets are part of the Generics, Established Brands, and Other segment.

5. INDEBTEDNESS

Credit Facility

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

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

The Term Facility matures in November 2027 and the Revolving Facility in November 2026. Each permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the LIBOR Rate (as defined in the Credit Agreement) in the case of LIBOR loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the LIBOR Rate (as defined in the Credit Agreement) in the case of loans under the Revolving Facility. The interest rate under the Term Facility was 7.06% at June 30, 2022. The Credit Facility has a subjective acceleration clause in case of a material adverse effect. The Term Facility includes a repayment schedule, pursuant to which $750 thousand of the loan will be paid in quarterly installments during the twelve months ended June 30, 2023. As of June 30, 2022, $3.0 million of the loan is recorded as current borrowings in the unaudited interim condensed consolidated balance sheets. As of June 30, 2022, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing.

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

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

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

The carrying value of the current and non-current components of the Term Facility as of June 30, 2022 and December 31, 2021 are:

	Current	
(in thousands)	June 30, 2022	December 31, 2021
Current borrowing on debt	$ 3,000	$ 3,000
Deferred financing costs	(2,150)	(2,150)
Current debt, net of deferred financing costs	$ 850	$ 850

	Non-Current	
(in thousands)	June 30, 2022	December 31, 2021
Non-current borrowing on debt	$ 295,500	$ 297,000
Deferred financing costs	(9,405)	(10,480)
Non-current debt, net of deferred financing costs and current component	$ 286,095	$ 286,520

As of June 30, 2022, we had a $298.5 million balance on the Term Facility. Of the $0.9 million of deferred debt issuance costs allocated to the Revolving Facility, $0.7 million is included in other non-current assets in the unaudited interim condensed consolidated balance sheets, and $0.2 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets.

The contractual maturity of our Term Facility is as follows for the years ending December 31:

(in thousands)	Term Facility
2022	$ 1,500
2023	3,000
2024	3,000
2025	3,000
2026	3,000
2027 and thereafter	285,000
Total	$ 298,500

The following table sets forth the components of total interest expense related to the Term Facility during the three and six months ended June 30, 2022 and interest expense under the Prior Credit Agreement during the three and six months ended June 30, 2021, as recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three and six months ended June 30, 2022 and 2021:

	Three Months Ended		Six Months Ended	
(in thousands)	June 30, 2022	June 30, 2021	June 30, 2022	June 30, 2021
Contractual coupon	$ 6,122	$ 2,386	$ 12,180	$ 4,690
Amortization of finance fees	590	176	1,181	352
Capitalized interest	(19)	(31)	(49)	(57)
	$ 6,693	$ 2,531	$ 13,312	$ 4,985

6. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

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

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

In April 2020, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under term facilities related to our Prior Credit Agreement. The interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Agreement with Truist Bank, the interest rate swap with a notional value of $168.6 million was novated and Truist Bank is the new counterparty. The swap is used to manage changes in LIBOR-based interest rates underlying a portion of the borrowing under the Term Facility. The interest rate swap provides an effective fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of June 30, 2022, the notional amount of the interest rate swap was $158.6 million and decreases quarterly by approximately $4.0 million until December 2023, after which it remains static until maturity in December 2026. As of June 30, 2022, the fair value of the interest rate swap asset recorded in derivatives and other non-current assets in the unaudited interim condensed consolidated balance sheets was $3.6 million. As of June 30, 2022, $5.4 million was recorded in accumulated other comprehensive loss, net of tax in the unaudited interim condensed consolidated balance sheets.

During the three and six months ended June 30, 2022, the change in fair value of the interest rate swaps was a gain of $2.9 million and $9.8 million, respectively. During the three and six months ended June 30, 2022, gains on the interest rate swap of $2.7 million and $8.5 million were recorded in accumulated other comprehensive loss, net of tax in our unaudited interim condensed consolidated statements of comprehensive (loss)/income, respectively. Differences between the hedged LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Facility based on the LIBOR rate. In the three and six months ended June 30, 2022, $1.0 million and $2.0 million of interest expense was recognized in relation to the interest rate swaps, respectively. Included in this amount for the three months ended June 30, 2022 and 2021 are reclassifications out of accumulated other comprehensive income/loss of $0.7 million and $0.9 million and during the six months ended June 30, 2022 and 2021 are $1.4 million and $1.8 million in expense, respectively, related to terminated and de-designated cash flow hedges.

7. EARNINGS (LOSS) PER SHARE

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

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

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

Earnings (loss) per share for the three and six months ended June 30, 2022 and 2021 are calculated for basic and diluted earnings (loss) per share as follows:

(in thousands, except per share amounts)	Basic Three Months Ended June 30,		Diluted Three Months Ended June 30,		Basic Six Months Ended June 30,		Diluted Six Months Ended June 30,	
	2022	2021	2022	2021	2022	2021	2022	2021
Net loss	$ (14,923)	$ (14,106)	$ (14,923)	$ (14,106)	$ (35,053)	$ (14,020)	$ (35,053)	$ (14,020)
Net income allocated to participating securities	—	—	—	—	—	—	—	—
Dividends on Series A convertible preferred stock	(407)	—	(407)	—	(812)	—	(812)	—
Net loss available to common shareholders	$ (15,330)	$ (14,106)	$ (15,330)	$ (14,106)	$ (35,865)	$ (14,020)	$ (35,865)	$ (14,020)
Basic Weighted-Average Shares Outstanding	16,272	12,085	16,272	12,085	16,205	12,045	16,205	12,045
Dilutive effect of stock options and ESPP			—	—			—	—
Diluted Weighted-Average Shares Outstanding			16,272	12,085			16,205	12,045
Loss per share	$ (0.94)	$ (1.17)	$ (0.94)	$ (1.17)	$ (2.21)	$ (1.16)	$ (2.21)	$ (1.16)

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, was 2.7 million and 1.7 million for the three months ended June 30, 2022 and 2021 and was 2.6 million and 1.7 million for the six months ended June 30, 2022 and 2021, respectively. For the three and six months ended June 30, 2022 and 2021, all potentially dilutive shares were anti-dilutive and excluded from the calculation of diluted loss per share because we recognized a net loss.

8. INVENTORIES

Inventories consist of the following as of:

(in thousands)	June 30, 2022	December 31, 2021
Raw materials	$ 59,176	$ 51,350
Packaging materials	6,414	5,475
Work-in-progress	879	652
Finished goods	33,936	31,969
	100,405	89,446
Reserve for excess/obsolete inventories	(7,860)	(7,753)
Inventories, net	$ 92,545	$ 81,693

Vendor Concentration

We source the raw materials for our products, including active pharmaceutical ingredients (“API”), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. As a result, we are dependent upon our current vendors to reliably supply the API required for on-going product manufacturing. During the three and six months ended June 30, 2022, we purchased approximately 18% and 17% of our inventory from one supplier, respectively. As of June 30, 2022, our amount payable to this supplier was $6.3 million. During the three and six months ended June 30, 2021, no single vendor represented more than 10% of inventory purchases.

9. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. (“BioSante”), we recorded goodwill of $1.8 million. As a result of our acquisition of WellSpring Pharma Services Inc., we recorded additional goodwill of $1.7 million in 2018. From our acquisition of Novitium in 2021, we recorded goodwill of $24.6 million. We assess the recoverability of the carrying value of goodwill as of October 31st of each year, and whenever events occur or circumstances change that would, more likely than not, reduce the fair value of our reporting unit below its carrying value. There have been no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value during the three and six months ended June 30, 2022. No impairment losses were recognized during the three and six months ended June 30, 2022 and 2021.

Intangible Assets

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

(in thousands)	June 30, 2022 Gross Carrying Amount	June 30, 2022 Accumulated Amortization	December 31, 2021 Gross Carrying Amount	December 31, 2021 Accumulated Amortization	Weighted Average Amortization Period
Definite-Lived Intangible Assets:					
Acquired ANDA intangible assets	$ 168,377	$ (64,128)	$ 168,536	$ (54,079)	8.5 years
NDAs and product rights	242,372	(150,853)	242,372	(138,835)	9.9 years
Marketing and distribution rights	17,157	(12,828)	17,157	(12,347)	5.5 years
Non-compete agreement	624	(557)	624	(513)	7.0 years
Customer relationships	24,900	(2,371)	24,900	(593)	7.0 years
Indefinite-Lived Intangible Assets:					
In process research and development	46,900	—	46,900	—	Indefinite
Total Intangible Assets, net	$ 500,330	$ (230,737)	$ 500,489	$ (206,367)	9.0 years

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

Amortization expense was $11.9 million and $10.1 million for the three months ended June 30, 2022 and 2021, respectively. Amortization expense was $24.4 million and $19.7 million for the six months ended June 30, 2022 and 2021, respectively.

We test for impairment of definite-lived intangible assets and indefinite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. In the three and six months ended June 30, 2022, we recognized a full impairment of a definite-lived ANDA asset with a remaining carrying value of $0.1 million. No such triggering events were identified during the three and six months ended June 30, 2021 and therefore no impairment loss was recognized in the three and six months ended June 30, 2021.

Expected future amortization expense is as follows:

(in thousands)	
2022 (remainder of the year)	$ 24,693
2023	50,770
2024	49,974
2025	47,870
2026	34,551
2027 and thereafter	61,735
Total	$ 269,593

Expected amortization expense is an estimate. Actual amounts of amortization expense may differ due to timing of regulatory approvals related to IPR&D assets, additional intangible assets acquired, impairment of intangible assets, and other events.

10. MEZZANINE AND STOCKHOLDERS' EQUITY

Stockholders' Equity

Authorized shares

We are authorized to issue up to 33.3 million shares of common stock with a par value of $0.0001 per share, 0.8 million shares of class C special stock with a par value of $0.0001 per share, and 1.7 million shares of undesignated preferred stock with a par value of $0.0001 per share at June 30, 2022.

There were 17.6 million and 17.4 million shares of common stock issued and outstanding as of June 30, 2022 and 16.9 million shares of common stock issued and outstanding as of December 31, 2021. During 2021, we issued 1.5 million shares related to a public offering of our common stock and 2.5 million shares as consideration in connection with the acquisition of Novitium.

There were 11 thousand shares of class C special stock issued and outstanding as of June 30, 2022 and December 31, 2021. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock is exchangeable, at the option of the holder, for one share of our common stock, at an exchange price of $90.00 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of our assets if we were to liquidate, dissolve, or wind-up the Company. The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption, or sinking fund rights.

Mezzanine Equity

PIPE Shares

Concurrently with the execution of the Merger Agreement, and as financing for a portion of the acquisition, on March 8, 2021, we entered into an Equity Commitment and Investment Agreement with Ampersand 2020 Limited Partnership (the "PIPE Investor"), pursuant to which we agreed to issue and sell to the PIPE Investor, and the PIPE Investor agreed to purchase, 25,000 shares of our Series A Convertible Preferred Stock (the "PIPE Shares"), for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million. This agreement closed and the 25,000 PIPE Shares were sold and issued for $25.0 million on November 19, 2021. The PIPE Shares are classified as mezzanine equity because the shares are mandatorily redeemable for cash upon a change in control, an event that is not solely in our control. We incurred $0.2 million in issuance costs associated with the transaction.

The PIPE Shares accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and will also participate, on a pro-rata basis, in any dividends that may be declared with respect to our common stock. The PIPE Shares are convertible into our common shares at the conversion price of $41.47 (i) beginning two years after their issuance date, at the election of ANI (in which case the PIPE Investor must convert all of the PIPE Shares), if the volume-weighted average price of our common stock for any 20 trading days out of 30 consecutive trading days exceeds 170% of the conversion price, and (ii) at any time after issuance, at the election of the PIPE Investor. As of June 30, 2022, the PIPE shares are currently convertible into a maximum of 602,901 shares of our common stock.

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

transaction consideration that the holder of the PIPE Shares would have received if it had converted into our common stock.

There were 25,000 shares of Series A convertible preferred stock outstanding as of June 30, 2022.

11. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of June 30, 2022, we had 0.2 million shares of common stock available under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount.

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of sales	$ 19	$ 4	$ 29	$ 8
Research and development	15	6	22	11
Selling, general, and administrative	39	23	60	46
	$ 73	$ 33	$ 111	$ 65

Stock Incentive Plan

Equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan (the “2022 Plan”), which was approved by our stockholders at the 2022 Annual Meeting of Stockholders (the “Annual Meeting”) held on April 27, 2022. Prior to this approval, we had been granting equity-based incentive awards under our Sixth Amended and Restated 2008 Stock Incentive Plan (the “Existing Plan”). The 2022 Plan was amended to, among other things, increase the number of shares reserved for issuance thereunder by 1,150,000 shares. As of June 30, 2022, 1.1 million shares of our common stock were available for issuance under the Existing Plan.

From time to time, we may grant stock options to employees through an inducement grant outside of our 2022 Plan to induce prospective employees to accept employment with us (the “Inducement Grants”). The options are granted at an exercise price equal to the fair market value of a share of our common stock on the respective grant date and are generally exercisable in four equal annual installments beginning on the first anniversary of the respective grant date. The grants are made pursuant to inducement grants outside of our stockholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

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

(in thousands)	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of sales	$ 124	$ 2	$ 259	$ 2
Research and development	180	149	345	263
Selling, general, and administrative	3,379	2,660	6,278	4,383
	$ 3,683	$ 2,811	$ 6,882	$ 4,648

A summary of stock option and restricted stock activity under the 2022 Plan and Inducement Grants during the six months ended June 30, 2022 and 2021 is presented below:

(in thousands)	Options	Inducement Grants	RSAs
Outstanding at December 31, 2020	756	180	352
Granted	84	61	457
Options Exercised/RSAs Vested	(5)	—	(111) (1)
Forfeited	(58)	—	(73)
Expired	—	—	—
Outstanding at June 30, 2021	777	241	625
Outstanding at December 31, 2021	747	241	707
Granted	36	—	669
Options Exercised/RSAs Vested	(1)	—	(209) (2)
Forfeited	(37)	—	(24)
Expired	—	—	—
Outstanding at June 30, 2022	745	241	1,143

(1) Includes 25 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 $0.8 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

(2) Includes 56 thousand shares purchased from employees to cover employee income taxes related to income earned upon vesting of restricted stock. The shares purchased are held in treasury and the $1.6 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

12. INCOME TAXES

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

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of June 30, 2022, we had provided a valuation allowance against consolidated net deferred tax assets of $0.4 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any such amounts accrued as of June 30, 2022 and December 31, 2021. We are subject to taxation in various U.S. jurisdictions, Canada, and India and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

For interim periods, we recognize an income tax provision/(benefit) based on our estimated annual effective tax rate, calculated on a worldwide consolidated basis, expected for the entire year. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in temporary and

estimated permanent differences, and excludes certain discrete items whose tax effect, when material, is recognized in the interim period in which they occur. These changes in temporary differences, permanent differences, and discrete items result in variances to the effective tax rate from period to period. We also have elected to exclude the impacts from significant pre-tax non-recognized subsequent events from our interim estimated annual effective rate until the period in which they occur. Our estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, changes in temporary differences, and permanent differences are revised, and as discrete items occur. Global Intangible Low-Taxed Income ("GILTI"), as defined in the Tax Cuts and Jobs Act of 2017, generated from our Canadian and Indian operations is subject to U.S. taxes, with certain defined exemptions, thresholds and credits. For financial reporting purposes we have elected to treat GILTI inclusions as a period cost.

For the three months ended June 30, 2022, we recognized an income tax benefit of $3.9 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 20.7% to pre-tax consolidated loss of $18.8 million reported during the period, as well as the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2022.

For the three months ended June 30, 2021, we recognized an income tax benefit of $4.0 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 22.3% to pre-tax consolidated loss of $18.2 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2021.

For the six months ended June 30, 2022, we recognized an income tax benefit of $9.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 21.6% to pre-tax consolidated loss of $44.7 million reported during the period, as well as the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2022.

For the six months ended June 30, 2021, we recognized an income tax benefit of $4.1 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax benefit rate of 22.4% to pre-tax consolidated loss of $18.1 million reported during the period, reduced by the net effects of certain discrete items occurring which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2021.

13. COMMITMENTS AND CONTINGENCIES

Operating Leases

All our existing leases as of June 30, 2022 are classified as operating leases. As of June 30, 2022, we had 13 material operating leases for facilities and office equipment with remaining terms expiring from 2022 through 2027 and a weighted average remaining lease term of 2.9 years. Many of our existing leases have fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. Discount rates used in the calculation of our lease liability ranged between 3.99% and 8.95%. Current lease liability is included in accrued expenses and other in the accompanying unaudited interim condensed consolidated balance sheets. Non-current lease liability is included in derivatives and other non-current liabilities in the accompanying unaudited interim condensed consolidated balance sheets.

Rent expense for the three and six months ended June 30, 2022 and 2021 consisted of the following:

(in thousands)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Operating lease costs	$ 143	$ 43	$ 269	$ 92
Variable lease costs	54	13	120	21
Total lease costs	$ 197	$ 56	$ 389	$ 113

A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2022	$ 251
2023	482
2024	468
2025	248
2026 and thereafter	126
Total	$ 1,575
Discount	(163)
Lease liability	1,412
Current lease liability	(413)
Non-current lease liability	$ 999

Government Regulation

Our products and facilities are subject to regulation by a number of federal and state governmental agencies, such as the Drug Enforcement Administration (“DEA”), the Food and Drug Administration (“FDA”), the Centers for Medicare and Medicaid Services (“CMS”), Health Canada, the Central Drugs Standard Control Organization (“CDSCO”), The Narcotics Control Bureau (“NCB”), and India’s Ministry of Health and Family Welfare (“MoHFW”). The FDA, in particular, maintains oversight of the formulation, manufacture, distribution, packaging, and labeling of all of our products. The DEA, Health Canada, and NCB maintain oversight over our products that are considered controlled substances.

Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone (“EEMT”) and Opium Tincture, are marketed without approved NDAs or ANDAs. During the three months ended June 30, 2022 and 2021, net revenues for these products totaled $2.9 million and $4.2 million, respectively. During the six months ended June 30, 2022 and 2021, net revenues for these products totaled $6.9 million and $8.0 million, respectively.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the three months ended June 30, 2022 and 2021 were $0.4 million and $0.6 million, respectively. Our contract manufacturing revenues for the group of unapproved products for the six months ended June 30, 2022 and 2021 were $1.1 million and $1.4 million, respectively.

Legal proceedings

We are involved, and from time to time may become involved, in various disputes, governmental and/or regulatory inquiries, investigations, government reimbursement related actions and litigation. These matters are complex and subject to significant uncertainties. As such, we cannot accurately predict the outcome, or the effects of the legal proceedings described below. While we believe that we have valid claims and/or defenses in the litigation and other

matters described below, litigation is inherently unpredictable, and the outcome of the proceedings could result in losses, including substantial damages, fines, civil or criminal penalties and injunctive or administrative remedies. We intend to vigorously prosecute and/or defend these matters, as appropriate; however, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations, and legal proceedings, individually or in the aggregate, could have a material adverse effect on our results of operations and/or cash flows in any given accounting period or on our overall financial condition.

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

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

Furthermore, like 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 consolidated statements of operations under the selling, general, and administrative expense line item.

Commercial Litigation

In November of 2017, we were served with a complaint filed by Arbor Pharmaceuticals, LLC, in the United States District Court for the District of Minnesota. The complaint alleged false advertising and unfair competition in violation of Section 43(a) of the Lanham Act, Section 1125(a) of Title 15 of the United States Code, and Minnesota State law, under the premise that we sold an unapproved Erythromycin Ethylsuccinate (“EES”) product during the period between September 27, 2016 and November 2, 2018. The complaint sought a trial by jury and monetary damages (inclusive of actual and consequential damages, treble damages, disgorgement of ANI profits, and legal fees) of an unspecified amount. Discovery in this action closed on March 31, 2019 and trial was scheduled to commence on August 25, 2021. On August 3, 2021, the Company entered into a Settlement Agreement with Arbor Pharmaceuticals, LLC to resolve all claims related to Civil Action 17-4910, Arbor Pharmaceuticals, LLC (“Arbor”) v. ANI Pharmaceuticals, Inc., which was pending trial in the United States District Court for the District of Minnesota. Under the terms of the agreement, ANI paid Arbor $8.4 million and Arbor dismissed the action with prejudice. Neither party admitted wrongdoing in reaching this settlement. The Company paid the settlement from cash on the balance sheet.

On December 3, 2020, class action complaints were filed against the Company on behalf of putative classes of direct and indirect purchasers of the drug Bystolic. On December 23, 2020, six individual purchasers of Bystolic, CVS, Rite Aid, Walgreen, Kroger, Albertsons, and H-E-B, filed complaints against the Company. On March 15, 2021, the plaintiffs in these actions filed amended complaints. All amended complaints are substantively identical. The plaintiffs in these actions allege that, beginning in 2012, Forest Laboratories, the manufacturer of Bystolic, entered into anticompetitive agreements when settling patent litigation related to Bystolic with seven potential manufacturers of a generic version of Bystolic: Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, Watson, and various of their corporate parents, successors, subsidiaries, and affiliates. ANI itself was not a party to patent litigation with Forest concerning Bystolic and did not settle patent litigation with Forest. The plaintiffs named the Company as a defendant based on the Company’s January 8, 2020 Asset Purchase Agreement with

Amerigen. The complaints alleged that the 2013 patent litigation settlement agreement between Forest and Amerigen violated federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs alleged they paid higher prices as a result of delayed generic competition. Plaintiffs sought damages, trebled or otherwise multiplied under applicable law, injunctive relief, litigation costs and attorneys' fees. The complaints did not specify the amount of damages sought from the Company or other defendants and the Company at this early stage of the litigation cannot reasonably estimate the potential damages that the plaintiffs will seek. The cases have been consolidated in the United States District Court for the Southern District of New York as In re Bystolic Antitrust Litigation, Case No. 20-cv-005735 (LJL). On April 23, 2021, the Company and other defendants filed motions to dismiss the amended complaints. 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 contain substantially similar claims. On April 19, 2022, the Company and other defendants filed motions to dismiss the newly amended complaints. On May 23, 2022, the plaintiffs filed oppositions to the motions to dismiss and, on June 24, 2022, the Company and other defendants filed replies to those oppositions. The motions to dismiss are now fully briefed and pending with the court. The Company disputes any liability in these matters.

