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

FORM 10-Q

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

For the quarterly period ended March 31, 2024

o **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 x No o

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 x No o

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	x	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	o
		Emerging growth company	o

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. o

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

As of May 3, 2024 there were 20,961,649 shares of common stock and 10,864 shares of class C special stock of the registrant outstanding.

ANI PHARMACEUTICALS, INC.
FORM 10-Q — Quarterly Report
For the Quarterly Period Ended March 31, 2024

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CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such statements include, but are not limited to, statements about future operations, strategies and growth potential, the revenue potential (licensing, royalty and sales) of products we sell, development timelines, expected timeframe for submission of new drug applications, abbreviated new drug applications, or supplemental new drug applications to the U.S. Food and Drug Administration (the "FDA"), pipeline or potential markets for our products, selling and marketing strategies and associated costs to support the sales of Purified Cortrophin® Gel (Repository Corticotropin Injection USP) ("Cortrophin Gel"), impact of accounting principles, litigation expenses, liquidity and capital resources, the impact of global pandemics on our business, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words, and the use of future dates. Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including those discussed in the "Risk Factors" section in Part I, Item 1A. of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and the following factors:

- Cortrophin Gel is our first rare disease pharmaceutical product. To the extent we are not able to continue to achieve commercial success with this product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted;
- our approved products, including Cortrophin Gel, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability;
- acquisitions and investments could disrupt our business and harm our financial position and operating results;
- the limited number of suppliers for our active pharmaceutical ingredients ("API") could result in lengthy delays in production if we need to change suppliers;
- 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;
- acceptance of our products at levels that will allow us to achieve profitability;
- our ability to develop, license or acquire, and commercialize new products;
- the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products;
- our ability to protect our intellectual property rights;
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- the impact of any litigation to which we are, or may become, a party;
- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries;
- our ability to maintain the services of our key executives and other personnel; and
- general business and economic conditions, such as inflationary pressures, geopolitical conditions including, but not limited to, the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies.

These factors should not be construed as exhaustive and should be read in conjunction with our other disclosures, including but not limited to our Annual Report on Form 10-K for the year ended December 31, 2023, including the factors described in "Item 1A. Risk Factors." Other risks may be described from time to time in our filings made under the securities laws, including our quarterly reports on Form 10-Q and our current reports on Form 8-K. New risks emerge from time to time. It is not possible for our management to predict all risks. The forward-looking statements contained in this document are made only as of the date of this document. We undertake no obligation to update or revise any forward-looking statement, whether as a result of new information, future events, or otherwise.

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

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Part I — FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (unaudited)

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES

Condensed Consolidated Balance Sheets

(in thousands, except share and per share amounts)

(unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current Assets		
Cash and cash equivalents	$ 228,597	$ 221,121
Accounts receivable, net of $91,825 and $97,262 of adjustments for chargebacks and other allowances at March 31, 2024 and December 31, 2023, respectively	172,418	162,079
Inventories	113,837	111,196
Assets held for sale	—	8,020
Prepaid expenses and other current assets	16,050	17,400
Investment in equity securities	9,655	—
Total Current Assets	540,557	519,816
Non-current Assets		
Property and equipment, net	48,526	44,593
Deferred tax assets, net of deferred tax liabilities and valuation allowance	87,607	90,711
Intangible assets, net	196,044	209,009
Goodwill	28,221	28,221
Derivatives and other non-current assets	13,569	12,072
Total Assets	$ 914,524	$ 904,422
Liabilities, Mezzanine Equity, and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	49,430	36,683
Accrued royalties	15,475	16,276
Accrued compensation and related expenses	9,526	23,786
Accrued government rebates	9,509	12,168
Income taxes payable	11,402	8,164
Returned goods reserve	32,853	29,678
Current contingent consideration	414	12,266
Accrued expenses and other	7,430	5,606
Total Current Liabilities	136,889	145,477
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	284,607	284,819
Non-current contingent consideration	11,160	11,718
Other non-current liabilities	5,055	4,809
Total Liabilities	$ 437,711	$ 446,823
Commitments and Contingencies (Note 12)		
Mezzanine Equity		
Convertible Preferred Stock, Series A, $0.0001 par value, 1,666,667 shares authorized; 25,000 shares issued and outstanding at March 31, 2024 and December 31, 2023	24,850	24,850
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 21,373,266 shares issued and 20,980,307 outstanding at March 31, 2024; 20,730,896 shares issued and 20,466,953 shares outstanding at December 31, 2023	2	2
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Treasury stock, 392,959 shares of common stock, at cost, at March 31, 2024 and 263,943 shares of common stock, at cost, at December 31, 2023	(18,742)	(10,081)
Additional paid-in capital	523,628	514,103
Accumulated deficit	(62,331)	(80,132)
Accumulated other comprehensive income, net of tax	9,406	8,857
Total Stockholders' Equity	451,963	432,749
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 914,524	$ 904,422

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

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

	Three Months Ended March 31,	
	2024	**2023**
Net Revenues	$ 137,430	$ 106,786
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	49,157	37,708
Research and development	10,511	5,924
Selling, general, and administrative	48,021	36,468
Depreciation and amortization	14,686	14,700
Contingent consideration fair value adjustment	90	961
Restructuring activities	—	1,130
Gain on sale of building	(5,347)	—
Total Operating Expenses, net	117,118	96,891
Operating Income	20,312	9,895
Other Income (Expense), net		
Unrealized gain on investment in equity securities	9,655	—
Interest expense, net	(4,600)	(7,696)
Other expense, net	(32)	(34)
Income Before Income Tax Expense	25,335	2,165
Income tax expense	7,128	726
Net Income	$ 18,207	$ 1,439
Dividends on Series A Convertible Preferred Stock	(406)	(406)
Net Income Available to Common Shareholders	$ 17,801	$ 1,033
Basic and Diluted Income Per Share:		
Basic Income Per Share	$ 0.84	$ 0.06
Diluted Income Per Share	$ 0.82	$ 0.06
Basic Weighted-Average Shares Outstanding	19,099	16,392
Diluted Weighted-Average Shares Outstanding	19,422	16,531

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

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

	Three Months Ended March 31,	
	2024	**2023**
Net Income	$ 18,207	$ 1,439
Other comprehensive income, net of tax:		
Foreign currency translation adjustment	(97)	107
Gain (loss) on interest rate swap	646	(1,143)
Total other comprehensive income, net of tax	549	(1,036)
Total comprehensive income, net of tax	$ 18,756	$ 403

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Changes in Mezzanine Equity and Stockholders' Equity
For the Three Months Ended March 31, 2024 and 2023
(in thousands)
(unaudited)

	Mezzanine Equity Series A Convertible Preferred Stock	Mezzanine Equity Series A Convertible Preferred Stock Shares	Common Stock Par Value	Common Stock Shares	Class C Special Stock	Additional Paid-in Capital	Treasury Stock Shares	Treasury Stock	Accumulated Other Comprehensive Income, Net of Tax	Accumulated Deficit	Total Mezzanine Equity and Stockholders' Equity
Balance, December 31, 2022	$ 24,850	25	$ 1	17,644	$ —	$ 403,900	149	$ (5,094)	$ 12,167	$ (97,285)	$ 338,539
Stock-based Compensation Expense	—	—	—	—	—	4,338	—	—	—	—	4,338
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	85	(3,549)	—	—	(3,549)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	5	—	157	—	—	—	—	157
Issuance of Restricted Stock Awards	—	—	—	520	—	—	—	—	—	—	—
Issuance of Performance Stock Units	—	—	—	85	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(28)	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(406)	(406)
Other Comprehensive Income	—	—	—	—	—	—	—	—	(1,036)	—	(1,036)
Net Income	—	—	—	—	—	—	—	—	—	1,439	1,439
Balance, March 31, 2023	$ 24,850	25	$ 1	18,226	$ —	$ 408,395	234	$ (8,643)	$ 11,131	$ (96,252)	$ 339,482
Balance, December 31, 2023	$ 24,850	25	$ 2	20,731	$ —	$ 514,103	264	$ (10,081)	$ 8,857	$ (80,132)	$ 457,599
Stock-based Compensation Expense	—	—	—	—	—	6,934	—	—	—	—	6,934
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	129	(8,661)	—	—	(8,661)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	31	—	2,591	—	—	—	—	2,591
Issuance of Restricted Stock Awards	—	—	—	542	—	—	—	—	—	—	—
Issuance of Performance Stock Units	—	—	—	74	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(5)	—	—	—	—	—	—	—
Dividends on Series A Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(406)	(406)
Other Comprehensive Income	—	—	—	—	—	—	—	—	549	—	549
Net Income	—	—	—	—	—	—	—	—	—	18,207	18,207
Balance, March 31, 2024	$ 24,850	25	$ 2	21,373	$ —	$ 523,628	393	$ (18,742)	$ 9,406	$ (62,331)	$ 476,813