On March 24, 2021, Azurity Pharmaceuticals, Inc. ("Azurity") filed a complaint in the United States District Court for the District of Minnesota against ANI Pharmaceuticals, Inc., asserting that ANI's vancomycin hydrochloride oral solution drug product infringes U.S. Patent No. 10,688,046. The complaint sought injunctive relief, damages, including lost profits and/or royalty, treble damages, and attorneys' fee and costs. On February 15, 2022, the Company entered into a settlement agreement with Azurity to resolve all claims related to this action. Under the terms of the agreement, Azurity granted ANI a non-exclusive, non-transferable, non-sublicensable, royalty-bearing license under its Patents to sell ANI product in the United States and dismissed the action with prejudice. In exchange, we paid Azurity $1.9 million of royalties from past sales and we will pay Azurity a royalty equal to 20% of gross margin of sales of the ANI product for a contractually defined term. We paid the settlement from cash on hand and the $1.9 million charge was recorded as cost of sales (excluding depreciation and amortization) on the consolidated statement of operations for the year ended December 31, 2021.

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

Industry Related Litigation

In July 2020, ANI and Novitium were served with a complaint brought in the First Judicial Court, County of Santa Fe, State of New Mexico by the Office of the Attorney General of the State of New Mexico against manufacturers and sellers of ranitidine products. The complaint asserts a public nuisance claim and a negligence claim against the generic ranitidine manufacturer defendants, including ANI and Novitium. The public nuisance claim asserts that the widespread sale of ranitidine products in the state created a public nuisance that requires a state-wide medical monitoring program of New Mexico residents for the development of colorectal cancer, stomach cancer, gastrointestinal disorders and liver disease. As damages, New Mexico asks that the defendants fund this medical monitoring program. The negligence claims assert that the defendants were negligent in selling the product, essentially alleging that it was unreasonable to have the product on the market. With respect to that claim, New Mexico asserts that it paid for ranitidine products through state-funded insurance and health-care programs. On December 15, 2020, the case was removed to federal court and transferred to the *In re Zantac* multidistrict litigation ("MDL") pending in the United States District Court for the Southern District of Florida. New Mexico moved for

remand to state court. The MDL court granted the remand motion on February 25, 2021. On April 16, 2021, New Mexico filed an amended complaint in the New Mexico First Judicial District Court in Santa Fe County. It did not name ANI in the amended complaint, effectively voluntarily dismissing ANI from the action. Novitium is named as a Defendant in the amended complaint. According to Novitium's records, Novitium sold approximately 42 bottles of ranitidine indirectly into New Mexico, and received no funds from any state funded health care plan or Medicaid. The Defendants filed a motion to dismiss the claims asserted in the New Mexico litigation based primarily on preemption. The motion was denied in August 2021.

In December 2020, the City of Baltimore served ANI and Novitium with a complaint against manufacturers and sellers of ranitidine products. The City of Baltimore complaint, which was filed in the Circuit Court for Baltimore City, tracks the allegations of the New Mexico complaint. The Baltimore action was removed to federal court and transferred to the *In re Zantac* MDL on February 1, 2021. The City of Baltimore moved for remand, which was granted on April 1, 2021. The parties stipulated to allow the City of Baltimore to file an amended complaint in the Circuit Court of Maryland for Baltimore City in "due course," without a specific filing deadline. On June 23, 2021, the City of Baltimore filed an amended complaint. The City of Baltimore did not name ANI in its amended complaint, effectively voluntarily dismissing ANI from the action. Novitium was named as a defendant in the amended complaint. Defendants in the Baltimore action filed a motion to dismiss on based primarily on preemption to which Novitium joined. The motion was granted as to all generic manufacturer defendants on January 28, 2022, and all claims against Novitium were dismissed with prejudice. The deadline for the City of Baltimore to file an appeal was February 28, 2022.

ANI and Novitium dispute any liability in these matters.

Product Liability Related Litigation

All manufacturers of the drug Reglan and its generic equivalent metoclopramide, including ANI, have faced allegations from plaintiffs in various states claiming bodily injuries as a result of ingestion of metoclopramide or its brand name, Reglan, prior to the FDA's February 2009 Black Box warning requirement ("legacy claims"). All these original legacy claims were settled or closed out, including a series of claims in California that were resolved by coordinated proceeding and settlement. Our insurance company assumed the defense of the legacy claims and paid all losses in settlement of the California legacy claims. In March 2019, we were served with a lawsuit in the Superior Court of California, County of Riverside, adding us as a defendant in a complaint filed in July 2017 that is alleged not to have been part of the original settled legacy claims. This new claim was dismissed with prejudice in July 2021 and the matter is now closed.

In June 2020, ANI was served with a personal injury complaint in the case of *Koepsel v. Boehringer Ingelheim Pharmaceuticals, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-80882-RLR, filed in the United States District Court for Southern District of Florida, in which the plaintiff alleges that he developed kidney cancer in 2018 as a result of taking over the counter medication containing ranitidine. The *Koepsel* action was filed within an existing multidistrict litigation concerning ranitidine-containing drugs pending in the Southern District of Florida before Judge Robin L. Rosenberg, *In re Zantac MDL*, 20 MDL 2924. A Master Personal Injury Complaint ("MPIC") in that MDL that was filed on June 22, 2020 also named ANI and Novitium as defendants. ANI was dismissed from the *Koepsel* case on August 21, 2020 and was dismissed from the MPIC on September 8, 2020. On December 31, 2020, after ANI was dismissed, the district court dismissed the MPIC claims against generic manufacturer defendants partially with prejudice and partially with leave to replead. The failure to warn and design defect claims were dismissed with prejudice on preemption grounds. An Amended Master Personal Injury Complaint was filed on February 8, 2021, which did not name ANI but did name Novitium. By opinion dated July 8, 2021, the district court dismissed all claims against the generic manufacturer defendants with prejudice on preemption grounds. That decision is on appeal to the Eleventh Circuit Court of Appeals.

ANI and Novitium were named in other individual personal injury complaints filed in MDL 20 MD 2924 in which plaintiffs allege that they developed cancer after taking prescription and over the counter medication containing ranitidine. ANI was served with complaints in five of those additional cases: *Cooper v. Boehringer Ingelheim Pharmaceuticals, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-81130-RLR (served September 30, 2020),

Lineberry v. Amneal Pharmaceuticals, LLC, et al., MDL No. 20-MD-2924, Case No. 9:20-cv-81079-RLR (served August 20, 2020), *Lovette v. Amneal Pharmaceuticals, LLC, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-81040-RLR (served August 26, 2020), *Hightower v. Pfizer, et al*, MDL No. 20-MD-2924, Case No. 9-20-cv-82214-RLR (served December 16, 2020) and *Bird v. Boehringer Ingelheim Pharmaceuticals, et al.*, MDL No. 20-MD-2924, Case No. 9-20-cv-80837-RLR (served December 30, 2020). We have informed counsel for the plaintiffs that ANI did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited two-month period of time, from July 2019 to September 2019. ANI's product was voluntarily recalled in January 2020. Each of the plaintiffs in the five pending cases alleges a cancer diagnosis prior to the time that ANI sold ranitidine, and we have informally sought dismissal from these cases on that basis. ANI was voluntarily dismissed from the *Cooper*, Lineberry and *Lovette* actions on November 20, 2020. ANI was voluntarily dismissed from the *Bird* action on March 15, 2021 and from the *Hightower* action on March 29, 2021.

Novitium has been named in 155 short form complaints filed by claimants in the MDL. Those complaints were effectively dismissed with prejudice with the MPIC on July 8, 2021. Counsel for the plaintiffs have been notified that Novitium did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited period of time, from December 2018 until September 2019. Novitium's product was voluntarily recalled in October 2019. Out of the 155 short form complaints, approximately 111 plaintiffs either were diagnosed with cancer before Novitium began manufacturing the product, only took over the counter ranitidine, or took ranitidine before Novitium began manufacturing it. Two of those 111 plaintiffs dismissed Novitium from their short form complaints. In light of the Court's dismissal of all claims with prejudice, Novitium has not pursued dismissal of the short form complaints against it at this time.

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

ANI and Novitium dispute any liability in these MDL matters.

Other Industry Related Matters

On or about September 20, 2017, the Company and certain of its employees were served with search warrants and/or grand jury subpoenas to produce documents and possibly testify relating to a federal investigation of the generic pharmaceutical industry. We have been cooperating and intend to continue cooperating with the investigation. However, no assurance can be given as to the timing or outcome of the investigation.

14. FAIR VALUE DISCLOSURES

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

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

fluctuates with the changes in LIBOR and, because the variable interest rates approximate market borrowing rates available to us, we believe the carrying values of these borrowings approximated their fair values at June 30, 2022.

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

Contingent Value Rights

Our contingent value rights ("CVRs"), which were granted coincident with our merger with BioSante and expire in June 2023, are considered contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of our projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs was immaterial as of June 30, 2022 and December 31, 2021. We also determined that the changes in such fair value were immaterial in the three and six months ended June 30, 2022 and 2021.

Interest Rate Swap

The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 6, the fair value of the interest rate swap was a $3.6 million asset as of June 30, 2022.

Contingent Consideration

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

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

Payment Type	Valuation Technique	Unobservable Input	Assumptions
Profit-based milestone payments	Probability-weighted discounted cash flow	Discount rate	14.0%
		Projected fiscal year of payment	2023-2029
Product development-based milestone payments	Probability-weighted discounted cash flow	Discount rate	17.9%
		Probability of payment	90.0%
		Projected fiscal year of payment	2023-2024

The following table presents the changes in contingent consideration balances classified as Level 3 balances for the three and six months ended June 30, 2022 and 2021:

(in thousands)	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021	Six Months Ended June 30, 2022	Six Months Ended June 30, 2021
Beginning balance	$ 32,053	$ —	$ 31,000	$ —
Measurement period adjustment	—	—	300	—

Change in fair value	(1,095)	—	(342)	—
Ending balance	$ 30,958	$ —	$ 30,958	$ —

The following table presents our financial assets and liabilities accounted for at fair value on a recurring basis as of June 30, 2022 and December 31, 2021, by level within the fair value hierarchy:

(in thousands) Description	Fair Value at June 30, 2022	Level 1	Level 2	Level 3
Assets				
Interest rate swap	$ 3,636	$ —	$ 3,636	$ —
Liabilities				
Contingent consideration	$ 30,958	$ —	$ —	$ 30,958
CVRs	$ —	$ —	$ —	$ —

Description	Fair Value at December 31, 2021	Level 1	Level 2	Level 3
Liabilities				
Contingent consideration	$ 31,000	$ —	$ —	$ 31,000
Interest rate swaps	$ 6,790	$ —	$ 6,790	$ —
CVRs	$ —	$ —	$ —	$ —

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

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

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

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

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

We measure our long-lived assets, including property, plant, and equipment, ROU assets, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. No such fair value impairment was recognized in the three and six months ended June 30, 2022 and 2021.

Acquired Non-Financial Assets Measured at Fair Value

In April 2021, we acquired three NDAs and an ANDA and certain related inventories from Sandoz, Inc. for total consideration of $20.7 million. We also incurred and paid $0.4 million in transaction costs directly related to the acquisition. The acquisition was funded via borrowings under the revolving facility portion of our prior credit facility. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $11.4 million as acquired intangible assets and $9.7 million of inventory at fair value, including $0.6 million of API, $1.0 million of sample inventory, and $8.1 million in finished goods inventory. In order to determine the fair value of the intangible assets, we used the present value of the estimated cash flows related to the product rights using a discount rate of 10%, which are level 3 unobservable inputs. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. The intangible assets are being amortized in full over a useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to June 30, 2022 and therefore no impairment loss was recognized for the six months ended June 30, 2022.

15. PURIFIED CORTROPHIN GEL PRE-LAUNCH CHARGES

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

Prior to the third quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts were consumed in research and development activities and recognized as research and development expense in the period in which they were incurred. In the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. The FDA granted approval of the sNDA of this product on October 29, 2021. Prior to FDA approval, under U.S. GAAP, we were prohibited from capitalizing these pre-launch purchases of materials as inventory, and accordingly, they were charged to expense in the period in which they were incurred. Subsequent to approval, these purchases are recorded as inventory at net realizable value. During the three and six months ended June 30, 2021, we recognized $0.5 million and $0.6 million, respectively, of charges related to purchases of pre-launch materials.

16. RELATED PARTY TRANSACTIONS

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

In connection with our acquisition of Novitium, we entered into employment agreements with the two executives and founders of Novitium, Muthusamy Shanmugam and Chad Gassert. Both serve as executive officers of the Company and Mr. Shanmugam also serves on the Company's board of directors. Mr. Shanmugam holds a minority interest in Scitus Pharma Services ("Scitus"), which provides clinical research services to Novitium, majority interest in SS Pharma LLC ("SS Pharma"), which acquires and supplies API to Novitium, majority interest in Esjay Pharma LLC ("Esjay"), which provides research and development and facilities consulting services, and a minority interest in Nuray Chemical Private Limited ("Nuray"), which manufactures and supplies API to Novitium. Mr. Gassert holds a minority interest in Scitus. During the three months ended June 30, 2022, we paid Esjay an immaterial amount, paid SS Pharma $0.7 million, and paid Scitus $0.7 million. During the three months ended June 30, 2022, there were no payments to Nuray. During the six months ended June 30, 2022, we paid Esjay $0.1 million, paid SS Pharma $1.6 million, paid Nuray $0.9 million, and paid Scitus $1.3 million. As of June 30, 2022, the outstanding balance due to Scitus was $50 thousand and the outstanding balance due to SS Pharma was $0.6 million. As of June 30, 2022, there were no outstanding balances due to Esjay and Nuray.

17. 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. Prior to 2022, based on this definition, we had concluded that we had one operating segment. Prior period segment disclosures have been recast for the new segment presentation. Effective in the first quarter of 2022 and prospectively, in conjunction with the principal completion of our buildout of infrastructure in the areas of commercialization of rare disease therapies and the launch of Cortrophin Gel, we determined that we have two operating segments as follows:

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

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

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

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

Financial information by reportable segment, including historical information that has been retroactively re-cast to reflect our two operating segments, is as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Net Revenues				
Generics, Established Brands, and Other	$ 63,653	$ 48,625	$ 126,838	$ 103,146
Rare Disease	10,202	—	11,494	—
Total net revenues	$ 73,855	$ 48,625	$ 138,332	$ 103,146
Segment earnings/(loss) before interest, taxes, depreciation and amortization ("EBITDA") and reconciliation to (loss)/income before income taxes				
Generics, Established Brands, and Other	15,473	14,660	30,004	36,499
Rare Disease	(6,663)	(4,473)	(17,111)	(5,751)
Depreciation and amortization	(13,764)	(11,324)	(28,321)	(22,222)
Corporate and other unallocated expenses[(1)]	(7,959)	(14,416)	(16,680)	(21,034)
Total operating loss	$ (12,913)	$ (15,553)	$ (32,108)	$ (12,508)
Interest expense, net	(6,669)	(2,531)	(13,282)	(4,985)
Other income/(expense), net	764	(67)	675	(582)
Loss before benefit for income taxes	$ (18,818)	$ (18,151)	$ (44,715)	$ (18,075)

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

Geographic Information

Our operations are located in the United States, Canada, and India. 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)				
Location of Operations	**2022**	**2021**	**2022**	**2021**
United States	$ 72,811	$ 47,580	$ 136,571	$ 100,907
Canada	1,044	1,045	1,761	2,239
Total Revenue	$ 73,855	$ 48,625	$ 138,332	$ 103,146

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

(in thousands)	June 30, 2022	December 31, 2021
United States	$ 38,964	$ 38,564
Canada[1]	4,552	13,831
India	255	276
Total property and equipment, net	$ 43,771	$ 52,671

(1) Amounts as of June 30, 2022 exclude the land and building at our Canada facility, which are classified as held for sale as of June 30, 2022. These assets have a carrying value of $8.0 million.

18. SUBSEQUENT EVENT

On July 21, 2022, we acquired four ANDAs from Oakrum Pharma, LLC for a purchase price of $8.0 million plus an immaterial amount for the purchase of API and finished goods inventory. The transaction was funded from cash on hand.

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, 2021 (the "2021 Annual Report"), as well as the information contained under Management's Discussion and Analysis of Financial Condition and Results of Operations and "Risk Factors" contained in the 2021 Annual Report, and Part II, Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q , and other information provided from time to time in our other filings with the SEC. This discussion contains forward-looking statements, based on current expectations and related to future events and our future financial performance, that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many important factors, including those set forth under "Risk Factors" in our 2021 Annual Report and this Quarterly Report on Form 10-Q.

EXECUTIVE OVERVIEW

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by building a successful Cortrophin Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. Our four pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, one is located in East Windsor, New Jersey, and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. On June 2, 2022, we announced that we intend to cease operations at our Oakville, Ontario, Canada manufacturing plant by first quarter 2023. This action is part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. We will transition the majority of products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites.

Strategy

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

Building a successful Purified Cortrophin Gel franchise

We acquired the NDAs for Cortrophin gel and Cortrophin-Zinc in January 2016 and executed long-term supply agreements with a supplier of our primary raw material for corticotrophin active pharmaceutical ingredient ("API"), a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin gel fill/finish contract manufacturer. During the second quarter of 2021, we submitted a Supplemental New Drug Application ("sNDA") to the FDA.

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

During 2021 and the first half of 2022, we invested in leadership, expertise and infrastructure in the areas of commercialization of rare disease therapies and developed a launch strategy and commercial plan for this product. In the fourth quarter of 2021 and first half of 2022, we hired a significant number of new employees and assembled and trained our rare disease field force. On January 24, 2022, we announced the commercial launch of Cortrophin Gel in the U.S. As

a result of the build out of our rare disease team, our expenditures in support of these efforts will be significantly higher in 2022 as compared to 2021.

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

We have grown our generics business through a combination of market share gains on existing products and new product launches. We have also successfully acquired numerous ANDAs through business and asset acquisitions, including, most recently, our acquisition of Novitium Pharma LLC ("Novitium"), including its portfolio of commercial and pipeline generic products, manufacturing and development facilities and expert workforce. We have begun to increase our focus on niche lower competition opportunities such as injectables, Paragraph IV, and Competitive Generic Therapy designation filings. Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses.

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

We have acquired the New Drug Applications ("NDAs") for and market Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, InnoPran XL, Oxistat, Veregen, and Pandel. We are innovating in our GTM strategy through creative partnerships. In addition, we will continue to explore opportunities in acquiring new brands to grow our established brands portfolio.

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

We built a CDMO business through our sites in Baudette, Minnesota and grew it through acquisitions. Our U.S.-based manufacturing and unique capabilities in high-potency, hormonal, steroid, and oncolytic products can be leveraged to expand our CDMO business.

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

Product Development Considerations

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

- ***Formulation Complexity.*** Our development and manufacturing capabilities enable us to manufacture pharmaceuticals that are difficult to produce, including highly potent, extended release, combination, and low dosage products. This ability to manufacture a variety of complex products is a competitive strength that we intend to leverage in selecting products to develop or manufacture.

- ***Patent Status.*** We seek to develop products whose branded bioequivalents do not have long-term patent protection or existing patent challenges.

- ***Market Size.*** When determining whether to develop or acquire an individual product, we review the current and expected market size for that product at launch, as well as forecasted price erosion upon conversion from branded to generic pricing. We endeavor to manufacture products with sufficient market size to enable us to enter the market with a strong likelihood of being able to price our products both competitively and at a profit.

- ***Profit Potential.*** We research the availability and cost of active pharmaceutical ingredients in determining which products to develop or acquire. In determining the potential profit of a product, we forecast our anticipated market share, pricing, including the expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.

- ***Manufacturing.*** We generally seek to develop and manufacture products at our own manufacturing plants in order to optimize the utilization of our facilities, ensure quality control in our products, and to more closely control the economic inputs and outputs of our products.

- ***Competition.*** When determining whether to develop or acquire a product, we research existing and expected competition. We seek to develop products for which we can obtain sufficient market share and may decline to develop a product if we anticipate significant competition. Our specialized manufacturing facilities provide a means of entering niche markets, such as hormone therapies, in which fewer generic companies are able to compete.

Recent Developments

Restructuring Update

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

Operating Segment Update

Prior to 2022, we had concluded that we had one operating segment. Effective in the first quarter of 2022 and prospectively, in conjunction with the principal completion of our buildout of infrastructure in the areas of commercialization of rare disease therapies and the launch of Cortrophin Gel, we determined that we now have two operating segments as follows:

- **Generics, Established Brands, and Other** – Consists of operations related to the development, manufacturing, and marketing of generic and established brand pharmaceuticals, including those sold through traditional channels, contract manufactured products (“CDMO”), 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.

Product Launches

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

Asset Acquisition

On July 21, 2022, we acquired four ANDAs from Oakrum Pharma, LLC for a purchase price of $8.0 million plus an immaterial amount for the purchase of API and finished goods inventory. The transaction was funded from cash on hand.

COVID-19 Impact

We continue to closely monitor the impact of the novel coronavirus (“COVID-19”) pandemic on our business and the geographic regions where we operate. While total market generic and brand prescriptions were depressed in earlier parts of 2021 as subsequent waves and variants of the virus impacted patient and customer behavior, prescriptions returned to pre-pandemic levels in late 2021 and into 2022. We continue to see disruptions to our supply chain from the COVID-19

pandemic during 2022, including significant lead times for purchases of materials. The pandemic has not impacted our access to capital and has not significantly impacted our use of funds.

We are unable to predict the impact that the COVID-19 pandemic will continue to have on our future financial condition, results of operations and cash flows due to numerous uncertainties, including the continued duration of the pandemic, the appearance of additional variants of the virus, the level of success of continued actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, among others.

GENERAL

Impacts to our 2022 and 2021 results of operations, including to net revenues, operating expenses, interest and other expense, net, and income taxes are described below. Our results of operations for the three and six months ended June 30, 2022 were impacted by the November 19, 2021 acquisition of Novitium and related activity subsequent to that date. The acquisition provides additional revenues and the incurrence of increased costs, including but not limited to the amortization of intangible assets acquired, other operating costs, and increased interest costs on borrowings used to finance the transaction. During the three and six months ended June 30, 2022, Novitium operations generated $19.9 million and $39.1 million in net revenues, respectively.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2022	2021	2022	2021
Net revenues	$ 73,855	$ 48,625	$ 138,332	$ 103,146
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	35,294	22,314	69,565	42,299
Research and development	4,165	2,805	9,439	5,773
Selling, general, and administrative	31,958	18,820	60,775	36,407
Depreciation and amortization	13,764	11,324	28,321	22,222
Contingent consideration fair value adjustment	(1,095)	—	(342)	—
Legal settlement expense	—	8,400	—	8,400
Purified Cortrophin Gel pre-launch charges	—	515	—	553
Restructuring activities	2,570	—	2,570	—
Intangible asset impairment charge	112	—	112	—
Operating loss	(12,913)	(15,553)	(32,108)	(12,508)
Interest expense, net	(6,669)	(2,531)	(13,282)	(4,985)
Other income/(expense), net	764	(67)	675	(582)
Loss before benefit for income taxes	(18,818)	(18,151)	(44,715)	(18,075)
Benefit for income taxes	3,895	4,045	9,662	4,055
Net loss	$ (14,923)	$ (14,106)	$ (35,053)	$ (14,020)

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net revenues	100.0 %	100.0 %	100.0 %	100.0 %
Operating expenses				
Cost of sales (exclusive of depreciation and amortization)	47.8 %	45.9 %	50.3 %	41.0 %
Research and development	5.6 %	5.8 %	6.8 %	5.6 %
Selling, general, and administrative	43.3 %	38.7 %	43.9 %	35.3 %
Depreciation and amortization	18.6 %	23.3 %	20.5 %	21.5 %
Contingent consideration fair value adjustment	(1.5)%	— %	(0.2)%	— %
Legal settlement expense	— %	17.3 %	— %	8.1 %
Purified Cortrophin Gel pre-launch charges	— %	1.1 %	— %	0.5 %
Restructuring activities	3.5 %	— %	1.9 %	— %
Intangible asset impairment charge	0.2 %	— %	0.1 %	— %
Operating loss	(17.5)%	(32.1)%	(23.3)%	(12.0)%
Interest expense, net	(9.0)%	(5.2)%	(9.6)%	(4.8)%
Other income/(expense), net	1.0 %	(0.1)%	0.5 %	(0.6)%
Loss before benefit for income taxes	(25.5)%	(37.4)%	(32.4)%	(17.4)%
Benefit for income taxes	5.3 %	8.3 %	7.0 %	3.9 %
Net loss	(20.2)%	(29.1)%	(25.4)%	(13.5)%

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED JUNE 30, 2022 AND 2021

Net Revenues

(in thousands)	Three Months Ended June 30, 2022	2021	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 49,863	$ 34,199	$ 15,664	45.8 %
Established brand pharmaceutical products	8,463	11,038	(2,575)	(23.3)%
Contract manufacturing	4,389	2,322	2,067	89.0 %
Royalty and other	938	1,066	(128)	(12.0)%
Generics, established brands, and other segment total net revenues	$ 63,653	$ 48,625	$ 15,028	30.9 %
Rare Disease Segment				
Rare disease pharmaceutical products	$ 10,202	—	$ 10,202	NM (1)
Total net revenues	$ 73,855	$ 48,625	$ 25,230	51.9 %

(1) Not meaningful

We derive substantially all of our revenues from sales of generic, established brand, and rare disease pharmaceutical products, contract manufacturing, royalties on net sales of certain products, and other services, including development services, and laboratory services. Many of our established brand products face competition from generic products and we expect them to continue to face competition from generic products in the future. Our generic products face competition from other generic products and we expect them to continue to face competition 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.

Our rare disease pharmaceutical product, Purified Cortrophin Gel, competes in the ACTH therapeutic category against one principal brand competitor.

Net revenues for the three months ended June 30, 2022 were $73.9 million compared to $48.6 million for the same period in 2021, an increase of 51.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $49.9 million during the three months ended June 30, 2022, an increase of 45.8% compared to $34.2 million for the same period in 2021. From a product perspective, the increase was substantially driven by revenues from commercial generic products acquired in our acquisition of Novitium, including Prazosin, Prednisone, Famotidine, Oxybutynin Chloride, Dapsone, and various other products. The increase was also due to increased revenues of Nebivolol, which ANI launched in September 2021. Increases were tempered by a decrease in revenues from sales of Nicardipine and Esterified Estrogen with Methyltestosterone ("EEMT") as well as several other legacy ANI generic products. The increase in net generic revenues was principally due to an increase in volumes and tempered by a decrease in average selling prices.

- Net revenues for established brand pharmaceutical products were $8.5 million during the three months ended June 30, 2022, a decrease of 23.3% compared to $11.0 million for the same period in 2021. From a product perspective, the net decrease was driven by a decrease in sales of InnoPran XL and Inderal XL. These decreases were tempered by an increase in sales of Inderal LA and Atacand. The decrease in revenues for the three months ended June 30, 2022 was principally due to prior period adjustments or change in estimates to variable consideration, including returns and rebates.

- Contract manufacturing revenues were $4.4 million during the three months ended June 30, 2022, an increase of 89.0% compared to $2.3 million for the same period in 2021, due to an increase in the volume of orders, primarily related to the addition of Novitium contract manufacturing revenues.

- Royalty and other revenues were $0.9 million during the three months ended June 30, 2022, a decrease of $0.1 million from $1.1 million for the same period in 2021, primarily due to decreases in product development revenues earned by ANI Canada. Royalty and other revenues in 2022 primarily consist of $0.3 million of royalty revenues related to Novitium arrangements and $0.5 million of product development service revenues.

- Net revenues of rare disease pharmaceutical products, which consist entirely of sales of Purified Cortrophin Gel, were $10.2 million during the three months ended June 30, 2022, as the product was launched in late January 2022. There were no sales of rare disease pharmaceutical products during the comparable prior year period.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended June 30, 2022	2021	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 35,294	$ 22,314	$ 12,980	58.2 %

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

For the three months ended June 30, 2022, cost of sales increased to $35.3 million from $22.3 million for the same period in 2021, an increase of $13.0 million, or 58.2%. The increase is primarily due to increased volumes of generic products, including $7.9 million of costs related to activity of Novitium during the three months ended June 30, 2022 with no comparable activity in the prior year period and an increase of $2.0 million related to increased sales of products subject to profit sharing arrangements. During the three months ended June 30, 2022 and 2021, we recognized $1.0

million and $1.5 million, respectively, in cost of sales representing the excess of fair value over cost for inventory acquired in acquisitions and subsequently sold during the three months ended June 30, 2022 and 2021.

Cost of sales, exclusive of the $1.0 million and $1.5 million net impact related to excess of fair value over the cost of inventory sold during the three months ended June 30, 2022 and 2021, respectively, as a percentage of net revenues increased to 46.5% during the three months ended June 30, 2022, from 42.8% during same period in 2021, primarily as a result of increased generic volumes in a period of declining average selling prices across generic and brand products and increased sales of products with profit sharing arrangements. These increases were tempered by sales of the rare disease pharmaceutical products which have higher margins.

During the three months ended June 30, 2022, we purchased approximately 18% of our inventory from one supplier. As of June 30, 2022, our amount payable to this supplier was $6.3 million. During the three months ended June 30, 2022 and 2021, no single vendor represented more than 10% of inventory purchases.

Other Operating Expenses

(in thousands)	Three Months Ended June 30, 2022	2021	Change	% Change
Research and development	$ 4,165	$ 2,805	$ 1,360	48.5 %
Selling, general, and administrative	31,958	18,820	13,138	69.8 %
Depreciation and amortization	13,764	11,324	2,440	21.5 %
Contingent consideration fair value adjustment	(1,095)	—	(1,095)	NM (1)
Legal settlement expense	—	8,400	(8,400)	(100.0)%
Purified Cortrophin Gel pre-launch charges	—	515	(515)	(100.0)%
Restructuring activities	2,570	—	2,570	NM (1)
Intangible asset impairment charge	112	—	112	NM (1)
Total other operating expenses	$ 51,474	$ 41,864	$ 9,610	23.0 %

(1) Not meaningful

Other operating expenses consist of research and development costs, selling, general, and administrative expenses, depreciation and amortization, contingent consideration fair value adjustment, legal settlement expense, Purified Cortrophin Gel pre-launch charges, restructuring activities, and intangible asset impairment charges.

For the three months ended June 30, 2022, other operating expenses increased to $51.5 million from $41.9 million for the same period in 2021, an increase of $9.6 million, or 23.0%, primarily as a result of the following factors:

- Research and development expenses increased from $2.8 million to $4.2 million, an increase of 48.5%, primarily due to expenses related to the Novitium activities during the three months ended June 30, 2022 and no comparable expenses in the three months ended June 30, 2021, and tempered by a $0.9 million decrease in expense associated with our Cortrophin development efforts.

- Selling, general, and administrative expenses increased from $18.8 million to $32.0 million, an increase of $13.1 million, or 69.8%, primarily due to a $12.4 million increase in sales and marketing expenses related to our launch of Purified Cortrophin Gel, increased expenses primarily related to the addition of Novitium headcount and activities during the three months ended June 30, 2022, with no comparable expenses in the 2021 period, and tempered by a $1.6 million decrease in transaction expenses related to the Novitium acquisition.

- Depreciation and amortization expense was $13.8 million for the three months ended June 30, 2022, compared to $11.3 million for the same period in 2021, an increase of $2.4 million. The increase is primarily due to the amortization of intangible assets acquired in the Novitium acquisition.

- As described in Note 14, *Fair Value Disclosures*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized a contingent

consideration fair value adjustment of $1.1 million income in the three months ended June 30, 2022. The income is principally due to an increase in the discount rate and tempered by the passage of time. No contingent consideration fair value adjustment was recognized in the three months ended June 30, 2021.

- As described in Note 13, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized a legal settlement expense of $8.4 million income related to the Arbor commercial matter in the three months ended June 30, 2021. No legal settlement expense was recognized in the three months ended June 30, 2022.

- We recognized restructuring activities of $2.6 million of expense in the three months ended June 30, 2022, in relation to the anticipated closure of our Oakville, Ontario, Canada facility. Costs included $1.4 million in termination benefits, $0.9 million in fixed asset impairments and accelerated depreciation, and $0.3 of other costs. No restructuring activities were recognized in the three months ended June 30, 2021.

- We recognized an impairment of $0.1 million in the three months ended June 30, 2022, in relation to an ANDA asset. No impairment charges were recognized in the three months ended June 30, 2021.

Other Expense, net

	Three Months Ended June 30,			
(in thousands)	2022	2021	Change	% Change
Interest expense, net	$ (6,669)	$ (2,531)	$ (4,138)	163.5 %
Other income/(expense), net	764	(67)	831	(1,240.3)%
Total other expense, net	$ (5,905)	$ (2,598)	$ (3,307)	127.3 %

For the three months ended June 30, 2022, we recognized total other expense, net of $5.9 million versus total other expense of $2.6 million for the same period in 2021, an increase of $3.3 million. Interest expense, net for the three months ended June 30, 2022 consisted primarily of interest expense on borrowings under our Term Facility. Interest expense, net for the three months ended June 30, 2021 consisted primarily of interest expense on borrowings under our Amended and Restated Credit Agreement, dated as of December 27, 2018 (the “Prior Credit Agreement”), among the Company, as borrower, and Citizens Bank with other lenders. The increase in interest expense is due to an increase in the debt outstanding during the three months ended June 30, 2022 coupled with an increased borrowing rate on the $300.0 million Term Facility as compared to the borrowing rate on the Prior Credit Agreement borrowings, and an increase in amortization of finance fees. During the three months ended June 30, 2022, there was $299.3 million of outstanding borrowings, compared to $184.6 million to $205.7 million during the comparable 2021 period. For the three months ended June 30, 2022 and 2021, there was less than $0.1 million of interest capitalized into construction in progress. Other income/(expense), net during the three months ended June 30, 2022 consists primarily of a $0.8 million gain on the sale of an ANDA.

Benefit for Income Taxes

	Three Months Ended June 30,			
(in thousands)	2022	2021	Change	% Change
Benefit for income taxes	$ 3,895	$ 4,045	$ (150)	(3.7)%

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

For the three months ended June 30, 2022, we recognized an income tax benefit of $3.9 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 20.7% to pre-tax consolidated loss of $18.8 million reported during the period, as well as the net effects of certain discrete items occurring in 2022 which impact our

income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2022.

For the three months ended June 30, 2021, we recognized an income tax benefit of $4.0 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 22.3% to pre-tax consolidated loss of $18.2 million reported during the period, reduced by the net effects of certain discrete items occurring in 2021
which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the three months ended June 30, 2021.

RESULTS OF OPERATIONS FOR THE SIX MONTHS ENDED JUNE 30, 2022 AND 2021

Net Revenues

(in thousands)	Six Months Ended June 30, 2022	2021	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 98,970	$ 66,812	$ 32,158	48.1 %
Established brand pharmaceutical products	16,915	18,555	(1,640)	(8.8)%
Contract manufacturing	7,293	4,895	2,398	49.0 %
Royalty and other	3,660	12,884	(9,224)	(71.6)%
Generics, established brands, and other segment total net revenues	$ 126,838	$ 103,146	$ 23,692	23.0 %
Rare Disease Segment				
Rare disease pharmaceutical products	$ 11,494	$ —	$ 11,494	NM (1)
Total net revenues	$ 138,332	$ 103,146	$ 35,186	34.1 %

(1) Not meaningful

Net revenues for the six months ended June 30, 2022 were $138.2 million compared to $103.1 million for the same period in 2021, an increase of 34.0%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $99.0 million during the six months ended June 30, 2022, an increase of 48.1% compared to $66.8 million for the same period in 2021. From a product perspective, the increase was principally driven by revenues from products acquired in our acquisition of Novitium, including Prazosin, Prednisone, Famotidine, Oxybutynin Chloride, Dapsone, and various other products. The increase was also due to increased revenues of Nebivolol, which ANI launched in September 2021. Increases were tempered by a decrease in revenues of Penicillamine, Propranolol Extended Release, EEMT, and Erythromycin Ethylsuccinate (“EES”). The increase in net generic revenues was principally due to an increase in volumes and tempered by a decrease in average selling prices.

  Generic prescription levels were suppressed when compared to pre-pandemic levels during the six months ended June 30, 2021, and primarily during the first quarter, which had a negative impact on our net sales of generic pharmaceutical products during the period. Prescriptions have returned to essentially pre-pandemic levels in 2022.

- Net revenues for established brand pharmaceutical products were $16.9 million during the six months ended June 30, 2022, a decrease of 8.8% compared to $18.6 million for the same period in 2021. From a product perspective, the net decrease was driven by a decrease in sales of Casodex and InnoPran XL. These decreases were tempered by an increase in sales of Atacand. The decrease in revenues for the six months ended June 30, 2022 was principally due to prior period adjustments or change in estimates to variable consideration, including returns and rebates.

  Sales of our established brand products were negatively impacted by the COVID-19 pandemic during the six months ended June 30, 2021, and primarily during the first quarter, as mitigation measures and other related

actions suppressed prescription levels during the period. Brand prescriptions have returned to essentially pre-pandemic levels in 2022.

- Contract manufacturing revenues were $7.3 million during the six months ended June 30, 2022, an increase of 49.0% compared to $4.9 million for the same period in 2021, due to an increase in the volume of orders, primarily related to Novitium contract manufacturing revenues in 2022 with no comparable revenues in 2021.

- Royalty and other revenues were $3.7 million during the six months ended June 30, 2022, a decrease of $9.2 million from $12.9 million for the same period in 2021, primarily due to the recognition of the final royalty of $11.2 million under the Kite Pharma, Inc. license agreement (Yescarta®) pursuant to the Tripartite Agreement in the six months ended June 30, 2021. Royalty revenue for the six months ended June 30, 2022 includes $2.1 million related to Novitium arrangements. There were no comparable revenues for this period in 2021.

- Net revenues of rare disease pharmaceutical products, which consists entirely of sales of Purified Cortrophin Gel, were $11.5 million during the six months ended June 30, 2022, as the product was launched in late January 2022. There were no sales of rare disease pharmaceutical products during the comparable prior year period.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Six Months Ended June 30, 2022	2021	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 69,565	$ 42,299	$ 27,266	64.5 %

For the six months ended June 30, 2022, cost of sales increased to $69.6 million from $42.3 million for the same period in 2021, an increase of $27.3 million, or 64.5%. The increase is primarily due to increased volumes of generic products, including $17.4 million of costs related to activity of Novitium during the six months ended June 30, 2022 with no comparable activity in the prior year period, and $4.8 million in costs representing the excess of fair value over cost for inventory acquired in an asset acquisition and a business combination, of which $3.2 million relates to inventory acquired from Novitium and included in the previously discussed $17.4 million of cost of sales. Charges for the excess of fair value over cost for inventory acquired in an asset acquisition were $1.5 million for the comparable period in 2021. Sales of products subject to profit sharing arrangements also accounted for a $0.9 million increase in the current year period.

Cost of sales, exclusive of the $4.8 million net impact related to excess of fair value over the cost of inventory sold during the period, as a percentage of net revenues increased to 46.8% during the six months ended June 30, 2022, from 39.6% during same period in 2021, primarily as a result of increased volumes in a period of declining average selling prices across generic and brand products, $11.2 million in royalty revenue during the comparable 2021 period with no associated cost of goods sold, and higher costs related to sales of products subject to profit sharing arrangements.

During the six months ended June 30, 2022, we purchased 17% of our inventory from one supplier. As of June 30, 2022, our amount payable to this supplier was $6.3 million. During the six months ended June 30, 2021, no single vendor represented more than 10% of inventory purchases.

Other Operating Expenses

(in thousands)	Six Months Ended June 30, 2022	2021	Change	% Change
Research and development	$ 9,439	$ 5,773	$ 3,666	63.5 %
Selling, general, and administrative	60,775	36,407	24,368	66.9 %
Depreciation and amortization	28,321	22,222	6,099	27.4 %
Contingent consideration fair value adjustment	(342)	—	(342)	NM [1]
Legal settlement expense	—	8,400	(8,400)	(100.0)%
Purified Cortrophin Gel pre-launch charges	—	553	(553)	(100.0)%
Restructuring activities	2,570	—	2,570	NM [1]

Intangible asset impairment charge	112	—	112	NM (1)
Total other operating expenses	$ 100,875	$ 73,355	$ 27,520	37.5 %

(1) Not meaningful

For the six months ended June 30, 2022, other operating expenses increased to $100.9 million from $73.4 million for the same period in 2021, an increase of $27.5 million, or 37.5%, primarily as a result of the following factors:

- Research and development expenses increased from $5.8 million to $9.4 million, an increase of 63.5%, primarily due to expenses related to the Novitium activities during the six months ended June 30, 2022 and no comparable expenses in the six months ended June 30, 2021, and tempered by a $1.6 million decrease in expense associated with our Cortrophin development efforts due to approval and launch of the product.

- Selling, general, and administrative expenses increased from $36.4 million to $60.8 million, an increase of $24.4 million, or 66.9%, primarily due to $23.4 million increase in sales and marketing expenses related to our launch of Purified Cortrophin Gel, increases related to the addition of Novitium headcount and activities during the six months ended June 30, 2022, with no comparable expenses in the 2021 period, and tempered by a $3.4 million decrease in transaction expenses related to the Novitium acquisition.

- Depreciation and amortization expense was $28.3 million for the six months ended June 30, 2022, compared to $22.2 million for the same period in 2021, an increase of $6.1 million. The increase is primarily due to the amortization of intangible assets acquired in the Novitium acquisition.

- As described in Note 14, *Fair Value Disclosures*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized a contingent consideration fair value adjustment of $0.3 million income in the six months ended June 30, 2022. The income is principally due to an increase in the discount rate and tempered by the passage of time. No contingent consideration fair value adjustment was recognized in the six months ended June 30, 2021.