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

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

	Three Months Ended March 31,	
	2024	2023
Cash Flows From Operating Activities		
Net income	$ 18,207	$ 1,439
Adjustments to reconcile net income to net cash and cash equivalents provided by operating activities:		
Stock-based compensation	6,934	4,338
Deferred taxes	3,104	773
Depreciation and amortization	14,686	14,700
Unrealized gain on investment in equity securities	(9,655)	—
Non-cash operating lease expense	373	—
Non-cash interest	102	987
Contingent consideration fair value adjustment	90	961
Gain on sale of building	(5,347)	—
Changes in operating assets and liabilities, net of acquisition:		
Accounts receivable, net	(10,339)	(9,275)
Inventories	(2,641)	1,701
Prepaid expenses and other current assets	1,353	1,513
Accounts payable	11,526	3,105
Accrued royalties	(801)	(350)
Current income taxes payable	3,238	92
Accrued government rebates	(2,658)	(2,265)
Returned goods reserve	3,174	713
Accrued expenses, accrued compensation, and other	(13,077)	2,992
Net Cash and Cash Equivalents Provided by Operating Activities	18,269	21,424
Cash Flows From Investing Activities		
Acquisition of product rights, intangible assets, and other related assets	—	(4)
Acquisition of property and equipment, net	(4,581)	(2,349)
Proceeds from the sale of building	13,514	—
Net Cash and Cash Equivalents Provided by (Used in) Investing Activities	8,933	(2,353)
Cash Flows From Financing Activities		
Payments on borrowings under credit agreements	(750)	(750)
Series A convertible preferred stock dividends paid	(406)	(406)
Proceeds from stock option exercises and ESPP purchases	2,591	157
Treasury stock purchases for restricted stock vests	(8,661)	(3,549)
Payments on contingent consideration	(12,500)	—
Net Cash and Cash Equivalents Used in Financing Activities	(19,726)	(4,548)
Net Change in Cash, Cash Equivalents, and Restricted Cash	7,476	14,523
Cash, cash equivalents, and restricted cash, beginning of period	221,121	53,234
Cash and cash equivalents, end of period	$ 228,597	$ 67,757
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period		
Cash and cash equivalents	$ 221,121	$ 48,228
Restricted cash	—	5,006
Cash, cash equivalents, and restricted cash, beginning of period	$ 221,121	$ 53,234
Supplemental disclosure for cash flow information:		
Cash paid for interest, net of amounts capitalized	$ 7,946	$ 4,293
Cash paid for income taxes	$ 852	$ 2,741
Supplemental non-cash investing and financing activities:		
Property and equipment purchased and included in accounts payable	$ 1,222	$ 729

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

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

1. BUSINESS, PRESENTATION, AND RECENT ACCOUNTING PRONOUNCEMENTS

Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, “ANI,” the “Company,” “we,” “us,” or “our”) is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. The Company is focused on delivering growth by scaling up the Rare Disease business through the launch of its lead asset, Cortrophin Gel, strengthening its generics business with enhanced development capability, innovation in established brands and leveraging its U.S. based manufacturing capabilities. The Company's three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, and one is located in East Windsor, New Jersey, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. The Company has ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC (“Novitium”) in November 2021. The Company has fully completed the transition of the products manufactured or packaged in Oakville to one of the three U.S. based manufacturing sites. In February 2024, the Company entered into an agreement for the sale of the Oakville site, for a price of $19.2 million Canadian Dollars, or approximately $ 14.2 million, based on the current exchange rate. The sale closed on March 28, 2024 (see Note 3).

The Company's operations are subject to certain risks and uncertainties including, among others, current and potential competitors with greater resources, dependence on significant customers, and possible fluctuations in financial results.

In May 2023, through a public offering, the Company completed the issuance and sale of 2,183,545 shares of ANI common stock, resul ting in net proceeds after issuance costs of $80.6 million.