- As described in Note 13, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, we recognized a legal settlement expense of $8.4 million income related to the Arbor commercial matter in the three months ended June 30, 2021. No legal settlement expense was recognized in the six months ended June 30, 2022.

- We recognized restructuring activities of $2.6 million of expense in the six months ended June 30, 2022, in relation to the anticipated closure of our Oakville, Ontario, Canada facility. Costs included $1.4 million in termination benefits, $0.9 million in fixed asset impairments and accelerated depreciation, and $0.3 of other costs. No restructuring activities were recognized in the three months ended June 30, 2021.

- We recognized an impairment of $0.1 million in the six months ended June 30, 2022, in relation to an ANDA asset. No impairment charges were recognized in the six months ended June 30, 2021.

Other Expense, net

(in thousands)	Six Months Ended June 30, 2022	2021	Change	% Change
Interest expense, net	$ (13,282)	$ (4,985)	$ (8,297)	166.4 %
Other income/(expense), net	675	(582)	1,257	(216.0)%
Total other expense, net	$ (12,607)	$ (5,567)	$ (7,040)	126.5 %

For the six months ended June 30, 2022, we recognized total other expense, net of $12.6 million versus total other expense of $5.6 million for the same period in 2021, an increase of $7.0 million. Interest expense, net for the six months ended June 30, 2022 consisted primarily of interest expense on borrowings under the Term Facility. Interest expense, net for the six months ended June 30, 2021 consisted primarily of interest expense on borrowings under our existing

Amended and Restated Credit Agreement, dated as of December 27, 2018 (the "Prior Credit Agreement"), among the Company, as borrower, and Citizens Bank with other lenders. The increase in interest expense is due to an increase in the debt outstanding during the six months ended June 30, 2022 coupled with an increased borrowing rate on the $300.0 million Term Facility as compared to the borrowing rate on the Prior Credit Agreement borrowings and an increase in amortization of finance fees. During the six months ended June 30, 2022, there was $299.3 million to $300.0 million of outstanding borrowings, compared to $186.9 million to $205.7 million during the comparable 2021 period. For the six months ended June 30, 2022 and 2021, there was less than $0.1 million of interest capitalized into construction in progress. The $1.3 million change in other income/(expense), net is primarily related to a $0.8 million gain on the sale of an ANDA in the six months ended June 30, 2022 and the non-recurrence of $0.4 million of expense associated with the final royalty receipt on the Kite license agreement during the six months ended June 30, 2021.

Benefit for Income Taxes

	Six Months Ended June 30,			
(in thousands)	2022	2021	Change	% Change
Benefit for income taxes	$ 9,662	$ 4,055	$ 5,607	138.3 %

For the six months ended June 30, 2022, we recognized an income tax benefit of $9.7 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 21.6% to pre-tax consolidated loss of $44.7 million reported during the period, as well as the net effects of certain discrete items occurring in 2022 which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2022.

For the six months ended June 30, 2021, we recognized an income tax benefit of $4.1 million. The income tax benefit resulted from applying an estimated annual worldwide effective tax rate of 22.4% to pre-tax consolidated loss of $18.1 million reported during the period, reduced by the net effects of certain discrete items occurring in 2021 which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the six months ended June 30, 2021.

LIQUIDITY AND CAPITAL RESOURCES

Debt Financing

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

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

The Term Facility matures in November 2027 and the Revolving Facility in November 2026. Each permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the LIBOR Rate (as defined in the Credit Agreement, which includes a floor of 0.75%) in the case of loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the LIBOR Rate (as defined in the Credit Agreement) in the case of loans under the Revolving Facility. The Credit Facility has a subjective acceleration clause in case of a material adverse effect. The Term Facility includes a repayment schedule, pursuant to which $750 thousand of the loan will be paid in quarterly installments during the 12 months ended December 31, 2022. As of June 30, 2022,

$3.0 million of principal of the loan was recorded as current borrowings in the consolidated balance sheet. As of June 30, 2022, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing.

Equity Financing

Concurrently with the execution of the Merger Agreement, on March 8, 2021, we entered into that certain Equity Commitment and Investment Agreement with Ampersand 2020 Limited Partnership (the "PIPE Investor") pursuant to which, on November 19, 2021, we issued and sold to the PIPE Investor, and the PIPE Investor purchased, 25,000 shares of our Series A Convertible Preferred Stock , for a purchase price of $1,000 per share and an aggregate purchase price of $25 million, in a private placement issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder.

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

We believe that our financial resources, consisting of current working capital, anticipated future operating revenue and corresponding collections from customers, and our Credit Facility, under which $40.0 million remains available for borrowing as of June 30, 2022, 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 provided by/(used in) by operating activities, investing activities, and financing activities for the periods indicated:

	Six Months Ended June 30,	
(in thousands)	2022	2021
Operating Activities	$ (30,426)	$ 20,909
Investing Activities	$ (2,782)	$ (22,687)
Financing Activities	$ (3,707)	$ 18,173

Net Cash (Used In) / Provided by Operations

Net cash used in operating activities was $30.4 million for the six months ended June 30, 2022, compared to $20.9 million provided by operating activities during the same period in 2021, a decrease of $51.3 million. The decrease was driven by our net loss and net changes in working capital including increases to accounts receivable and inventory of $21.9 million and $10.9 million, respectively since December 31, 2021, due in part to a number of new product launches during the six months ended June 30, 2022.

Net Cash Used in Investing Activities

Net cash used in investing activities for the six months ended June 30, 2022 was $2.8 million, principally due to the $3.3 million of capital expenditures partially offset by $0.8 million of proceeds from the sale of long-lived assets during the period. Net cash used in investing activities for the six months ended June 30, 2021 was $22.7 million, principally due to

the acquisition of three NDAs and an ANDA from Sandoz, Inc. for $20.7 million in consideration and $1.6 million of capital expenditures during the period.

Net Cash (Used in) / Provided by Financing Activities

Net cash used in financing activities for the six months ended June 30, 2022 was $3.7 million, principally due to the $1.5 million maturity payments on the Term Facility, $1.6 million of treasury stock purchased in relation to restricted stock vests, and $0.8 million convertible preferred stock dividends paid. Net cash provided by financing activities was $18.2 million for the six months ended June 30, 2021, principally due to borrowings of $24.0 million on the Revolving Facility, $5.2 million of maturity payments on the term facilities related to our Prior Credit Agreement, and $0.8 million of treasury stock purchased in relation to restricted stock vests.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our unaudited interim condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. In our consolidated financial statements, estimates are used for, but not limited to, stock-based compensation, revenue recognition, allowance for credit losses, variable consideration determined based on accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, including contingent consideration in acquisitions, fair value of long-lived assets, income tax provision or benefit, deferred taxes and valuation allowance, determination of right-of-use assets and lease liabilities, purchase price allocations, and the depreciable lives of long-lived assets.

A summary of our significant accounting policies is included in Part II, Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2021. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. Such policies are summarized in Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2021.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

CONTRACTUAL OBLIGATIONS

As of June 30, 2022, our contractual obligations have not changed materially from the amounts reported in our most recent Annual Report on Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

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

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

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

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

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

In April 2020, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under term facilities related to our Prior Credit Agreement. The interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Facility with Truist Bank, the interest rate swap with a notional value of $158.6 million was novated and is now with Truist Bank and is used to manage changes in LIBOR-based interest rates underlying a portion of the borrowing under the Term Facility. We are exposed to interest rate risk on the unhedged portion of our Term Facility and if interest rates increased or decreased by 1%, interest expense would have increased or decreased by approximately $1.4 million. If our Revolving Facility were fully drawn and interest rates increased or decreased by 1%, interest expense would have increased or decreased by approximately $0.4 million. The interest rate swap provides an effective fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

We are exposed to risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the quarter ended June 30, 2022 by approximately $2,000.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated and Indian rupee-denominated transactions from ANI Pharmaceuticals Canada Inc. and our Indian subsidiary from the Canadian dollar to the U.S. dollar and the Indian-rupee to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the quarter ended June 30, 2022.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of June 30, 2022. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting, except as noted below.

On November 19, 2021, we acquired all the issued and outstanding equity interests of Novitium Pharma LLC ("Novitium"). In conjunction with the transaction, we are currently in the process of integrating Novitium's policies, processes, people, technology, and operations into the consolidated company, and integrating Novitium's operations into our system of internal control over financial reporting, resulting in certain newly implemented or adapted controls.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 13, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

Item 1A. Risk Factors

In addition to the other information set forth in this report, please carefully consider the factors described under the heading "Risk Factors" in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2021 in Part I, Item 1A. Risk Factors. The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition, and/or operating results. There have been no material changes to those risk factors since their disclosure in our most recent Annual Report on Form 10-K.

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

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased[1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or approximate dollar value) of Shares that may yet be Purchased Under the Plans or Programs
April 1 - April 30, 2022	15,057	$ 29.89	—	$ —
May 1 - May 31, 2022	780	$ 25.28	—	$ —
June 1 - June 30, 2022	567	$ 23.77	—	$ —
Total	16,404	$ 29.46	—	

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Employment Agreement between Meredith Cook and the Company, dated June 21, 2022.
10.2	ANI Pharmaceuticals, Inc. Executive Incentive Bonus Plan (incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on February 28, 2022 (File No. 001-31812)).
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended June 30, 2022 formatted in Inline XBRL: (i) Condensed Consolidated Balance Sheets; (ii) Condensed Consolidated Statements of Operations; (iii) Condensed Consolidated Statements of Comprehensive Income; (iv) Condensed Consolidated Statements of Changes in Stockholders' Equity; (v) Condensed Consolidated Statements of Cash Flows; and (vi) Notes to Condensed Consolidated Financial Statements.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

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

ANI Pharmaceuticals, Inc. (Registrant)

Date: August 8, 2022

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

Date: August 8, 2022

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

EXECUTIVE EMPLOYMENT AGREEMENT

EXECUTIVE EMPLOYMENT AGREEMENT (this "**Agreement**") between ANI Pharmaceuticals, Inc. (the "**Company**") and Meredith Cook ("**Executive**") dated as of June 21, 2022. Each of the Company and Executive are sometimes referred to herein individually as a "**Party**" and together as the "**Parties**."

WHEREAS, the Company wishes to employ Executive, and Executive wishes to be employed by the Company on the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the mutual promises, terms, covenants and conditions set forth herein and the performance of each, the Parties hereto, intending to be legally bound, hereby agree as follows:

1. Employment.

(a) Commencement Date. Executive shall commence employment on July 18, 2022, or such earlier or later date as the parties may agree (the actual date Executive commences employment, the "**Commencement Date**").

(b) Duties. The Company hereby employs Executive in the position of Senior Vice President, General Counsel & Company Secretary, effective as of the Commencement Date. Executive shall have all such responsibilities, duties and authorities as are consistent with the position of a Senior Vice President, General Counsel & Company Secretary and shall report to Nikhil S Lalwani, the President & CEO of the Company (your "**Supervisor**"). Executive shall work out of the Company's New Jersey office on a full-time basis.

(c) Full-time Employment. Executive hereby accepts this employment upon the terms and conditions contained herein and agrees to devote substantially all of Executive's business time, attention and efforts to promote and further the business, interests, objectives and affairs of the Company, and Executive shall not be engaged in any other business activity pursued for gain, profit or other pecuniary advantage without the prior written consent of the Company; provided, however, that the foregoing limitations shall not be construed as prohibiting Executive from serving on civic, charitable or other boards or committees, managing personal or family investments and personal passive investments in securities or from engaging in other activities from time to time, in each case that will not interfere in any material respect with the performance of Executive's duties hereunder. Executive shall faithfully adhere to, execute and fulfill in all material respects all policies established by the Company in writing and made available to Executive, consistent with the other terms of this Agreement.

2. Compensation. For all services rendered by Executive in any capacity required hereunder, the Company shall compensate Executive as follows:

(a) Base Salary. During the Term, the Company shall pay Executive, as compensation for Executive's services, a base salary at a gross annual rate of Three Hundred Sixty Thousand dollars ($360,000), less all required tax withholdings and other applicable

deductions, in accordance with the Company's standard payroll procedures. The annual compensation specified in this subsection (a), together with any modifications in such compensation that the Company may make from time to time in accordance with the following sentence, is referred to in this Agreement as the "**Base Salary**." Executive's Base Salary will be subject to review in accordance with the Company's normal performance review practices. Effective as of the date of any change to Executive's Base Salary, the Base Salary as so changed shall be considered the new Base Salary for all purposes of this Agreement.

(b) Benefits and Other Compensation. Executive shall be entitled to receive additional benefits and compensation from the Company as follows:

(i) Sign-on Bonus on the first payroll date after Commencement Date, at a gross value of twenty-five thousand dollar ($25,000), less all required tax withholdings and other applicable deductions, in accordance with the Company's standard payroll procedures. Executive shall be required to pay back the Sign-on Bonus to Company if she Terminates without Good Reason or if the Company Terminates her employment with Good Reason, on or prior to December 31, 2022;

(ii) Twenty (20) days paid vacation in each calendar year (pro-rated for partial calendar years worked). Unused vacation shall not carry forward except to the extent expressly provided in the Company's written policies;

(iii) Payment of such premiums (or such portion thereof as is provided by the Company's plans) for coverage for Executive and her spouse and eligible dependents under any insurance plans that the Company may have in effect from time to time, on terms no less favorable to Executive than those generally provided to similarly situated employees of the Company;

(iv) The Company shall allow Executive to participate in all other Company-wide employee benefits as may, from time to time, be made available generally to any other executives of the Company, including the Company's 401(k) plan;

(v) Reimbursement for business travel and other out-of-pocket expenses reasonably incurred by Executive in the performance of her duties, including without limitation, mobile phone expenses and membership fees associated with related professional associations. All reimbursable expenses shall be subject to any pre-approval process established by Company policy and shall be appropriately documented in reasonable detail by Executive upon submission of any request for reimbursement, and in a format consistent with the Company's expense reporting policy and shall be reimbursed promptly;

(vi) Executive shall be entitled to such holiday and personal days as may, from time to time, be made available generally to any other executives of the Company;

(vii) Following each year of employment during the Term, the Company shall reimburse Executive, up to a maximum of three thousand dollars

($3,000.00) per annum, for the annual premium paid by the Executive for a term life insurance policy that will pay a benefit on the death of Executive to one or more beneficiaries designated by the Executive from time to time; and

(viii) Executive shall be entitled to such other benefits as may, from time to time, be made generally available to similarly situated executive officers of the Company, excluding any individually negotiated benefits in place prior to the date of this Agreement, including, without limitation, any tax gross-ups.

(c) Annual Incentive Bonus. Executive shall be eligible to receive an incentive bonus for each complete or partial fiscal year of the Company that ends during the Term (the "**Incentive Bonus**"), subject to the terms of this Agreement and achievement of the applicable performance goals. With respect to each fiscal year during the Term, Executive's target Incentive Bonus shall be fifty percent (50%) of her Base Salary for such year, it being understood that Executive may earn a greater or lesser amount based on the level of achievement of the applicable performance goals. The Incentive Bonus shall be pro-rated for any partial fiscal year. The Compensation Committee (the "**Compensation Committee**") of the Company's Board of Directors (the "**Board**") shall establish the applicable performance goals required to be met by Executive in connection therewith no later than March 15th of such fiscal year. Executive's actual Incentive Bonus amount for a particular year shall be determined by the Compensation Committee based on Executive's achievement of such performance goals. Except as provided in Sections 3(e) or 8, as applicable, Executive shall not be entitled to receive an Incentive Bonus payment for any fiscal year unless Executive is employed by the Company (or any subsidiary of the Company) on the last day of such fiscal year.

(d) Long-Term Incentive Awards. Commencing with the Company's 2023 fiscal year, Executive shall receive annual long-term incentive awards under the ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan (the "**ANI Stock Plan**") or any successor plan, in such forms and in such amounts as determined in the sole discretion of the Compensation Committee. On the Commencement Date, Executive will be granted equity in the Company with an aggregate value of Six Hundred Thousand dollars ($600,000) (the "**Equity Value**"), which shall be one hundred percent (100%) in the form of a restricted stock award (the "**Inducement Award**"). The Inducement Award is intended to cover the initial equity award and annual equity award for 2022 and, therefore, the Company does not intend to provide Executive with an additional equity award during fiscal year 2022.

(i) *Restricted Stock Award*. On the Commencement Date, the Company shall grant Executive a restricted stock award with respect to that number of shares of the Company's common stock equal to the quotient of (x) one hundred percent (100%) of the Equity Value *divided by* (y) the volume weighted average of the closing price of the Company's stock price for the ten (10) trading days ending on, and including, the Commencement Date (the "**RSA**"). Executive should consult with Executive's own tax advisor concerning the tax risks associated with accepting a restricted stock award. The RSA will be subject to the terms and conditions of the ANI Stock Plan and a restricted stock award agreement to be entered into by and between Executive and the Company, both of which documents are incorporated herein by reference. Subject to any

vesting acceleration rights Executive shall have, the RSA will vest as to twenty-five percent (25%) of the total shares subject to the RSA on each annual anniversary of the Commencement Date, so that the RSA will be fully vested four (4) years from the Commencement Date, subject to Executive continuing to provide services to the Company through each vesting date.

(e) No Other Compensation or Benefits; Payment. The compensation and benefits specified in this Section 2 shall be in lieu of any and all other compensation and benefits, provided, however, that nothing in this Agreement shall prevent the Board from increasing the Base Salary or awarding additional incentive compensation to Executive in its sole and absolute discretion. Payment of all compensation and benefits to Executive hereunder shall be made in accordance with the relevant Company policies in effect from time to time, including normal payroll practices, and shall be subject to all applicable employment and withholding taxes.

(f) Cessation of Employment. In the event Executive shall cease to be employed by the Company for any reason, then Executive's compensation and benefits shall cease on the date of such cessation of employment, except as otherwise provided herein or in any applicable Company employee benefit plan or program.

(g) Taxes. Executive shall make payment of all required taxes, whether Federal, state, provincial or local in nature, including but not limited to income taxes, Social Security taxes, Federal Unemployment Compensation taxes that are required to be paid by her pursuant to any applicable law. The Company shall have the right to withhold from the sums payable to Executive hereunder such amounts, if any, as may be required by the Internal Revenue Code of 1986, as amended (the "**Code**") or any other like statute which is, or may become, applicable to the provisions hereof.

3. Term; Termination; Rights on Termination. The term of this Agreement shall begin on the Commencement Date and continue until terminated in accordance with the provisions of this Agreement (the "**Term**"). This Agreement and Executive's employment may be terminated in any one of the following ways:

(a) Death. The death of Executive shall immediately terminate this Agreement.

(b) Disability. If, as a result of Executive's incapacity due to physical or mental illness, Executive shall not have performed her material duties hereunder on a full-time basis for either (a) one hundred and twenty (120) consecutive days or (b) one hundred and eighty (180) days in any consecutive twelve (12) months ("**Disability**"), Executive's employment under this Agreement may be terminated by the Company upon thirty (30) days' written notice if Executive is unable to resume performing her material duties at the conclusion of such notice period. Executive's compensation during any period of Disability prior to the Termination Date shall be the amounts normally payable to her in accordance with her then current annual Base Salary.

(c) Termination.

(i) *For Good Cause*. The Company may terminate this Agreement immediately (subject to any applicable notice and cure period set forth below) upon written notice (the "**Termination Notice**") to Executive for "**Good Cause**", which shall be defined as Executive's: (A) conviction of or plea of *nolo contendere* to a felony or any other crime involving fraud or dishonesty; (B) breach of any material term of this Agreement or any other agreement between the Parties which is not cured within twenty
(20) days of written notice to Executive or which constitutes a second instance of the same breach within a single calendar year; (C) intentional or willful breach of any material published corporate policy of the Company that is generally applicable to executives of the Company, which remains uncured after twenty (20) days' written notice thereof to Executive or which constitutes a second violation of such policy within a single calendar year; (D) gross negligence or willful misconduct in performing her duties hereunder, or the willful failure to follow lawful directives of the Board or her Supervisor (unless due to death or Disability), which is not cured within twenty (20) days of written notice to Executive or which constitutes a second instance of any breach within a single calendar year; (E) acts or omissions or course of conduct that constitute fraud or embezzlement; (F) acts or omissions or course of conduct that constitute dishonesty, misrepresentation, misappropriation or deliberate injury or attempted injury by Executive having a material adverse effect on the reputation, business or assets of the Company and its subsidiaries taken as a whole, which is not cured within twenty (20) days of written notice to Executive or which constitutes a second instance of any breach within a single calendar year; or (G) if Executive is debarred pursuant to Section 306 of the United States Federal Food, Drug and Cosmetics Act (21 U.S.C §§301 et seq.) or 42 U.S.C.
§1320a-7. In the event of a termination for Good Cause, Executive shall have no right to any severance compensation. The Company shall set forth in the Termination Notice a detailed description of the grounds for which Executive is being terminated for Good Cause, and Executive shall have the right to cure such matters to the extent provided above. In the event Executive does cure such matters in accordance with and to the extent permitted by the foregoing provisions, then the Company shall not be entitled to terminate Executive for Good Cause with respect to such cured matters, except as provided in clauses (B), (C), (D) and (F).

(ii) *Without Good Cause*. In addition to the provisions of Section 3(c)(i), the Company may, at any time, terminate this Agreement upon thirty (30) days' written notice to Executive, if such termination is approved by the Board (any such termination other than for Good Cause being a termination "**Without Good Cause**"). In the event of such a termination, Executive shall have the right to receive severance compensation as set forth below in Sections 3(e) or 8, as applicable.

(iii) *Termination by Executive for Good Reason*. The Executive shall be entitled to resign or otherwise terminate her employment for Good Reason. In the event of such a termination, Executive shall have the right to receive severance compensation as set forth below in Sections 3(e) or 8, as applicable. For purposes hereof, "**Good Reason**" shall mean the occurrence of any of the following that is not cured within thirty

(30) days of Executive's written notice that the occurrence constitutes Good Reason: (A) a material reduction of Executive's position, title, duties, or responsibilities with the Company; (B) a material reduction of Executive's Base Salary; (C) a material breach by the Company of this Agreement; or (D) the Company requiring Executive to move or relocate Executive's primary place of employment from her then existing place of employment (as of the Commencement Date, Princeton, NJ) by more than thirty-five (35) miles; provided that (1) any notice of Good Reason must be given by Executive to the Company within sixty (60) days of the date Executive becomes aware of the occurrence set forth in clauses (A) – (D) above and (2) any resignation by Executive while the Company has "Good Cause" for termination of Executive and as to which it has previously given written notice to Executive of the basis of such Good Cause prior to the resignation, shall not be considered to be a resignation without Good Reason. The Executive shall not have the right to terminate her employment for Good Reason unless the Executive actually terminates employment within ninety (90) days following delivery of the Executive's written notice of Good Reason.

(iv) *Termination by Executive Without Good Reason*. Executive may resign without Good Reason on thirty (30) days' prior written notice to the Company. If Executive so resigns or otherwise terminates her employment for any reason, she shall have no right to any severance compensation.

(d) Payment Through Termination. Upon termination of this Agreement for any reason provided above, Executive shall be entitled to receive (i) all compensation earned as of the Termination Date, (ii) all benefits and reimbursements due through the Termination Date,
(iii) vested benefits accrued through the Termination Date under the Company's benefits plans which shall be payable in accordance with the terms of such plans, and (iv) unless Executive's employment is terminated by the Company for Good Cause, the full Incentive Bonus otherwise earned and payable to Executive for the fiscal year ending immediately prior to her Termination Date, based on actual performance and to be paid when Incentive Bonus payments for the applicable fiscal year are paid to other executives. Additional compensation subsequent to termination, if any, shall be due and payable to Executive only to the extent and in the manner expressly provided herein. All other rights and obligations under this Agreement shall cease as of the Termination Date, except that Executive's obligations under Sections 4, 5, 6, 7, 9 and 19 and Executive's rights under Section 11 shall survive such termination in accordance with their terms.

(e) Severance Payments Due Upon Termination by Company Without Good Cause or by Executive for Good Reason. Except in the event of a termination of employment in connection with a Change in Control as provided in Section 8 below in which case the provisions thereof shall apply and Executive shall not be entitled to receive payments under this clause (e):

(i) If (x) Executive's employment is terminated by the Company Without Good Cause or by Executive with Good Reason, (y) Executive executes a general release of all claims and rights that Executive may have against the Company and its related entities and their respective stockholders, members, officers, directors, managers and employees relating to Executive's employment and/or termination (other

than claims and rights for compensation and benefits provided for hereunder) in the form attached hereto as Exhibit A (the "**Release**") during the period commencing on Executive's termination of employment and ending sixty (60) days after Executive's termination of employment or on such earlier date as specified by the Company in such Release (the "**Release Period**") and does not revoke such Release before it becomes effective, binding and irrevocable, and (z) Executive complies with the surviving obligations contained in Sections 4, 5, 6, 7, 9 and 19, then the Company shall:

(A) Continue to pay Executive her then current Base Salary, payable in regular installments in accordance with the Company's standard payroll procedures but no less frequently than bi-monthly procedures for a period equal to twelve (12) months following the Termination Date (the "**Severance Period**");

(B) If Executive elects to receive continuation coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, as amended ("**COBRA**"), pay Executive on a monthly basis for the Severance Period, an amount equal to a percentage (based on the portion of the monthly premium costs covered by the Company for Executive's group health, dental and/or vision coverage in effect as of the Termination Date), of Executive's monthly COBRA premium payment (if any) under the Company's group health, dental and vision plans; provided, however, that the obligations of the Company under this clause
(B) shall cease upon Executive becoming eligible to participate in a plan of another employer providing substantially similar group health benefits to Executive and her eligible family members and dependents or upon termination of Executive's COBRA coverage;

(C) If such termination occurs after June 30th in any calendar year, pay Executive a pro-rated Incentive Bonus for the fiscal year during which Executive's employment is terminated (prorated based on the days elapsed in such fiscal year through the Termination Date);

(D) A lump sum cash payment equal to the Executive's annual maximum Incentive Bonus Amount, payable on the first payroll date following the first anniversary of the Termination Date (all of the payments in clauses (A) -
(D) together, the "**Severance Payments**"); and

(E) All of the Executive's options to purchase the common stock of the Company and any awards of restricted common stock received by Executive in each case that are unvested, outstanding and subject to time vesting shall vest with respect to that number of shares subject thereto that would have vested during the Severance Period had Executive remained employed by the Company during such period (any unvested and outstanding performance-based awards shall be subject to the terms and conditions of the ANI Stock Plan and the award agreement by and between Executive and the Company pursuant to which each such award was granted). In addition, any vested options (after taking into

account the vesting acceleration) shall remain exercisable through the eighteen (18) month anniversary of the Termination Date (but in no event beyond the original term of the equity award), it being understood that to the extent any options that are intended to be "incentive stock options" for purposes of Section 422 of the Code are exercised after the three month anniversary of the Termination Date, such options will cease to be treated as "incentive stock options" for purposes of Section 422 of the Code.

(ii) The amount of the Incentive Bonus payments described in clause (i)(C) shall be determined based on the maximum Incentive Bonus for such fiscal year and shall be paid to Executive when Incentive Bonus payments for the applicable fiscal year are paid to other executives of the Company.

(iii) All Severance Payments shall be suspended until the date that the Release becomes effective and irrevocable; provided, however, that if the Release Period begins in one calendar year and ends in the subsequent calendar year, the Severance Payments will be suspended until the later of (A) January 1 of such subsequent calendar year and (B) the date the Release becomes effective and irrevocable. All Severance Payments that but for the preceding sentence are due and payable on the date the suspension of Severance Payments ends will be paid to Executive on the first regularly scheduled payroll payment date following the date the suspension of Severance Payments ends.

(iv) It is acknowledged and agreed that Executive shall not be required to mitigate the amount of any payment provided for in this Section 3(e) by seeking other employment or otherwise and Severance Payments will not be offset for any reason.

(f) Resignation. Regardless of the reason for the Termination of Employment (as defined below), Executive shall, effective as of Termination Date (as defined below), be deemed to have resigned from the Board, if applicable, and any positions as an officer of the Company and shall complete any paperwork requested by the Company to document such resignation(s).

4. Non-Solicitation; Non-Competition.

(a) General. The Parties acknowledge that Executive has and will continue to perform essential services for the Company, its employees and its stockholders during the Term and Executive will be exposed to and given access to and work with a considerable amount of Confidential Information and she has and will continue to become familiar with the Company's and its controlled affiliates' trade secrets, methods of doing business, business plans and other valuable Confidential Information concerning the Company and its controlled affiliates and their customers and suppliers and that her services have been and will be of special, unique and extraordinary value to the Company and its affiliates. The Parties also expressly recognize and acknowledge that (i) the personnel of the Company have been trained by and are a valuable to the Company that that it will incur substantial recruiting and training expenses if the Company must hire new personnel or retrain existing personnel to fill vacancies and (ii) it could seriously

impair the good will and diminish the value of the Company's business should Executive compete with the Company in a manner prohibited by this Agreement. The Parties acknowledge that the covenants have an extended duration, however they agree that these covenants are reasonable and necessary for the protection of the Company, its stockholders and employees. For these and other reasons and the fact there are many other employment opportunities available to Executive if her employment is terminated, the Parties, are in full and complete agreement that the restrictive covenants in this Section 4 are fair and reasonable and are entered into freely, voluntarily and knowingly.

(b) Non-Competition. During the Term and for the Applicable Restricted Period thereafter, Executive shall not, without the prior written consent of the Company, thereafter, directly or indirectly: (i) own, manage, operate, finance, join, advise, consult with or perform services for (or supervise or oversee those doing so), or control or participate in the ownership, management, operation, financing or control of, any Person engaged in any Competitive Activity; (ii) serve as an officer, director, shareholder, employee, partner, member. manager, agent, representative, advisor, volunteer, consultant, contractor, creditor or otherwise of, any Person engaged in a Competitive Activity, or (iii) except as permitted below, own any interest in, consult with, render services to or otherwise assist any Person that does anything contemplated by the foregoing clauses (i) and (ii), unless in any case: (A) the revenue or profit from such Competitive Activities do not, in the aggregate comprise more than five percent (5%) of the aggregate revenues or profits of such Person and (B) Employee is not directly employed by or directly managing the business or division of such Person that is engaged in the Competitive Activities (it being understood that being employed as President, Chief Executive Officer or Chief Financial Officer of a company falling within the exception set forth in clause (A) above should be deemed to violate the restriction contained in this clause (B)). Nothing herein will prohibit Executive from being a passive owner of less than five percent (5%) of the outstanding stock of any class of a corporation which is publicly traded, so long as Executive has no active participation in the business of such corporation.

(c) Non-solicitation of Executives. During the Term and for the Applicable Restricted Period thereafter, Executive will not, directly or indirectly, in any manner (whether on her own account, as an owner, operator, officer, director, partner, manager, employee, agent, contractor, consultant or otherwise): (i) recruit, solicit or otherwise attempt to employ or retain or enter into any business relationship with any current employee of or consultant to the Company or any of its controlled affiliates (or any Person who was an employee of or consultant to the Company within the prior six (6) month period), (ii) induce or attempt to induce any current employee of, or consultant to, the Company or any of its controlled affiliates (or any Person who was an employee of or consultant to the Company within the prior six (6) month period), to leave the employ of the Company or any such controlled affiliates, or in any way interfere with the relationship between the Company or any of its controlled affiliates and any of their employees or consultants or (iii) employ or retain or enter into any business relationship with any Person who was an employee of or consultant to the Company or any of its controlled affiliates within the prior six (6) month period; provided, however, that the foregoing restriction shall not restrict (A) general advertisements or listing for employment openings not specifically targeted at employees of the Company; or (B) hiring or offering to hire any person as a result of such general advertisements or any employee or consultant who was terminated by the

Company.

(d) *Non-disparagement*. Executive agrees not to make any negative or disparaging statements or communications regarding either the Company or its affiliates or any of their respective operations, officers, directors or stockholders. The Company agrees to instruct its officers and directors not to make any negative or disparaging statements or communications regarding Executive. The covenant contained in this Section 4(d) shall not prevent either Party from providing truthful testimony in proceedings to enforce or defend their rights under this Agreement.

(e) *Covenants Separate*. The covenants in this Section 4 are severable and separate, and the unenforceability of any specific covenant shall not affect the provisions of any other covenant.

(f) *Independent*. All of the covenants in this Section 4 shall be construed as an agreement independent of any other provision in this Agreement, and the existence of any claim or cause of action of Executive against the Company, whether predicated on this Agreement or otherwise, shall not constitute a defense to the enforcement of such covenants. The existence of any claim or cause of action by the Executive against the Company or any of its affiliates, whether predicated on this Agreement or otherwise, will not constitute a defense to the enforcement by the Company of the provisions of Section 4, which will be enforceable notwithstanding the existence of any breach by the Company. Notwithstanding the foregoing, Executive will not be prohibited from pursuing such claims or causes of action against the Company. Executive consents to the Company notifying any future employer of Executive's obligations under Section 4 of this Agreement.

(g) *Prohibitions*. Notwithstanding any of the foregoing, if any applicable law shall reduce the time period during which or the geographic scope in which Executive shall be prohibited from engaging in any competitive activity described in this Section 4, the period of time for which Executive shall be prohibited pursuant to this Section 4 shall be the maximum time permitted by law.

(h) *Definitions*. For purposes of this Agreement, the following terms have the following meanings:

(i) "**Applicable Restricted Period**" means the twelve (12) month period following the Termination Date.

(ii) "**Brand Company Product**" means a Company Product that is marketed (or anticipated to be marketed) under a New Drug Application, with the exception of any authorized generic product, which will be considered a "Generic Company Product."

(iii) "**Company Products**" means the pharmaceutical products that are manufactured, marketed, distributed, sold or licensed by the Company or are in the Company's pipeline of products as of the Termination Date; provided, that a product (other than Corticotropin) shall not be deemed a "Company Product" as that term is used

herein if the revenues and/or projected revenues attributable to such product accounted for (or are projected to account for) less than 5% of the net revenues of the Company for the most recent period of twelve (12) complete calendar months preceding the Termination Date and for any period of twelve (12) complete calendar months beginning on the first day of the calendar month in which the Termination Date occurs and ending on the second anniversary of such date. For the avoidance of doubt, Corticotrophin shall be deemed a Company Product regardless of the net revenues accounted for or projected to be accounted for by it.

(iv) "**Competitive Activity**" - means, as of any relevant date:

(A) With respect to the Generic Company Products, the development, manufacturing, marketing, distribution or sale, or licensing of any pharmaceutical product in the Territory (1) that is an AB-rated generic equivalent of the same Reference Listed Drug product as a Generic Company Product and for which there are four or fewer AB-rated generic equivalent competitors or (2) that is a direct competitor of any Company Product that is a DESI Product and that utilizes the same active pharmaceutical ingredients as such DESI Product;

(B) With respect to the Brand Company Products, the development, manufacturing, marketing, distribution or sale, or licensing of: (1) any pharmaceutical product in the Territory that is an AB-rated generic equivalent of a Brand Company Product and (2) for which either (I) there are three or fewer AB-rated generic equivalent competitors or (II) AB-rated generic equivalents have been available for commercial sale in the Territory for no more than three years; and

(C) The development, manufacturing, marketing, distribution or sale, or licensing of any product utilizing Corticotropin as the active pharmaceutical ingredient.

(v) "**DESI Product**" means the following Company Products: (A) esterified estrogen methyltestosterone and (B) opium tincture.

(vi) "**Generic Company Product**" means a Company Product that is (A) marketed (or anticipated to be marketed) under an Abbreviated New Drug Application and/or (B) any authorized generic product.

(vii) "**Person**" means any individual, corporation, partnership, group. association or other person, as such term is used in Section 13(d) or Section 14(d) of the Securities Exchange Act of 1934, as amended, other than the Company and its affiliates.

(viii) "**Termination Date**" means the effective date of the Termination of Employment.

(ix) "**Termination of Employment**" means the (i) termination of Executive's employment relationship with the Company and all of its affiliates or (ii)

change in Executive's employment relationship with the Company considered a "separation from service" under Section 409A of the Code.

(x) "**Territory**" means the United States and its territories and possessions and anywhere else in the world where, as of the Termination Date, the Company is manufacturing, marketing, distributing or selling or licensing any Company Product.

5. Inventions. Executive hereby assigns and agrees to assign all her interests in Inventions (as defined below) and tangible embodiments thereof and all intellectual property and proprietary rights therein to the Company or its nominee. The term "**Inventions**" means any and all ideas inventions, improvements, technology, know-how and discoveries, whether patentable or not and whether a Trade Secret (defined below) or not, and any and all works of authorship (as defined in Section 102 of the U.S. Copyright Act), trademarks, trade names, slogans, logos, processes patents and other intellectual property, which are conceived or made by Executive, solely or jointly with another person or persons, during the Term and which Executive makes or conceives as a result of or in connection with her employment by the Company or with the use of any of the Company's personnel, equipment, resources or other assets. Executive agrees that all Inventions shall be deemed works made-for-hire for the Company within the meaning of the copyright laws of the United States or any similar or analogous law or statute of any other jurisdiction, and accordingly, the Company shall be the sole and exclusive author and owner of all copyrights and copyright rights in the Inventions for all purposes and in any and all media and means now known or which may hereafter be devised, throughout the universe in perpetuity. Should any arbitrator or court of competent jurisdiction ever hold that the Inventions do not constitute works made-for-hire, Executive hereby irrevocably assigns to the Company, and agrees that the Company shall be the sole and exclusive owner of, all right, title and interest in and to all copyrights and copyright rights in the Inventions. Executive reserves no rights with respect to any Inventions. Executive agrees that in furtherance of the foregoing, she shall deliver to the Company all tangible embodiments of the Inventions in her possession, custody or control and execute and deliver to the Company all such documents, including, without limitation, patent and copyright applications and assignments, as the Company reasonably shall deem necessary to further document the Company's ownership rights in the Inventions or tangible embodiments thereof and to provide the Company the full and complete benefit thereof. Without limiting the foregoing, Executive further agrees to cooperate with and assist the Company, at the Company's expense, with all lawful efforts of the Company to protect, register, obtain, establish, acquire, prosecute, maintain, perfect, enforce and/or defend the Company's rights in or to the Inventions, including, without limitation, executing and delivering to the Company any and all instruments or documents and/or providing testimony requested by the Company for any such purpose. Executive acknowledges and agrees that Executive is not entitled to any additional compensation for any of her obligations under this Section 5, except for the reimbursement of reasonable and necessary expenses incurred by Executive in performing her obligations hereunder.

6. Confidential Information and Trade Secrets. Executive acknowledges and agrees that all Confidential Information (defined below), and Trade Secrets (defined below) obtained, conceived or compiled by (solely or jointly with another person or persons) or disclosed to

Executive shall be and remain, as between Executive and the Company, the exclusive property of the Company and shall be subject at all times to the Company's discretion and control. Executive agrees that the Confidential Information constitutes a protectable business interest of the Company and its affiliates and covenants and agrees that at all times during the Term and at all times following the Termination of Employment, Executive will not, directly or indirectly, disclose any Confidential Information to any third party or use, any such Confidential Information or Trade Secrets, except only (i) as is required by Executive to perform her duties under this Agreement for the benefit of the Company and then only after taking reasonable precautions, including, obtaining the written agreement of any third party to whom such disclosure is made, to ensure that the confidentiality of Confidential Information and Trade Secrets is strictly maintained., (ii) in order to enforce or defend her rights under this Agreement or other written agreement between Executive and the Company (or its affiliates), or (iii) as required by law.

For purposes hereof, "**Confidential Information**" means and means any and all confidential, proprietary or Trade Secret information of the Company or its controlled affiliates not within the public domain, whether disclosed, directly or indirectly, verbally, in writing (including electronically) or by any other means in tangible or intangible form, including that which is conceived or developed by Executive, applicable to or in any way related to: (i) the present or future business activities, products and services, and customers of the Company or its controlled affiliates; (ii) the research and development of the Company or its controlled affiliates; or (iii) the business of any customers or suppliers of the Company or its controlled affiliates. Such Confidential Information includes the following property or information of the Company or its controlled affiliates, by way of example and without limitation, trade secrets, processes, formulas, data, program documentation, customer lists, pricing information, designs, drawings, algorithms, source code, object code, technology, formulae, models, know-how, improvements, pharmaceutical drug and/or devise technologies, inventions, licenses, techniques, all plans or strategies for marketing, development and pricing, government filings and/or reports, inventions, research, development, schematics, designs, test methods and samples, documents, agreements, business plans, financial statements, profit margins and all information concerning existing or potential clients, suppliers or vendors. Confidential Information of the Company also means all similar information disclosed to the Company by third parties that is subject to confidentiality obligations.

The Company shall not be required to advise Executive specifically of the confidential nature of any such information, nor shall the Company be required to affix a designation of confidentiality to any tangible item, in order to establish and maintain its confidential nature. Notwithstanding the preceding to the contrary, Confidential Information shall not include general industry information or information that is publicly available or readily discernable from publicly available products or literature; information that the Executive lawfully acquires from a source other than the Company or its controlled affiliates or any customer or supplier of the Company or any of its controlled affiliates (provided that such source is not bound by a confidentiality agreement with the Company or any of its controlled affiliates); information that is required to be disclosed pursuant to any law, regulation, rule of any governmental body or authority, or stock exchange, or court order; or information that reflects Executive's own skills, knowledge, know- how and experience gained prior to employment or service and outside of any connection to or

relationship with the Company or any of its controlled affiliates, or the predecessors of any such entities.

For purposes hereof, the term "**Trade Secret**" shall have the meaning given in the Delaware enactment of the Uniform Trade Secrets Act, and shall include, without limitation, the whole or any portion or phase of any scientific or technical information, design, process, formula, concept, data organization, manual, other system documentation, or any improvement of any thereof, in any case that is valuable and secret (in the sense that it is not generally known to the Company's competitors).

Notwithstanding the foregoing, the U.S. Defend Trade Secrets Act of 2016 ("**DTSA**") provides that an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (iii) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, DTSA provides that an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (A) files any document containing the trade secret under seal; and (B) does not disclose the trade secret, except pursuant to court order.

7. Return of Corporation Property; Termination of Employment. At such time as Executive's employment with the Company is terminated for any reason, she shall be required to participate in an exit interview for the purpose of assuring a proper termination of her employment and her obligations hereunder. On or before the actual date of Executive's termination of employment with the Company, Executive shall return to the Company all records, materials and other physical objects relating to her employment with the Company, including, without limitation, all Company credit cards, computers, personal digital assistants and access keys and all materials and things embodying, relating to, containing or derived from any Inventions, Trade Secrets or Confidential Information.