Basis of Presentation

The accompanying unaudited interim condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) for interim financial information. In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements include all adjustments, consisting of normal recurring adjustments, which are necessary to present fairly the Company's financial position, results of operations, comprehensive income, and cash flows. The consolidated balance sheet at December 31, 2023 has been derived from audited financial statements as of that date. The unaudited interim condensed consolidated statements of operations are not necessarily indicative of the results that may occur for the full fiscal year. Certain information and footnote disclosure normally included in financial statements prepared in accordance with U.S. GAAP have been omitted pursuant to instructions, rules, and regulations prescribed by the U.S. Securities and Exchange Commission (the “SEC”). Therefore, these unaudited interim condensed consolidated financial statements should be read in conjunction with the Company's audited financial statements and notes thereto previously distributed in the Company's Annual Report on Form 10-K for the year ended December 31, 2023 (the “2023 Form 10-K”), as filed with the SEC.

Principles of Consolidation

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

Foreign Currency

The Company has ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. The Company currently has a subsidiary located in India. The Canada-based subsidiary conducted its transactions in U.S. dollars and Canadian dollars, but its functional currency was the U.S. dollar. The India-based subsidiary generally conducts its transactions in Indian rupees, which is also its functional currency. The results of any non-U.S. dollar transactions and balances are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. The gain or loss on transactions denominated in foreign currencies and the translation impact of local currencies to U.S. dollars was immaterial for the three months ended March 31, 2024 and 2023. Unless otherwise noted, all references to “$” or “dollar” refer to the U.S. dollar. The Company’s asset and liability accounts are translated using the current exchange rate as of the balance sheet date, except for shareholders’ equity accounts, which are translated using historical rates. Net revenues and expense accounts are translated using an average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company’s foreign subsidiaries into U.S. dollars are accumulated as a separate component of shareholders’ equity within accumulated other comprehensive income, net of tax.

Use of Estimates

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

Restructuring Activities

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

Investment in Equity Securities

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

Assets Held-for-Sale

The Company classifies assets held-for-sale if all held-for-sale criteria is met pursuant to ASC 360-10, *Property, Plant and Equipment*. Criteria include management commitment to sell the disposal group in its present condition and the sale being deemed probable of being completed within one year. Assets classified as held-for-sale are not depreciated and are measured at the lower of their carrying amount or fair value less cost to sell. The Company assesses the fair value of a disposal group, less any costs to sell, each reporting period it remains classified as held-for-sale and reports any subsequent changes as an adjustment to the carrying value of the disposal group, as long as the new carrying value does not exceed the initial carrying value of the disposal group. The Company determined that the Oakville, Ontario, Canada property met the held-for-sale criteria. As of December 31, 2023, approximately $8.0 million of assets held for sale were recorded on the consolidated balance sheets. The Oakville, Ontario property was sold on March 28, 2024, and therefore no longer exists as of March 31, 2024. See Note 3 to the condensed consolidated financial statements for additional information.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

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

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

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

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

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

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

The Company recognizes revenue in accordance with ASC 606, *Revenue from Contracts with Customers*. Revenue is recognized using the following steps:

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

Revenues are primarily derived from sales of generic, rare disease, and established brand pharmaceutical products, royalties, and other pharmaceutical services. Revenue is recognized when obligations under the terms of contracts with customers are satisfied, which generally occurs when control of the products sold are transferred to the customer. Variable consideration is estimated after the consideration of applicable information that is reasonably available. The Company generally does not have incremental costs to obtain contracts that would otherwise not have been incurred. The Company does not adjust revenue for the promised amount of consideration for the effects of a significant financing component because our customers generally pay us within 100 days.

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

	Three Months Ended	
Products and Services		
(in thousands)	**March 31, 2024**	**March 31, 2023**
Sales of generic pharmaceutical products	$ 70,217	$ 63,713
Sales of established brand pharmaceutical products, royalties, and other pharmaceutical services	30,276	26,743
Sales of rare disease pharmaceutical products	36,937	16,330
Total net revenues	$ 137,430	$ 106,786

	Three Months Ended	
Timing of Revenue Recognition		
(in thousands)	**March 31, 2024**	**March 31, 2023**
Performance obligations transferred at a point in time	$ 137,430	$ 106,411
Performance obligations transferred over time	—	375
Total	$ 137,430	$ 106,786

In the three months ended March 31, 2024 and 2023, the Company did not incur, and therefore did not defer, any material incremental costs to obtain or fulfill contracts. The Company recognized a decrease of $0.1 million to net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2024, 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 $5.1 million to net revenue from performance obligations satisfied in prior periods during the three months ended March 31, 2023, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. Additionally, as of March 31, 2024, and December 31, 2023, there was no deferred revenue recorded on the condensed consolidated balance sheet.