8. Change in Control.

(a) If, and only if, the Change in Control Conditions have been met, then, subject to Executive's continued compliance with the terms and conditions of this Agreement, including under Sections 4, 5, 6, 7, 9 and 19 which will continue, Executive will become entitled to the following as severance benefits ("**CIC Benefits**") (CIC Benefits will not be considered compensation or earnings under any pension, savings or other retirement plan of the Company unless so provided under the terms of the applicable plan):

(i) The Company shall continue to pay Executive her then current Base Salary during the CIC Severance Period, which amounts will be payable in regular installments in accordance with the Company's standard payroll procedures, but no less frequently than bi-monthly procedures for the CIC Severance Period.

(ii) Not later than the last to occur of: (A) the Termination Date and (B) ten (10) days following the consummation of a Change in Control (either such date, a "**Bonus Payment Date**"), the Company shall pay to Executive a lump sum cash payment equal to the Applicable Percentage of the Executive's maximum target Incentive Bonus established for the calendar year in which the Termination of Employment occurs (100% of such maximum target bonus, the "**Bonus Amount**"). In addition, the Company shall also pay to Executive a lump sum cash payment equal to the Bonus Amount on each of the first two (2) anniversaries of the Bonus Payment Date. As used herein, the term "**Applicable Percentage**" shall mean the following (expressed as a percentage): (x) the number of days elapsed between January 1 of the year in which the Termination Date occurs and such Termination Date, divided by (y) 365.

(iii) If Executive elects to receive continuation coverage under COBRA, the Company shall pay to Executive on a monthly basis during the CIC Severance Period, an amount equal to a percentage (based on the portion of the monthly premium costs covered by the Company for Executive's group health, dental and/or vision coverage under the Company's group health, dental and vision plans in effect as of the date on which the Termination of Employment occurs), of Executive's monthly COBRA premium payment (if any) under the Company's group health, dental and vision plan; provided, however, that the obligations of the Company under this clause (iii) shall cease upon Executive becoming eligible to participate in a plan of another employer providing substantially similar group health benefits to Executive and her eligible family members and dependents or upon termination of Executive's COBRA coverage.

(iv) All of the Executive's options to purchase the common stock of the Company and any awards of restricted common stock received by Executive in each case that are unvested, outstanding and subject to time vesting shall vest in their entirety (any unvested and outstanding performance-based awards shall be subject to the terms and conditions of the ANI Stock Plan and the award agreement by and between Executive and the Company pursuant to which each such award was granted). In addition, any vested options (after taking into account the vesting acceleration) shall remain exercisable through the expiration date of such options, it being understood that to the extent any options that are intended to be "incentive stock options" for purposes of Section 422 of the Code are exercised after the three month anniversary of the Termination Date, such options will cease to be treated as "incentive stock options" for purposes of Section 422 of the Code.

(v) The Company shall pay up to ten thousand ($10,000) for out- placement counseling and assistance provided by a reputable out-placement firm selected by the Company; provided that such payment will only be available if such service is engaged no later than ninety (90) days after the date on which Executive's employment by the Company terminates.

(vi) If it is determined (by the reasonable computation of the Company's financial or tax advisors), that any compensation received (or deemed to be received) by Executive from the Company pursuant to this Section 8 (collectively, the

"**Potential Parachute Payments**") is or will become subject to any excise tax under Section 4999 of the Code or any similar tax payable under any United States federal, state, local or other law (such excise tax and all such similar taxes collectively, "**Excise Taxes**"), then such Potential Parachute Payments shall be equal to the Reduced Amount. The "**Reduced Amount**" shall be either (x) the largest portion of the Potential Parachute Payments that would result in no portion of the Potential Parachute Payments being subject to the Excise Tax; or (y) the largest portion, up to and including the total, of the Potential Parachute Payments, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in Executive's receipt, on an after-tax basis, of the greater amount of the Potential Parachute Payments. Any reduction made pursuant to this Section 8 shall be made in accordance with the following order of priority: (i) stock options whose exercise price exceeds the fair market value of the optioned stock ("**Underwater Options**") (ii) Full Credit Payments (as defined below) that are payable in cash, (iii) non-cash Full Credit Payments that are taxable, (iv) non- cash Full Credit Payments that are not taxable (v) Partial Credit Payments (as defined below) and (vi) non-cash employee welfare benefits. In each case, reductions shall be made in reverse chronological order such that the payment or benefit owed on the latest date following the occurrence of the event triggering the excise tax will be the first payment or benefit to be reduced (with reductions made pro-rata in the event payments or benefits are owed at the same time). "**Full Credit Payment**" means a payment, distribution or benefit, whether paid or payable or distributed or distributable pursuant to the terms of this Agreement or otherwise, that if reduced in value by one dollar reduces the amount of the parachute payment (as defined in Section 280G of the Code) by one dollar, determined as if such payment, distribution or benefit had been paid or distributed on the date of the event triggering the excise tax. "**Partial Credit Payment**" means any payment, distribution or benefit that is not a Full Credit Payment.

(b) It is acknowledged and agreed that Executive shall not be required to mitigate the amount of any payment provided for in this Section 8 by seeking other employment or otherwise. It is further acknowledged that the CIC Benefits payable under this Section 8 shall only be applicable to the first Change in Control to occur after the date hereof and not in the event of any subsequent Change in Control. In addition, the benefits provided for under Sections 3(e) and 8 are mutually exclusive; in the event Executive receives CIC Benefits, then she shall not be eligible to receive Severance Payments under Section 3(e) and the CIC Benefits shall be the only payments received following the termination of her employment with the Company. Any Severance Payments already received by Executive if the Termination Date has occurred prior to a Change in Control, shall be deemed to have been CIC Benefits upon consummation of a Change in Control for purposes of this Section 8.

(c) In order for Executive to be eligible to receive and to continue to receive the CIC Benefits as set forth in this Section 8: (i) upon Termination of Employment, the Executive must execute a Release during the Release Period described in Section 3(e) and must not revoke such release before it becomes effective and irrevocable and (b) the Executive must abide by each of the other terms and conditions of this Agreement including under Sections 4, 5, 6, 7, 9 and 19. Notwithstanding any provision in this Section 8, any CIC Benefits payable to

Executive before the expiration of the Release Period, shall be suspended; provided, however, that if the Release Period begins in one calendar year and ends in the subsequent calendar year, any CIC Benefits will be suspended until the later of (A) January 1 of such subsequent calendar year and (B) the date the Release becomes effective and irrevocable. All CIC Benefits that but for the preceding sentence are due and payable on the date the suspension of CIC Benefits ends will be paid to Executive on the first regularly scheduled payroll payment date following the date the suspension of CIC Benefits ends.

(d) For purposes of this Section 8, the following terms will have the following meanings:

(i) "**Change in Control**" means the consummation of the first to occur of any transaction in which:

(A) One Person (or more than one Person acting as a group) acquires (or has acquired during the 12-month period ending on the date of the most recent acquisition by such Person or group) assets of the Company (including its subsidiaries) that have a total gross fair market value equal to more than fifty percent (50%) of the total gross fair market value of all of the assets of the Company immediately before such acquisition or acquisitions, or

(B) One Person, or more than one Person acting as a group, acquires ownership of equity securities of the Company (including by way of merger, consolidation or otherwise) that, together with all equity securities of the Company previously held by such Person or group, constitutes more than fifty percent (50%) of the total fair market value or total voting power of equity securities of the Company.

Notwithstanding the foregoing, a Change in Control shall not include (1) any transaction effected for reincorporation purposes or (2) any transaction that does not constitute a change of ownership of the Company or a substantial portion of its assets within the meaning of Treasury Regulation Section 1.409A-3(i)(5)(v) or (vii).

(ii) "**Change in Control Conditions**" means that all of the following have occurred:

(A) (1) a Termination of Employment by the Company has occurred for any reason other than for Good Cause or (2) a Termination of Employment by Executive for Good Reason has occurred; and

(B) A Change in Control has been consummated; and

(C) The Termination of Employment, has occurred either: (1) within the period beginning on the date of the consummation of the Change in Control and ending on the last day of the twenty-fourth (24^{th}) month following the consummation of a Change in Control; or (2) prior to a Change in Control, if such

Termination of Employment was either a condition of the Change in Control or was at the documented request or insistence of a Person which is a party or an affiliate of a party to the transaction that constitutes or results in to the Change in Control.

(iii) "**CIC Severance Period**" means a period of twenty-four (24) months following the Termination Date.

9. Remedies. Because of the difficulty of measuring economic losses to the Company as a result of a breach of any of the covenants contained in Sections 4, 5, 6 7 or 19 because of the immediate and irreparable damage that such a breach is likely to cause the Company for which it would have no other adequate remedy, Executive agrees that each of the covenants of Sections 4, 5, 6 7 or 19 may be enforced by the Company, by permanent, preliminary and temporary injunctions and restraining orders, in addition to any other remedies allowable at law or in equity. In addition, in the event of a breach or violation by Executive of Sections 4, 5, 6 7 or 19 then, solely for purposes of this Section 9, the Severance Period or CIC Severance Period, as applicable, will be tolled until such breach or violation has been duly cured.

10. No Prior Agreements. Executive hereby represents and warrants to the Company that the execution of this Agreement by Executive and her employment by the Company and the performance of her duties hereunder will not violate or be a breach of any agreement with a former employer, client or any other person or entity.

11. D&O Insurance and Indemnification. During the term of this Agreement and through the sixth (6^{th}) anniversary of the termination of Executive's employment, the Company shall maintain coverage for the Executive as a named insured on all directors' and officers' insurance maintained by the Company for the benefit of its directors and officers on at least the same basis as all other covered individuals. On the Commencement Date. the Company and Executive will enter into an indemnification agreement substantially in the form attached as Exhibit B.

12. Pre-Employment Conditions. For purposes of federal immigration law, Executive will be required, if Executive has not already, to provide to the Company documentary evidence of Executive's identity and eligibility for employment in the United States. Such documentation must be provided to the Company within three (3) business days of the Commencement Date, or the Company's employment relationship with Executive may be terminated.

13. Section 409A.

(a) The Parties agree to treat any Severance Payments or CIC Benefits made to Executive pursuant to this Agreement as compensatory payments and to make such Severance Payments or CIC Benefits through the Company's payroll. The Company will deduct and withhold from any such Severance Payments or CIC Benefits all applicable local, state, federal or other withholding and payroll taxes required to be deducted and withheld when making Severance Payments or CIC Benefits.

(b) The portion, if any, of the Severance Benefits or CIC Benefits paid or

provided to Executive pursuant to this Agreement that constitutes deferred compensation for purposes of Section 409A of the Code ("**Section 409A**") shall be referred herein as the "**Deferred Compensation Separation Benefits**." Notwithstanding any provision in this Agreement to the contrary:

(i) If Executive's Termination of Employment occurs on or after October 15th of any calendar year, any Deferred Compensation Separation Payments that would otherwise be payable to the Executive pursuant to this Agreement during the calendar year in which such Termination of Employment occurs shall be suspended until the first payroll payment date following the later of the first day of the following calendar year or the date the general release described in Section 4 of this Agreement becomes effective, binding and irrevocable.

(ii) If Executive is a "specified employee" (as defined in 26 C.F.R Section 1.409A-1(i)) at the time of her Termination of Employment, any such Deferred Compensation Separation Payments that are otherwise payable to Executive pursuant to this Agreement during the period commencing on Executive's Termination of Employment and ending on the earlier of the (x) the last day of the sixth calendar month beginning after Executive's Termination of Employment or (y) the date of Executive's death (the "**Section 409A Specified Employee Suspension Period**") will be suspended until the first payroll payment date that occurs on or after the end of the Section 409A Specified Employee Suspension Period.

(c) For purposes of determining the portion, if any, of the Severance Benefits or CIC Benefits that constitute Deferred Compensation Separation Benefits, the portion of any Severance Benefits or CIC Benefits paid or provided under this Agreement that satisfies the requirements of the "short-term deferral" rule set forth in 26 C.F.R. Section 1.409A-1(b)(4) or the "separation pay" exception set forth in 26 C.F.R Section 1.409A-1(b)(9)(iii) or (v) shall not constitute Deferred Compensation Separation Benefits for purposes of this Section 13, and consequently shall be paid to Executive in accordance with Sections 3(e) and 8 of this Agreement, as applicable without regard to Section 13(b). Each payment in any series of payments payable under this Agreement is intended to constitute a separate payment for purposes of 26 C.F.R. Section 1.409A-2(b)(2).

(d) To the extent any reimbursement of costs and expenses (including reimbursement of COBRA premiums pursuant to Section 3(e) and 8 provided for under this Agreement constitutes taxable income to Executive for federal income tax purposes, such reimbursements shall be made as soon as practicable after Executive provides proper documentation supporting reimbursement but in no event later than December 31 of the calendar year next following the calendar year in which the expenses to be reimbursed are incurred. With regard to any provision herein that provides for reimbursement of expenses or in-kind benefits, except as permitted by Section 409A, (i) the right to reimbursement or in-kind benefits is not subject to liquidation or exchange for another benefit, and (ii) the amount of expenses eligible for reimbursement, or in-kind benefits, provided during any taxable year shall not affect the expenses eligible for reimbursement, or in-kind benefits to be provided, in any other taxable year.

(e) The foregoing provisions are intended to comply with the requirements of Section 409A so that none of the Severance Benefits or CIC Benefits paid or provided hereunder will be subject to the additional tax imposed under Section 409A, and any ambiguities herein will be construed to so comply. To the extent necessary to comply with Section 409A, references herein to "termination of employment," "Termination of Employment" and terms of similar effect shall be deemed to be references to the Executive's "separation from service" as defined in Section 409A. Any ambiguities or ambiguous terms herein will be interpreted to be exempt from or so comply with the requirements of Section 409A. In no event will the Company reimburse Executive for any Section 409A-related taxes resulting from any amount paid under the Agreement or otherwise. The Company and Executive will work together in good faith to consider either (i) amendments to this Agreement; or (ii) revisions to the Agreement with respect to the payment of any benefits to the Executive hereunder, which are necessary or appropriate to avoid imposition of any additional tax or income recognition prior to the actual payment to the Executive under Section 409A. Notwithstanding anything in the Agreement to the contrary, the Company reserves the right, in its sole discretion and without the consent of Executive, to take such reasonable actions and make any amendments to the Agreement as it deems necessary, advisable or desirable to comply with Section 409A or to otherwise avoid income recognition under Section 409A or imposition of any additional tax prior to the actual payment of any benefits under this Agreement.

14. Binding Effect; Assignment. This Agreement shall be binding upon, inure to the benefit of and be enforceable by the Parties hereto and their respective heirs, legal representatives, successors and permitted assigns. Executive understands that she has been selected for employment by the Company on the basis of her personal qualifications, experience and skills. Executive agrees, therefore, that she cannot assign all or any portion of her performance under this Agreement.

15. Entire Agreement. This Agreement and the exhibits attached hereto constitute the entire agreement and understanding between the Parties with respect to the subject matter hereof, and supersede all other understandings and negotiations with respect thereto.

16. Notice. All notices, requests, permissions, waivers and other communications hereunder shall be in writing and shall be deemed to have been duly given (a) five business days following sending by registered or certified mail, postage prepaid, (b) when sent, if sent by e- mail during normal business hours and received at the recipient's location during normal business hours, and otherwise on the next day, (c) when delivered, if delivered personally to the intended recipient and (d) one business day following sending by overnight delivery via a national courier service and, in each case, addressed to a Party at the following address for such Party:

To the Company:

ANI Pharmaceuticals, Inc. 210
Main Street West Baudette, MN
56623
Attn: General Counsel or the Chief Financial Officer Telephone No.:
218-634-3500
E-Mail: stephen.carey@anipharmaceuticals.com

To Executive:

Meredith Cook
at the contact information on file with the Company

Either Party may, by notice given in accordance with this Section, specify a new address for notices under this Agreement.

17. Severability; Headings. It is the intention of the Parties that the provisions herein shall be enforceable to the fullest extent permitted under applicable law, and that the unenforceability of any provision or provisions hereof, or any portion thereof, shall not render unenforceable or otherwise impair any other provisions or portions thereof. Each term, condition, covenant or provision of this Agreement shall be viewed as separate and distinct, and in the event that any such term, covenant or provision shall be held by a court of competent jurisdiction to be invalid, the remaining provisions shall continue in full force and effect. The Section headings herein are for reference purposes only and are not intended in any way to describe, interpret, define or limit the extent or intent of this Agreement or of any part hereof.

18. No Third-Party Beneficiaries. Except as otherwise provided in this Agreement, this Agreement is for the sole benefit of the Parties hereto (and their respective heirs, legal representatives, successors and permitted assigns), and nothing herein expressed or implied shall give or be construed to give to any person, other than the Parties hereto (and their respective heirs, legal representatives, successors and permitted assigns), any legal or equitable rights hereunder.

19. Cooperation with Litigation. During and following the Executive's Termination of Employment with the Company (regardless of the reason for Executive's Termination of Employment with the Company and which Party initiates the Termination of Employment with the Company), Executive agrees to cooperate with and make herself readily available to the Company, the Company's Chief Legal Officer (or equivalent position within the Company) and/or its advisers, as the Company may reasonably request, to assist it in any matter regarding the Company and its subsidiaries and parent companies, including giving truthful testimony in any litigation, potential litigation or any internal investigation or administrative, regulatory, judicial or quasi-judicial proceedings involving the Company over which Executive has knowledge, experience or information. Executive acknowledges that this could involve, but is not limited to, responding to or defending any regulatory or legal process, providing information

in relation to any such process, preparing witness statements and giving evidence in person on behalf of the Company. The Company shall reimburse any reasonable expenses incurred by Executive as a consequence of complying with her obligations under this Section, provided that such expenses are approved in advance by the Company.

20. Dispute Resolution. Any and all controversies, disputes or claims arising out of, or relating to, this Agreement and its negotiation, execution, performance, non-performance, interpretation, termination, construction or the transactions contemplated hereby shall be heard and determined in the courts of the State of New York sitting in the Borough of Manhattan and the United States District Court for the Southern District of New York. The Parties hereto hereby irrevocably submit to the exclusive jurisdiction and venue of such courts in any such proceeding and irrevocably and unconditionally waive the defense of an inconvenient forum, or lack of jurisdiction to the maintenance of any such proceeding. The consents to jurisdiction and venue set forth herein shall not constitute general consents to service of process in the State of New York and shall have no effect for any purpose except as provided in this Section 20 and shall not be deemed to confer rights on any Person other than the Parties hereto. Each Party hereto agrees that the service of process upon such Party in any proceeding arising out of or relating to this Agreement shall be effective if notice is given by overnight courier at the address set forth in the books and records of the Company. Each of the Parties also agrees that any judgment against a Party in connection with any proceeding arising out of or relating to this Agreement may be enforced in any court of competent jurisdiction, either within or outside of the United States. A certified or exemplified copy of such judgment shall be conclusive evidence of the fact and amount of such judgment.

21. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York, without giving effect to the principles of conflicts of law thereof.

22. Counterparts. This Agreement may be executed in any number of counterparts (which may be delivered by facsimile or in PDF format), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

23. Amendments; Waivers. No amendment or modification of the terms or conditions of this Agreement shall be valid unless in writing and signed by the Parties. A waiver by either Party of a breach of any provision of this Agreement shall not constitute a general waiver, or prejudice the other Party's right otherwise to demand strict compliance with that provision.

24. Certain Acknowledgements. EXECUTIVE ACKNOWLEDGES THAT, BEFORE SIGNING THIS AGREEMENT, SHE WAS GIVEN AN OPPORTUNITY TO READ IT, CAREFULLY EVALUATE IT, AND ASK ANY QUESTIONS SHE MAY HAVE HAD REGARDING IT OR ITS PROVISIONS. EXECUTIVE ALSO ACKNOWLEDGES THAT SHE HAD THE RIGHT TO HAVE THIS AGREEMENT REVIEWED BY AN ATTORNEY OF HER CHOOSING AND THAT THE COMPANY GAVE HER A REASONABLE PERIOD OF TIME TO DO SO IF SHE SO WISHED. EXECUTIVE FURTHER ACKNOWLEDGES THAT SHE IS NOT BOUND BY ANY AGREEMENT WHICH WOULD PREVENT HER

FROM PERFORMING HER DUTIES AS SET FORTH HEREIN, NOR DOES SHE KNOW OF ANY OTHER REASON WHY SHE WOULD NOT BE ABLE TO PERFORM HER DUTIES AS SET FORTH HEREIN.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties hereto have executed this Executive Employment Agreement as of the day and year first above written.

Company:

ANI PHARMACEUTICALS, INC.

By: /s/ Nikhil Lalwani
Name: Nikhil Lalwani
Title: Chief Executive Officer

Executive:

By: /s/ Meredith Cook
Name: Meredith Cook

Exhibit A: General Release of All Claims Exhibit B: Indemnification Agreement

[*SIGNATURE PAGE TO EXECUTIVE EMPLOYMENT AGREEMENT*]

EXHIBIT A

GENERAL RELEASE OF ALL CLAIMS

[See Attached]

GENERAL RELEASE OF ALL CLAIMS

This General Release of All Claims (the "***Release***") between ANI Pharmaceuticals, Inc. (the "***Company***") and Meredith Cook (referred to hereinafter as "***you***" or the "***Executive***") shall be effective as of the Effective Date (as defined below). Each of the Company and Executive are sometimes referred to herein individually as a "***Party***" and together as the "***Parties***."

1. General Releases and Waivers of Claims.

(a) General Release. In consideration for receiving the severance payments and benefits described in Section [3(e)]/[8] of the Employment Agreement by and between you and the Company effective as of [DATE] (the "***Employment Agreement***"), and for other good and valuable consideration, the sufficiency of which you hereby acknowledge, you hereby waive and release to the maximum extent permitted by applicable law any and all claims or causes of action, whether or not now known, against the Company and/or its respective predecessors, successors, past or present and related entities (collectively, including the Company, the "***Entities***") and/or the Entities' respective past or present stockholders, members, officers, directors, insurers, partners, managers, employees and employee benefit plans (collectively with the Entities, the "***Released Parties***"), with respect to any matter related to your employment with the Company or the termination of that employment relationship other than claims and rights for any accrued compensation and benefits provided for in Section 3(d) of the Employment Agreement and the severance payments and benefits. This waiver and release includes, without limitation, claims to wages, including overtime or minimum wages, bonuses, incentive compensation, equity compensation, vacation pay or any other compensation or benefits; any claims for failure to provide accurate itemized wage statements, failure to timely pay final pay or failure to provide meal or rest breaks; claims for any loss, cost, damage, or expense arising out of any dispute over the non-withholding or other tax treatment or employment classification, claims under the Employee Retirement Income Security Act (ERISA); claims for attorneys' fees or costs; any and all claims for stock, stock options or other equity securities of the Company; claims of wrongful discharge, constructive discharge, emotional distress, defamation, invasion of privacy, fraud, breach of contract, and breach of the covenant of good faith and fair dealing; any claims of discrimination, harassment, or retaliation based on sex, age, race, national origin, disability or on any other basis, under Title VII of the Civil Rights Act of 1964, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act, or any other federal, state, or local law prohibiting discrimination and/or harassment; and claims under the New York State Human Rights Law, the New York Equal Rights Law, the New York Whistleblower Protection Law, the New York Family Leave Law, the New York Equal Pay Law, the New York City Human Rights Law, the California Fair Employment and Housing Act, claims under the California Labor Code, the California Business and Professions Code, and all other laws and regulations relating to employment, any applicable laws of the State of California, the State of New Jersey, the State of New York, and the State of Massachusetts, and all other laws and regulations.

You covenant not to sue the Released Parties for any of the claims released above, agree not to participate in any class, collective, representative, or group action that may include

any of the claims released above, and will affirmatively opt out of any such class, collective, representative or group action. Further, you agree not to participate in, seek to recover in, or assist in any litigation or investigation by other persons or entities against the Released Parties with respect to matters related to the Company, except as required by law. Your release covers only those claims that arose prior to the execution of this Release. Execution of this Release does not bar any claim for breach of this Release. Additionally, nothing in this Release precludes you from participating in any investigation or proceeding before any federal or state agency or governmental body. However, while you may file a charge and participate in any such proceeding, by signing this Release, you waive any right to bring a lawsuit against the Released Parties with respect to matters related to the Company, and waive any right to any individual monetary recovery in any such proceeding or lawsuit; provided, however, nothing in this Release is intended to impede your ability to report securities law violations to the Securities and Exchange Commission under the Dodd-Frank Act, or to receive a monetary award from a government administered whistleblower-award program. Nothing in this Release waives your right to testify or prohibits you from testifying in an administrative, legislative, or judicial proceeding concerning alleged criminal conduct or alleged sexual harassment when you have been required or requested to attend the proceeding pursuant to a court order, subpoena or written request from an administrative agency or the legislature.

Notwithstanding the foregoing, the waiver and release contained in this Release does not apply to (i) any current or future rights or claims for indemnification you may have pursuant to the Indemnification Agreement entered into between you and the Company effective [DATE] (the "***Indemnification Agreement***"), or your indemnification rights under any insurance policy in place and the Company's internal governing documents; (ii) any vested benefits under an employee benefit plan sponsored by the Company to which you are legally entitled; (iii) any claims to enforce your rights under this Release or the surviving provisions of the Employment Agreement; (iv) the right to share in any claim with respect to being a stockholder of the Company; provided that any such recover is predicated on you not individually bringing any claim or cause of action or actively participating in, or assisting in any way, with respect to any stockholder initiated cause of action; or (v) any claim which, as a matter of law, cannot be released by private agreement. If any provision of the waiver and release contained in this Release is found to be unenforceable, it shall not affect the enforceability of the remaining provisions and a court shall enforce all remaining provisions to the full extent permitted by law.

(b) ADEA Waiver. You acknowledge that you are knowingly and voluntarily waiving and releasing any rights you may have under the Federal Age Discrimination in Employment Act ("***ADEA Waiver***") and that the consideration given for the ADEA Waiver is in addition to anything of value to which you are already entitled. You further acknowledge that: your ADEA Waiver does not apply to any claims that may arise after you sign this Release; you should consult with an attorney prior to executing this Release; (c) you have [21/45][1] calendar days within which to consider this Release (although you may choose to execute this Release earlier); (d) you have 7 calendar days following the execution of this Release to revoke your

[1] NTD: Review period to be determined as it depends on the circumstances around the termination of employment.

execution of the Release; and (e) the Release will not be effective until the eighth day after you sign this Release provided that you have not revoked it ("***Effective Date***"). You agree that any modifications, material or otherwise, made to this Release do not restart or affect in any manner the original [21/45]-day consideration period provided in this section. To revoke the Release after any execution, you must email [NAME] written notice of revocation at [EMAIL] prior to the end of the 7-day period. You acknowledge that your consent to this Release is knowing and voluntary. The offer described in this Release will be automatically withdrawn if you do not sign the Release within the [21/45]-day consideration period.

(c) Unknown Claims Waiver. You understand and acknowledge that you are releasing potentially unknown claims, and that you may have limited knowledge with respect to some of the claims being released. You acknowledge that there is a risk that, after signing this Release, you may learn information that might have affected your decision to enter into this Release. You assume this risk and all other risks of any mistake in entering into this Release. You agree that this Release is fairly and knowingly made. In addition, you expressly waive and release any and all rights and benefits conferred upon you by the provisions of Section 1542 of the Civil Code of the State of California (or any analogous law of any other state), which reads substantially as follows:

"A GENERAL RELEASE DOES NOT EXTEND TO CLAIMS THAT THE CREDITOR OR RELEASING PARTY DOES NOT KNOW OR SUSPECT TO EXIST IN HER OR HER FAVOR AT THE TIME OF EXECUTING THE RELEASE AND THAT, IF KNOWN BY HIM OR HER, WOULD HAVE MATERIALLY AFFECTED HIS OR HER SETTLEMENT WITH THE DEBTOR OR RELEASED PARTY."

You understand and agree that claims or facts in addition to or different from those which are now known or believed by you to exist may hereafter be discovered, but it is your intention to release all claims that you have or may have against the Released Parties, whether known or unknown, suspected or unsuspected.

2. **No Other Amounts/Benefits Owed**. Except as provided herein and for any accrued obligations owed under Section 3(d) of the Employment Agreement, you acknowledge and agree that you have been paid for all of your services with the Company and you have not earned any wages, salary, incentive compensation, bonuses, commissions or similar payments or benefits or any other compensation or amounts that have not already been paid to you. You further agree that, prior to the execution of this Release, you were not entitled to receive any further payments or benefits from the Company, and the only payments and benefits that you are entitled to receive from the Company in the future are the severance payments and benefits mentioned in Section 1(a) above.

3. **Restrictive Covenants; Inventions; Confidentiality**. The provisions set forth in Section 4 (Non-Solicitation; Non-Competition), Section 5 (Inventions), Section 6 (Confidential Information and Trade Secrets) and Section 19 (Cooperation with Litigation) of the Employment Agreement are hereby incorporated by reference into this Release (collectively, the "***Executive Obligations***"). Because of the difficulty of measuring economic losses to the Company as a result

of a breach of any of the covenants related to the Executive Obligations because of the immediate and irreparable damage that such a breach is likely to cause the Company for which it would have no other adequate remedy, Executive agrees that each of the covenants related to the Executive Obligations may be enforced by the Company, by permanent, preliminary and temporary injunctions and restraining orders, in addition to any other remedies allowable at law or in equity.

4. **Breach/Remedies**. If the Company determines that you breached any of your obligations under this Release, the Employment Agreement or as otherwise imposed by law, the Company will be entitled to recover all severance and other consideration paid or provided under this Release and the Employment Agreement and to obtain all other relief provided by law or equity.

5. **Mutual Non-disparagement**. Executive agrees not to make any negative or disparaging statements or communications regarding either the Company or its affiliates or any of their respective operations, officers, directors or stockholders. The Company agrees to instruct its officers and directors not to make any negative or disparaging statements or communications regarding Executive. The covenant contained in this Section 5 shall not prevent either Party from providing truthful testimony in proceedings to enforce or defend their rights under this Agreement.

6. **No Admission**. Nothing contained in this Release shall constitute or be treated as an admission by the Company of any liability, wrongdoing, or violation of law.

7. **Proceedings**. The Executive has not filed any complaint, charge, claim or proceeding against the Company before any local, state or federal agency, court or other body relating to the Executive's employment or the termination thereof.

8. **Return of Company Property**. You agree that as of [DATE] (your "***Termination Date***"), you will return to the Company any and all Company records, materials and other physical objects relating to your employment with the Company, including, without limitation, all Company credit cards, phone cards, equipment, documents (in paper and electronic form), computers, personal digital assistants and access keys and all materials and things embodying, relating to, containing or derived from any Inventions, Trade Secrets or Confidential Information (as each such term is defined in your Employment Agreement) and you will return and/or destroy all Company property stored in electronic form or media (including, but not limited to, any Company property stored in your personal computer, USB drives or in a cloud environment).

9. **Cooperation with the Company**. In addition, the Executive shall cooperate with and assist the Company in the investigation of, preparation for or defense of any actual or threatened third party claim, investigation or proceeding involving the Company or its predecessors or affiliates and arising from or relating to, in whole or in part, the Executive's employment with the Company or its predecessors or affiliates for which the Company reasonably requests the Executive's assistance, which cooperation and assistance shall include,

but not be limited to, providing truthful testimony and assisting in information and document gathering efforts. Executive will be reimbursed for any reasonable and necessary expenses related to the Executive's compliance with this Section 9.

10. **Indemnification**. Notwithstanding anything to the contrary, the Indemnification Agreement shall remain in effect following the Termination Date pursuant to its terms. Further, the Company agrees to maintain, at its cost, D&O insurance that will cover the Executive for a period of six (6) years following the Termination Date, on the same basis as provided to current executives of the Company during such period.

11. **Arbitration**. Except for any claim for injunctive relief arising out of a breach of a party's obligations to protect the other's confidential and/or proprietary information, to ensure rapid and economical resolution of any disputes regarding this Agreement, you and the Company agree that any and all claims, disputes or controversies of any nature whatsoever arising out of, or relating to, this Agreement, or its interpretation, enforcement, breach, performance or execution, shall be resolved by final, binding and confidential arbitration in New York, NY conducted under the Judicial Arbitration and Mediation Service (JAMS) Streamlined Arbitration Rules & Procedures, which can be reviewed at http://www.jamsadr.com/rules- streamlined-arbitration/. You and the Company each acknowledge that by agreeing to this arbitration procedure, you and the Company waive the right to resolve any such dispute, claim or demand through a trial by jury or judge or by administrative proceeding. The arbitrator, and not a court, shall also be authorized to determine whether the provisions of this paragraph apply to a dispute, controversy, or claim sought to be resolved in accordance with these arbitration procedures. The arbitrator may in his or her discretion award attorneys' fees to the prevailing party. All claims, disputes, or controversies subject to arbitration as set forth in this paragraph must be submitted to arbitration on an individual basis and not as a representative, class and/or collective action proceeding on behalf of other individuals. Claims will be governed by applicable statutes of limitations. This arbitration agreement shall be construed and interpreted in accordance with the laws of the State of New York and the Federal Arbitration Act ("***FAA***"). In the case of a conflict, the FAA will control.

12. **Opportunity to Consult with Counsel**. The Executive acknowledges that she has had an opportunity to consult with and be represented by counsel of the Executive's choosing in the review of this Release, that she has been advised by the Company to do so, that she is fully aware of the contents of the Release and of its legal effect, that the preceding paragraphs recite the sole consideration for this Release, and that she enters into this Release freely, without duress or coercion, and based on her own judgment and wishes and not in reliance upon any representation or promise made by the Company, other than those contained herein.

13. **No Reemployment or Workers' Compensation**. You acknowledge that you will have no right to employment with the Company after the Termination Date and that you shall not apply for reemployment with the Company after the Termination Date. You further acknowledge and agree that you did not suffer an injury covered by workers' compensation in the course and scope of your employment with the Company.

14. **Section 409A**. The intent of the Parties is that payments and benefits under this Agreement comply with, or are exempt from, Section 409A of the Internal Revenue Code of 1986, as amended ("***Section 409A***"), to the extent subject thereto, and accordingly, to the maximum extent permitted, this Agreement will be interpreted and administered to be exempt therewith and the remainder to be interpreted and administered to be in compliance therewith. Each amount to be paid or benefit to be provided under this Agreement shall be construed as a separate payment for purposes of Section 409A. Notwithstanding anything contained herein to the contrary, you will not be considered to have terminated employment for purposes of any payments under this Agreement that are subject to Section 409A until you have incurred a "separation from service" within the meaning of Section 409A. Without limiting the foregoing and notwithstanding anything contained herein to the contrary, to the extent required in order to avoid an accelerated or additional tax under Section 409A, amounts that would otherwise be payable and benefits that would otherwise be provided to you during the six-month period immediately following your separation from service shall instead be paid on the first business day after the date that is six months following your separation from service (or, if earlier, upon your death).

15. **Confidentiality; Invention Assignment**. You agree that you will remain bound by any previously executed standard Company agreement related to confidential information and assignment of inventions that is in addition to the provisions in the Employment Agreement (such additional agreement, the "***Confidential Information Agreement***").

16. **Entire Agreement**. You agree that except as otherwise expressly provided in this Release (including the specified surviving provisions of the Employment), the Confidential Information Agreement (if any) and the Indemnification Agreement, this Release renders null and void any and all prior or contemporaneous agreements between you and the Company or any affiliate of the Company. You and the Company agree that this Release (and the agreements referred to herein) constitutes the entire agreement between you and the Company and any affiliate of the Company regarding the subject matter of this Release, and that this Release may be modified only in a written document signed by you and a duly authorized officer of the Company.

17. **Choice of Law**. This Release shall be construed and interpreted in accordance with the laws of the State of New York without giving effect to provisions governing the choice of law.

18. **Severability**. The provisions of this Release are severable. If any provision of this Release is held invalid or unenforceable, such provision shall be deemed deleted from this Release and such invalidity or unenforceability shall not affect any other provision of this Release, the balance of which will remain in and have its intended full force and effect; provided, however that if such invalid or unenforceable provision may be modified so as to be valid and enforceable as a matter of law, such provision shall be deemed to have been modified so as to be valid and enforceable to the maximum extent permitted by law.

19. **Headings**. The headings of the Sections of this Release are provided for convenience only. They do not alter or limit, in any way, the text of any Section of this Release.

20. **Execution in Counterparts**. You agree that this Release may be executed in counterparts, each of which shall be an original, but all of which together shall constitute one agreement. Execution of a facsimile copy or scanned image shall have the same force and effect as execution of an original, and a facsimile signature or scanned image of a signature shall be deemed an original and valid signature.

[Signature Page Follows]

To accept this Release, please sign and date this Release and return it to me. You have until 5:00 p.m. ET on the date that is [21/45] days following your receipt of this Release to review and consider this Release and to provide me with an executed copy thereof, but in no event may you execute this Release prior to your Termination Date. Please indicate your agreement with the above terms by signing below.

Sincerely,

ANI PHARMACEUTICALS, INC.

By:_____
(Signature)

Name:_____ Title:

As set forth above in Section 1(b) above, you have up to [21/45] days after receipt of this Release within which to review it and to discuss with an attorney of your own choosing, at your own expense, whether or not you wish to sign it. Furthermore, you have 7 days after you have signed this Release during which time you may revoke this Release. If you wish to revoke this Release, you may do so by delivering a letter of revocation to [NAME], the Company's [TITLE], no later than the close of business on the 7th day after you sign this Release. Because of the revocation period, if you don't revoke this Release, you understand that this Release shall not become effective or enforceable until the 8th day after the date you sign this Release.

My agreement with the terms of this Release is signified by my signature below. Furthermore, I acknowledge that I have read and understand this Release and that I sign this release of all claims voluntarily, with full appreciation that at no time in the future may I pursue any of the rights I have waived in this Release.

Signed _____ Dated: _____
Meredith Cook

EXHIBIT B

INDEMNIFICATION AGREEMENT

[See Attached]

INDEMNIFICATION AGREEMENT

THIS INDEMNIFICATION AGREEMENT, made and executed this 17th day of June, 2022, by and between ANI Pharmaceuticals, Inc., a Delaware corporation (the "Company"), and [NAME], an individual resident of the State of New Jersey (the "Indemnitee").

WHEREAS, the Company is aware that, in order to induce highly competent persons to serve the Company as officers, the Company must provide such persons with adequate protection through insurance and indemnification against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the Company;

WHEREAS, the Company recognizes that the increasing difficulty in obtaining officers' liability insurance, the increases in the cost of such insurance and the general reductions in the coverage of such insurance have increased the difficulty of attracting and retaining such persons;

WHEREAS, the Board of Directors of the Company has determined that it is essential to the best interests of the Company's stockholders that the Company act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify such persons to the fullest extent permitted by applicable law so that they will continue to serve the Company free from undue concern that they will not be so indemnified; and

WHEREAS, the Indemnitee is willing to serve, continue to serve, and take on additional service for or on behalf of the Company or any of its direct or indirect subsidiaries on the condition that he/she be so indemnified.

NOW, THEREFORE, in consideration of the premises and the mutual promises and covenants contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Company and the Indemnitee do hereby agree as follows:

1. Service by the Indemnitee. The Indemnitee agrees to serve and/or continue to serve as an officer of the Company faithfully and will discharge his/her duties and responsibilities to the best of his/her ability so long as the Indemnitee is duly appointed in accordance with the provisions of the Amended and Restated Certificate of Incorporation, as amended (the "Certificate"), and Bylaws, as amended (the "Bylaws") of the Company and the General Corporation Law of the State of Delaware, as amended (the "DGCL"), or until his/her earlier death, resignation or removal. The Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or other obligation imposed by operation by law), in which event the Company shall have no obligation under this Agreement to continue to retain the Indemnitee in any such position. Nothing in this Agreement shall confer upon the Indemnitee the right to continue in the employ of the Company or affect the right of the Company to terminate the Indemnitee's employment at any time in the sole discretion of the Company, with or without cause, subject to any contract rights of the Indemnitee created or existing otherwise than under this Agreement.

2. Indemnification. The Company shall indemnify the Indemnitee against all Expenses (as defined below), judgments, fines and amounts paid in settlement actually and reasonably incurred by the

Indemnitee as provided in this Agreement to the fullest extent permitted by the Certificate, Bylaws and DGCL or other applicable law in effect on the date of this Agreement and to any greater extent that applicable law may in the future from time to time permit. Without diminishing the scope of the indemnification provided by this Section 2, the rights of indemnification of the Indemnitee provided hereunder shall include, but shall not be limited to, those rights hereinafter set forth, except that no indemnification shall be paid to the Indemnitee:

(a) on account of any action, suit or proceeding in which judgment is rendered against the Indemnitee for disgorgement of profits made from the purchase or sale by the Indemnitee of securities of the Company pursuant to the provisions of Section 16(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or similar provisions of any federal, state or local statutory law;

(b) on account of conduct of the Indemnitee which is finally adjudged by a court of competent jurisdiction to have been knowingly fraudulent or to constitute willful misconduct;

(c) in any circumstance where such indemnification is expressly prohibited by applicable law;

(d) with respect to liability for which payment is actually made to the Indemnitee under a valid and collectible insurance policy of the Company or under a valid and enforceable indemnity clause, Bylaw or agreement (other than this Agreement) of the Company, except in respect of any liability in excess of payment under such insurance, clause, Bylaw or agreement;

(e) if a final decision by a court having jurisdiction in the matter shall determine that such indemnification is not lawful (and, in this respect, both the Company and the Indemnitee have been advised that it is the position of the Securities and Exchange Commission that indemnification for liabilities arising under the federal securities laws is against public policy and is, therefore, unenforceable, and that claims for indemnification should be submitted to the appropriate court for adjudication); or

(f) in connection with any action, suit or proceeding by the Indemnitee against the Company or any of its direct or indirect subsidiaries or the directors, officers, employees or other Indemnitees of the Company or any of its direct or indirect subsidiaries, (i) unless such indemnification is expressly required to be made by law, (ii) unless the proceeding was authorized by the Board of Directors of the Company,
(iii) unless such indemnification is provided by the Company, in its sole discretion, pursuant to the powers vested in the Company under applicable law, or (iv) except as provided in Sections 11 and 13 hereof.