As of March 31, 2024, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $3.0 million, which consists of firm orders for contract manufactured products. The Company recognizes revenue for these performance obligations as they are satisfied, which is anticipated within six months.

Variable consideration

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

The following table summarizes activity in the condensed consolidated balance sheets for accruals and allowances for the three months ended March 31, 2024 and 2023, respectively:

	Accruals for Chargebacks, Returns, and Other Allowances				
(in thousands)	**Chargebacks**	**Government Rebates**	**Returns**	**Administrative Fees and Other Rebates**	**Prompt Payment Discounts**
Balance at December 31, 2022	$ 148,562	$ 10,872	$ 33,399	$ 9,442	$ 6,488
Accruals/Adjustments	146,113	4,461	4,640	12,026	5,483
Credits Taken Against Reserve	(193,859)	(6,726)	(3,931)	(12,018)	(6,538)
Balance at March 31, 2023 (1)	$ 100,816	$ 8,607	$ 34,108	$ 9,450	$ 5,433
Balance at December 31, 2023	$ 84,208	$ 12,168	$ 29,678	$ 11,412	$ 4,865
Accruals/Adjustments	131,097	5,952	12,521	14,811	5,635
Credits Taken Against Reserve	(137,779)	(8,611)	(9,346)	(13,085)	(5,641)
Balance at March 31, 2024 (1)	$ 77,526	$ 9,509	$ 32,853	$ 13,138	$ 4,859

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

Credit Concentration

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

During the three months ended March 31, 2024, there were four customers that accounted for 10% or more of net revenues. During the three months ended March 31, 2023, there were three customers that accounted for 10% or more of net revenues. As of March 31, 2024, accounts receivable from these customers totaled 81% of Accounts receivable, net.

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

	Three Months Ended	
	March 31, 2024	**March 31, 2023**
Customer 1	34 %	33 %
Customer 2	13 %	15 %
Customer 3	10 %	14 %
Customer 4	13 %	7 %

3. RESTRUCTURING

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

There were no restructuring activities recorded in the three months ended March 31, 2024 and as of March 31, 2024, there was no severance or other employee benefits accrued on the unaudited interim condensed consolidated balance sheet.

For the three months ended March 31, 2023, restructuring activities resulted in expenses of $1.1 million. This included $0.2 million of severance and other employee benefit costs and $0.7 million of accelerated depreciation costs and $0.2 million for other miscellaneous costs.

In conjunction with the exit of the Canadian facility, the Company has determined that the land and building at the Oakville, Ontario, Canada plant (the "Property") will be sold together and met the criteria to be classified as held for sale as of March 31, 2023. The land and building had a net carrying value of approximately $8.0 million, which was presented as assets held for sale on the accompanying condensed consolidated balance sheet at December 31, 2023. These assets are part of the Generics, Established Brands, and Other segment. As of March 31, 2024 these assets were no longer classified as held for sale.

On February 15, 2024, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement (the "Agreement") with 1540700 Ontario Limited ("Buyer") for the sale of the Property for a total purchase price of $19.2 million Canadian Dollars, or approximately $14.2 million, based on the current exchange rate, subject to certain market adjustments. The purchase of the Property is being made on an “as is” basis and the Agreement provides for customary closing conditions and indemnification obligations, as well as limited representations and warranties.

During February 2024, and in accordance with the Agreement, the Buyer deposited a total of approximately $ 1.9 million Canadian Dollars, or approximately $1.4 million in refundable deposits in escrow as part of the total purchase price. On March 28, 2024 the Company completed the sale of the Property. After payment of commissions, real estate taxes, and other related costs of approximately $0.7 million, the Company received a net proceeds of approximately $13.5 million at closing. The gain on the sale of the Property was approximately $ 5.3 million, recorded in the unaudited interim condensed consolidated statements of operations.