3. Actions or Proceedings Other Than an Action by or in the Right of the Company. The Indemnitee shall be entitled to the indemnification rights provided in this Section 3 if the Indemnitee was or is a party or witness or is threatened to be a party or witness to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative in nature, other than an action by or in the right of the Company, by reason of the fact that the Indemnitee is or was a director, officer, employee, agent or fiduciary of the Company, or any of its direct or indirect subsidiaries, or is or was serving at the request of the Company, or any of its direct or indirect subsidiaries, as a director, officer, employee, agent or fiduciary of any other entity, including, but not limited to, another corporation, partnership, limited liability company, employee benefit plan, joint venture, trust or other enterprise, or by reason of any act or omission by him/her in such capacity. Pursuant to this Section 3, the Indemnitee shall be indemnified against all Expenses, judgments, penalties (including excise and similar taxes), fines and

amounts paid in settlement which were actually and reasonably incurred by the Indemnitee in connection with such action, suit or proceeding (including, but not limited to, the investigation, defense or appeal thereof), if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his/her conduct was unlawful.

4. Actions by or in the Right of the Company. The Indemnitee shall be entitled to the indemnification rights provided in this Section 4 if the Indemnitee was or is a party or witness or is threatened to be made a party or witness to any threatened, pending or completed action, suit or proceeding brought by or in the right of the Company to procure a judgment in its favor by reason of the fact that the Indemnitee is or was a director, officer, employee, agent or fiduciary of the Company, or any of its direct or indirect subsidiaries, or is or was serving at the request of the Company, or any of its direct or indirect subsidiaries, as a director, officer, employee, agent or fiduciary of another entity, including, but not limited to, another corporation, partnership, limited liability company, employee benefit plan, joint venture, trust or other enterprise, or by reason of any act or omission by him/her in any such capacity. Pursuant to this Section 4, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by him/her in connection with the defense or settlement of such action, suit or proceeding (including, but not limited to the investigation, defense or appeal thereof), if the Indemnitee acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company; provided however, that no such indemnification shall be made in respect of any claim, issue, or matter as to which the Indemnitee shall have been adjudged to be liable to the Company, unless and only to the extent that the Court of Chancery of the State of Delaware or the court in which such action, suit or proceeding was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, the Indemnitee is fairly and reasonably entitled to be indemnified against such Expenses actually and reasonably incurred by him/her which such court shall deem proper.

5. Good Faith Definition. For purposes of this Agreement, the Indemnitee shall be deemed to have acted in good faith and in a manner the Indemnitee reasonably believed to be in or not opposed to the best interests of the Company, or, with respect to any criminal action or proceeding to have had no reasonable cause to believe the Indemnitee's conduct was unlawful, if, among other things, such action was based on (i) the records or books of the account of the Company or other enterprise, including financial statements; (ii) the advice of legal counsel for the Company or other enterprise; or (iii) information or records given in reports made to the Company or other enterprise by an independent certified public accountant or by an appraiser or other expert selected with reasonable care by the Company or other enterprise.

6. Indemnification for Expenses of Successful Party. Notwithstanding the other provisions of this Agreement, to the extent that the Indemnitee has served on behalf of the Company, or any of its direct or indirect subsidiaries, as a witness or other participant in any class action or proceeding, or has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Section 3 and 4 hereof, or in defense of any claim, issue or matter therein, including, but not limited to, the dismissal of any action without prejudice, the Indemnitee shall be indemnified against all Expenses actually and reasonably incurred by the Indemnitee in connection therewith, regardless of whether or not the Indemnitee has met the applicable standards of Section 3 or 4 and without any determination pursuant to Section 8.

7. Partial Indemnification. If the Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of the Expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred by the Indemnitee in connection with the investigation, defense, appeal or settlement of such suit, action, investigation or proceeding described in Section 3 or 4 hereof, but is not entitled to indemnification for the total amount thereof, the Company shall nevertheless indemnify the Indemnitee for the portion of such Expenses, judgments, penalties, fines and amounts paid in settlement actually and reasonably incurred by the Indemnitee to which the Indemnitee is entitled.

8. Procedure for Determination of Entitlement to Indemnification.

(a) To obtain indemnification under this Agreement, the Indemnitee shall submit to the Company a written request, including documentation and information which is reasonably available to the Indemnitee and is reasonably necessary to determine whether and to what extent the Indemnitee is entitled to indemnification. The Secretary of the Company shall, promptly upon receipt of a request for indemnification, advise the Board of Directors in writing that the Indemnitee has requested indemnification. Any Expenses incurred by the Indemnitee in connection with the Indemnitee's request for indemnification hereunder shall be borne by the Company. The Company hereby indemnifies and agrees to hold the Indemnitee harmless for any Expenses incurred by the Indemnitee under the immediately preceding sentence irrespective of the outcome of the determination of the Indemnitee's entitlement to indemnification.

(b) Upon written request by the Indemnitee for indemnification pursuant to Section 3 or 4 hereof, the entitlement of the Indemnitee to indemnification pursuant to the terms of this Agreement shall be determined by the following person or persons, who shall be empowered to make such determination:
(i) if a Change in Control (as hereinafter defined) shall have occurred, by Independent Counsel (as hereinafter defined) (unless the Indemnitee shall request in writing that such determination be made by the Board of Directors (or a committee thereof) in the manner provided for in clause (ii) of this Section 8(b)) in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee; or
(ii) if a Change in Control shall not have occurred, (A)(1) by the Board of Directors of the Company, by a majority vote of Disinterested Directors (as hereinafter defined) even though less than a quorum, or (2) by a committee of Disinterested Directors designated by majority vote of Disinterested Directors, even though less than a quorum, or (B) if there are no such Disinterested Directors or, even if there are such Disinterested Directors, if the Board of Directors, by the majority vote of Disinterested Directors, so directs, by Independent Counsel in a written opinion to the Board of Directors, a copy of which shall be delivered to the Indemnitee. Such Independent Counsel shall be selected by the Board of Directors and approved by the Indemnitee. Upon failure of the Board of Directors to so select, or upon failure of the Indemnitee to so approve, such Independent Counsel shall be selected by the Chancellor of the State of Delaware or such other person as the Chancellor shall designate to make such selection. Such determination of entitlement to indemnification shall be made not later than 45 days after receipt by the Company of a written request for indemnification. If the person making such determination shall determine that the Indemnitee is entitled to indemnification as to part (but not all) of the application for indemnification, such person shall reasonably prorate such part of indemnification among such claims, issues or matters. If it is so determined that the Indemnitee is entitled to indemnification, payment to the Indemnitee shall be made within ten days after such determination.

9. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification, the Indemnitee shall be presumed to be entitled to indemnification hereunder and the Company shall have the burden of proof in the making of any determination contrary to such presumption.

(b) If the Board of Directors, or such other person or persons empowered pursuant to Section 8 to make the determination of whether the Indemnitee is entitled to indemnification, shall have failed to make a determination as to entitlement to indemnification within 45 days after receipt by the Company of such request, the requisite determination of entitlement to indemnification shall be deemed to have been made and the Indemnitee shall be absolutely entitled to such indemnification, absent actual and material fraud in the request for indemnification or a prohibition of indemnification under applicable law. The termination of any action, suit, investigation or proceeding described in Section 3 or 4 hereof by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, shall not, of itself: (i) create a presumption that the Indemnitee did not act in good faith and in a manner which he/she reasonably believed to be in or not opposed to the best interests of the Company, and, with respect to any criminal action or proceeding, that the Indemnitee has reasonable cause to believe that the Indemnitee's conduct was unlawful; or (ii) otherwise adversely affect the rights of the Indemnitee to indemnification, except as may be provided herein.

10. Advancement of Expenses. All reasonable Expenses actually incurred by the Indemnitee in connection with any threatened or pending action, suit or proceeding shall be paid by the Company in advance of the final disposition of such action, suit or proceeding, if so requested by the Indemnitee, within 20 days after the receipt by the Company of a statement or statements from the Indemnitee requesting such advance or advances. The Indemnitee may submit such statements from time to time. The Indemnitee's entitlement to such Expenses shall include those incurred in connection with any proceeding by the Indemnitee seeking an adjudication or award in arbitration pursuant to this Agreement. Such statement or statements shall reasonably evidence the Expenses incurred by the Indemnitee in connection therewith and shall include or be accompanied by a written affirmation by the Indemnitee of the Indemnitee's good faith belief that the Indemnitee has met the standard of conduct necessary for indemnification under this Agreement and an undertaking by or on behalf of the Indemnitee to repay such amount if it is ultimately determined that the Indemnitee is not entitled to be indemnified against such Expenses by the Company pursuant to this Agreement or otherwise. Each written undertaking to pay amounts advanced must be an unlimited general obligation but need not be secured, and shall be accepted without reference to financial ability to make repayment.

11. Remedies of the Indemnitee in Cases of Determination not to Indemnify or to Advance Expenses. In the event that a determination is made that the Indemnitee is not entitled to indemnification hereunder or if the payment has not been timely made following a determination of entitlement to indemnification pursuant to Sections 8 and 9, or if Expenses are not advanced pursuant to Section 10, the Indemnitee shall be entitled to a final adjudication in an appropriate court of the State of Delaware or any other court of competent jurisdiction of the Indemnitee's entitlement to such indemnification or advance. Alternatively, the Indemnitee may, at the Indemnitee's option, seek an award in arbitration to be conducted by a single arbitrator pursuant to the rules of the American Arbitration Association, such award to be made within 60 days following the filing of the demand for arbitration. The Company shall not oppose the Indemnitee's right to seek any such adjudication or award in arbitration or any other claim. Such judicial

proceeding or arbitration shall be made de novo, and the Indemnitee shall not be prejudiced by reason of a determination (if so made) that the Indemnitee is not entitled to indemnification. If a determination is made or deemed to have been made pursuant to the terms of Section 8 or Section 9 hereof that the Indemnitee is entitled to indemnification, the Company shall be bound by such determination and shall be precluded from asserting that such determination has not been made or that the procedure by which such determination was made is not valid, binding and enforceable. The Company further agrees to stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement and is precluded from making any assertions to the contrary. If the court or arbitrator shall determine that the Indemnitee is entitled to any indemnification hereunder, the Company shall pay all reasonable Expenses actually incurred by the Indemnitee in connection with such adjudication or award in arbitration (including, but not limited to, any appellate proceedings).

12. Notification and Defense of Claim. Promptly after receipt by the Indemnitee of notice of the commencement of any action, suit or proceeding, the Indemnitee will, if a claim in respect thereof is to be made against the Company under this Agreement, notify the Company in writing of the commencement thereof; but the omission to so notify the Company will not relieve the Company from any liability that it may have to the Indemnitee otherwise than under this Agreement or otherwise, except to the extent that the Company may suffer material prejudice by reason of such failure. Notwithstanding any other provision of this Agreement, with respect to any such action, suit or proceeding as to which the Indemnitee gives notice to the Company of the commencement thereof:

(a) The Company will be entitled to participate therein at its own expense.

(b) Except as otherwise provided in this Section 12(b), to the extent that it may wish, the Company, jointly with any other indemnifying party similarly notified, shall be entitled to assume the defense thereof with counsel reasonably satisfactory to the Indemnitee. After notice from the Company to the Indemnitee of its election to so assume the defense thereof, the Company shall not be liable to the Indemnitee under this Agreement for any legal or other Expenses subsequently incurred by the Indemnitee in connection with the defense thereof other than reasonable costs of investigation or as otherwise provided below. The Indemnitee shall have the right to employ the Indemnitee's own counsel in such action or lawsuit, but the fees and Expenses of such counsel incurred after notice from the Company of its assumption of the defense thereof shall be at the expense of the Indemnitee unless (i) the employment of counsel by the Indemnitee has been authorized by the Company, (ii) the Indemnitee shall have reasonably concluded that there may be a conflict of interest between the Company and the Indemnitee in the conduct of the defense of such action and such determination by the Indemnitee shall be supported by an opinion of counsel, which opinion shall be reasonably acceptable to the Company, or
(iii) the Company shall not in fact have employed counsel to assume the defense of the action, in each of which cases the fees and Expenses of counsel shall be at the expense of the Company. The Company shall not be entitled to assume the defense of any action, suit or proceeding brought by or on behalf of the Company or as to which the Indemnitee shall have reached the conclusion provided for in clause (ii) above.

(c) The Company shall not be liable to indemnify the Indemnitee under this Agreement for any amounts paid in settlement of any action, suit or proceeding effected without its written consent, which consent shall not be unreasonably withheld. The Company shall not be required to obtain the consent of the Indemnitee to settle any action, suit or proceeding which the Company has undertaken to defend if the

Company assumes full and sole responsibility for such settlement and such settlement grants the Indemnitee a complete and unqualified release in respect of any potential liability.

(d) If, at the time of the receipt of a notice of a claim pursuant to this Section 12, the Company has an officer liability insurance in effect, the Company shall give prompt notice of the commencement of such proceeding to the insurers in accordance with the procedures set forth in the respective policies. The Company shall thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such proceeding in accordance with the terms of the policies.

13. Other Right to Indemnification. The indemnification and advancement of Expenses provided by this Agreement are cumulative, and not exclusive, and are in addition to any other rights to which the Indemnitee may now or in the future be entitled under any provision of the Bylaws or Certificate of the Company, any vote of stockholders or Disinterested Directors, any provision of law or otherwise. Except as required by applicable law, the Company shall not adopt any amendment to its Bylaws or Certificate the effect of which would be to deny, diminish or encumber the Indemnitee's right to indemnification under this Agreement.

14. Officer Liability Insurance. The Company shall maintain officers' liability insurance for so long as the Indemnitee's services are covered hereunder, provided and to the extent that such insurance is available on a commercially reasonable basis. In the event the Company maintains officers' liability insurance, the Indemnitee shall be named as an insured in such manner as to provide the Indemnitee the same rights and benefits as are accorded to the most favorably insured of the Company's officers. However, the Company agrees that the provisions hereof shall remain in effect regardless of whether liability or other insurance coverage is at any time obtained or retained by the Company, except that any payments made to, or on behalf of, the Indemnitee under an insurance policy shall reduce the obligations of the Company hereunder.

15. Spousal Indemnification. The Company will indemnify the Indemnitee's spouse to whom the Indemnitee is legally married at any time the Indemnitee is covered under the indemnification provided in this Agreement (even if the Indemnitee did not remain married to him or her during the entire period of coverage) against any pending or threatened action, suit, proceeding or investigation for the same period, to the same extent and subject to the same standards, limitations, obligations and conditions under which the Indemnitee is provided indemnification herein, if the Indemnitee's spouse (or former spouse) becomes involved in a pending or threatened action, suit, proceeding or investigation solely by reason of his or her status as the Indemnitee's spouse, including, without limitation, any pending or threatened action, suit, proceeding or investigation that seeks damages recoverable from marital community property, jointly- owned property or property purported to have been transferred from the Indemnitee to his/her spouse (or former spouse). The Indemnitee's spouse or former spouse also may be entitled to advancement of Expenses to the same extent that the Indemnitee is entitled to advancement of Expenses herein. The Company may maintain insurance to cover its obligation hereunder with respect to the Indemnitee's spouse (or former spouse) or set aside assets in a trust or escrow fund for that purpose.

16. Intent. This Agreement is intended to be broader than any statutory indemnification rights applicable in the State of Delaware and shall be in addition to any other rights the Indemnitee may have under the Company's Certificate, Bylaws, applicable law or otherwise. To the extent that a change in

applicable law (whether by statute or judicial decision) permits greater indemnification by agreement than would be afforded currently under the Company's Certificate, Bylaws, applicable law or this Agreement, it is the intent of the parties that the Indemnitee enjoy by this Agreement the greater benefits so afforded by such change. In the event of any change in applicable law, statute or rule which narrows the right of a Delaware corporation to indemnify its officer, employee, agent or fiduciary, such change, to the extent not otherwise required by such law, statute or rule to be applied to this Agreement, shall have no effect on this Agreement or the parties' rights and obligations hereunder.

17. Attorney's Fees and Other Expenses to Enforce Agreement. In the event that the Indemnitee is subject to or intervenes in any action, suit or proceeding in which the validity or enforceability of this Agreement is at issue or seeks an adjudication or award in arbitration to enforce the Indemnitee's rights under, or to recover damages for breach of, this Agreement the Indemnitee, if he/she prevails in whole or in part in such action, shall be entitled to recover from the Company and shall be indemnified by the Company against any actual expenses for attorneys' fees and disbursements reasonably incurred by the Indemnitee.

18. Effective Date. The provisions of this Agreement shall cover claims, actions, suits or proceedings whether now pending or hereafter commenced and shall be retroactive to cover acts or omissions or alleged acts or omissions which heretofore have taken place. The Company shall be liable under this Agreement, pursuant to Sections 3 and 4 hereof, for all acts of the Indemnitee while serving as an officer, notwithstanding the termination of the Indemnitee's service, if such act was performed or omitted to be performed during the term of the Indemnitee's service to the Company.

19. Duration of Agreement. This Agreement shall survive and continue even though the Indemnitee may have terminated his/her service as an officer, employee, agent or fiduciary of the Company or as a director, officer, employee, agent or fiduciary of any other entity, including, but not limited to another corporation, partnership, limited liability company, employee benefit plan, joint venture, trust or other enterprise or by reason of any act or omission by the Indemnitee in any such capacity. This Agreement shall be binding upon the Company and its successors and assigns, including, without limitation, any corporation or other entity which may have acquired all or substantially all of the Company's assets or business or into which the Company may be consolidated or merged, and shall inure to the benefit of the Indemnitee and his/her spouse, successors, assigns, heirs, devisees, executors, administrators or other legal representations. The Company shall require any successor or assignee (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company, by written agreement in form and substance reasonably satisfactory to the Company and the Indemnitee, expressly to assume and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform if no such succession or assignment had taken place.

20. Disclosure of Payments. Except as expressly required by any Federal or state securities laws or other Federal or state law, neither party shall disclose any payments under this Agreement unless prior approval of the other party is obtained.

21. Severability. If any provision or provisions of this Agreement shall be held invalid, illegal or unenforceable for any reason whatsoever, (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including, but not limited to, all portions of any Sections of this Agreement

containing any such provision held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (b) to the fullest extent possible, the provisions of this Agreement (including, but not limited to, all portions of any paragraph of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that are not themselves invalid, illegal or unenforceable) shall be construed so as to give effect to the intent manifest by the provision held invalid, illegal or unenforceable.

22. Counterparts. This Agreement may be executed by one or more counterparts, each of which shall for all purposes be deemed to be an original but all of which together shall constitute one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought shall be required to be produced to evidence the existence of this Agreement.

23. Captions. The captions and headings used in this Agreement are inserted for convenience only and shall not be deemed to constitute part of this Agreement or to affect the construction thereof.

24. Definitions. For purposes of this Agreement:

(a) "Change in Control" shall mean the occurrence of any one of the following:

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

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

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

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

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

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

(b) "Continuity Directors" shall mean any individuals who are members of the Board on the effective date of this Agreement and any individual who subsequently becomes a member of the Board whose election, or nomination for election by the Company's stockholders, was approved by a vote of at least a majority of the Continuity Directors (either by specific vote or by approval of the Company's proxy statement in which such individual is named as a nominee for director without objection to such nomination).

(c) "Disinterested Director" shall mean a director of the Company who is not or was not a party to the action, suit, investigation or proceeding in respect of which indemnification is being sought by the Indemnitee.

(d) "Expenses" shall include all attorneys' fees, retainers, court costs, transcript costs, fees of experts, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, and all other disbursements or expenses incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating or being or preparing to be a witness in any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative in nature.

(e) "Independent Counsel" shall mean a law firm or a member of a law firm that neither is presently nor in the past five years has been retained to represent (i) the Company or the Indemnitee in any matter material to either such party or (ii) any other party to the action, suit, investigation or proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" shall not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or the Indemnitee in an action to determine the Indemnitee's right to indemnification under this Agreement.

25. Entire Agreement, Modification and Waiver. This Agreement constitutes the entire agreement and understanding of the parties hereto regarding the subject matter hereof, and no supplement, modification or amendment of this Agreement shall be binding unless executed in writing by both parties hereto. No waiver of any of the provisions of this Agreement shall be deemed or shall constitute a waiver of any other provisions hereof (whether or not similar) nor shall such waiver constitute a continuing waiver. No supplement, modification or amendment of this Agreement shall limit or restrict any right of the Indemnitee under this Agreement in respect of any act or omission of the Indemnitee prior to the effective date of such supplement, modification or amendment unless expressly provided therein.

26. Notices. All notices, requests, demands or other communications hereunder shall be in writing and shall be deemed to have been duly given if (a) delivered by hand with receipt acknowledged by the party to whom said notice or other communication shall have been directed, (b) mailed by certified or registered mail, return receipt requested with postage prepaid, on the date shown on the return receipt,
(c) sent by a recognized next-day courier service on the first business day following the date of dispatch or
(d) delivered by facsimile transmission on the date shown on the facsimile machine report:

(i) If to the Indemnitee to:

Meredith Cook

at the address on file with the Company

(ii) If to the Company, to:

ANI Pharmaceuticals, Inc. 210
Main Street West

Baudette, Minnesota 56623 Attn:
Chief Executive Officer Fax: [(302)
482-8645]

or to such other address as may be furnished to the Indemnitee by the Company or to the Company by the Indemnitee, as the case may be.

27. Governing Law. The parties hereto agree that this Agreement shall be governed by, and construed and enforced in accordance with, the laws of the State of Delaware, applied without giving effect to any conflicts-of-law principles.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the day and year first above written.

ANI PHARMACEUTICALS, INC.

By:_____

Name: _____

Title: _____

INDEMNITEE:

Meredith Cook

Exhibit 31.1

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

I, Nikhil Lalwani, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2022

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

Exhibit 31.2

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

I, Stephen P. Carey, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2022

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

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended June 30, 2022 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

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

Dated: August 8, 2022

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

Dated: August 8, 2022

/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.