4. INDEBTEDNESS

Credit Facility

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

On November 19, 2021, the Company, as borrower, entered into a credit agreement (the “Credit Agreement”) with Truist Bank and other lenders, which provides for credit facilities consisting of (i) a senior secured term loan facility in an aggregate principal amount of $300.0 million (the “Term Facility”) and (ii) a senior secured revolving credit facility in an aggregate commitment amount of $40.0 million, which may be used for revolving credit loans, swingline loans and letters of credit (the “Revolving Facility,” and together with the Term Facility, the “Credit Facility”). The Term Facility proceeds were used to finance the cash portion of the consideration under the Merger Agreement, repay the existing credit facility, and pay fees, costs and expenses incurred in connection with the merger. The Term Facility matures in November 2027 and the Revolving Facility in November 2026. The Credit Facility has a subjective acceleration clause in case of a material adverse effect.

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

The Credit Facility permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread as defined in the Credit Facility. As of March 31, 2024, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

The interest rate under the Term Facility was 11.44% at March 31, 2024.

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

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

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

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

	Non-Current	
(in thousands)	**March 31, 2024**	**December 31, 2023**
Non-current borrowing on debt	$ 290,250	$ 291,000
Deferred financing costs	(5,643)	(6,181)
Non-current debt, net of deferred financing costs and current component	$ 284,607	$ 284,819

As of March 31, 2024, outstanding principal was $293.3 million on the Term Facility. Of the $0.6 million of unamortized deferred debt issuance costs allocated to the Revolving Facility, $0.3 million is included in other non-current assets in the unaudited interim condensed consolidated balance sheets, and $0.3 million is included in prepaid expenses and other current assets in the unaudited interim condensed consolidated balance sheets.

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

(in thousands)	**Term Facility**
2024 (remainder of the year)	$ 2,250
2025	3,000
2026	3,000
2027	285,000
Total	$ 293,250

The following table sets forth the components of total interest expense related to the Term Facility during the three months ended March 31, 2024 and 2023, as recognized in the accompanying unaudited interim condensed consolidated statements of operations for the three months ended March 31, 2024 and 2023:

	Three Months Ended	
(in thousands)	**March 31, 2024**	**March 31, 2023**
Contractual coupon	$ 6,913	$ 7,350
Amortization of finance fees	591	591
Capitalized interest	(112)	(21)
	$ 7,392	$ 7,920

5. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

In April 2020, the Company entered into an interest rate swap with Citizens Bank, N.A. to manage its exposure to changes in LIBOR-based interest rates underlying total borrowings under term facilities related to the Prior Credit Agreement, and the interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Agreement with Truist Bank, the interest rate swap with a notional value of $168.6 million at origin on November 21, 2021 was novated and Truist Bank is the new counterparty.

As described further below, the Company amended its Credit Agreement to transition from LIBOR to SOFR due to the cessation of LIBOR, and accordingly, the interest rate swap transitioned from LIBOR to SOFR. The swap is used to manage changes in SOFR-based interest rates underlying a portion of the borrowing under the Term Facility.

The interest rate swap provides an effective fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of March 31, 2024, the notional amount of the interest rate swap was $139.4 million and decreased quarterly by approximately $4.0 million until December 2023, after which it remains static until maturity in December 2026. As of March 31, 2024, the fair value of the interest rate swap asset recorded in other non-current assets in the unaudited interim condensed consolidated balance sheets was $7.7 million. As of March 31, 2024, $9.6 million was recorded in accumulated other comprehensive income, net of tax in the unaudited interim condensed consolidated balance sheets.

During the three months ended March 31, 2024, the gain on the fair value of the interest rate swaps, net of tax recorded in accumulated other comprehensive income in the unaudited interim condensed consolidated statements of comprehensive income was approximately $0.6 million. Differences between the hedged SOFR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Facility based on the SOFR rate. In the three months ended March 31, 2024 and 2023, $1.6 million of interest income and $0.5 million of interest expense was recognized in relation to the interest rate swaps. Included in this amount for the three months ended March 31, 2024 and 2023 are reclassifications out of accumulated other comprehensive income of $0.2 million of interest income and $ 0.7 million, respectively, related to terminated and de-designated cash flow hedges.

In conjunction with the amendment of the Credit Agreement (see note 4), the Company’s derivative positions automatically transitioned to SOFR, the designated fallback terms, as determined by the International Swaps and Derivatives Association on August 1, 2023. Concurrently, the Company updated its hedge documentation to reflect the change of the benchmark index, which changed solely as a result of reference rate reform. Under ASC 848, *Reference Rate Reform*, hedge accounting may continue without de-designation if certain criteria are met. For cash flow hedges in which the designated hedged risk is LIBOR (or another rate that is expected to be discontinued), the guidance allows an entity to assert that it remains probable that the hedged forecasted transaction will occur. The Company applied the optional expedient within ASC 848 to conclude the updates to the hedge relationship due to reference rate reform did not have a material impact on the Company's consolidated financial statements.

6. EARNINGS PER SHARE

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

For periods of net income, and when the effects are not anti-dilutive, diluted earnings per share is calculated by dividing net income available to common stockholders by the weighted-average number of shares outstanding plus the impact of all potential dilutive common shares, consisting primarily of common stock options, shares to be purchased under our Employee Stock Purchase Plan ("ESPP"), and performance stock units, using the more dilutive of the treasury stock or the two-class method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share.

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

Earnings per share for the three months ended March 31, 2024 and 2023 are calculated for basic and diluted earnings per share as follows:

	Basic		Diluted	
(in thousands, except per share amounts)	**Three Months Ended March 31,**		**Three Months Ended March 31,**	
	2024	**2023**	**2024**	**2023**
Net income available to common shareholders	$ 17,801	$ 1,033	$ 17,801	$ 1,033
Earnings allocated to participating securities	(1,805)	(113)	(1,778)	(113)
Net income available to common shareholders	$ 15,996	$ 920	$ 16,023	$ 920
Basic Weighted-Average Shares Outstanding	19,099	16,392	19,099	16,392
Dilutive effect of common stock options, ESPP, and performance stock units			323	139
Diluted Weighted-Average Shares Outstanding			19,422	16,531
Earnings per share	$ 0.84	$ 0.06	$ 0.82	$ 0.06

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, was 2.3 million for the three months ended March 31, 2024. The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings per share, was 2.6 million for the three months ended March 31, 2023.

7. INVENTORIES

Inventories consist of the following as of:

(in thousands)	**March 31, 2024**	**December 31, 2023**
Raw materials	$ 55,115	$ 62,237
Packaging materials	9,854	9,617
Work-in-progress	3,017	3,144
Finished goods	45,851	36,198
Inventories	$ 113,837	$ 111,196

Vendor Concentration

Raw materials are sourced for products, including active pharmaceutical ingredients ("API"), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the cost and time required to validate a second source of supply. As a result, the Company is dependent upon our current vendors to reliably supply the API required for on-going product man ufacturing. During the three months ended March 31, 2024, we purchased approximately 25% of our raw material inventory from one supplier. During the three months ended March 31, 2023, no single vendor represented more than 10% of our raw material inventory purchases.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of the 2013 merger with BioSante Pharmaceuticals, Inc. ("BioSante"), the Company recorded goodwill of $ 1.8 million. As a result of the acquisition of WellSpring Pharma Services Inc. in 2018, the Company recorded goodwill of $1.7 million. From the acquisition of Novitium in 2022, the Company recorded goodwill of $24.6 million. As of March 31, 2024, the Company has two operating segments, which were also deemed the Company's two reporting units, Generics, Established Brands, and Other reporting unit and the Rare Disease reporting unit. All of the goodwill is recorded in the Generics, Established Brands, and Other reporting unit.

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

Intangible Assets

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

	March 31, 2024			December 31, 2023			Remaining Weighted Average
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Amortization Period(1)
Definite-Lived Intangible Assets:							
Acquired ANDAs intangible assets	$ 209,780	$ (106,701)	$ 103,079	$ 209,780	$ (100,660)	$ 109,120	5.0 years
NDAs and product rights	244,871	(190,656)	54,215	244,871	(184,861)	60,010	3.0 years
Marketing and distribution rights	17,157	(14,512)	2,645	17,157	(14,271)	2,886	2.8 years
Customer relationships	24,900	(8,595)	16,305	24,900	(7,707)	17,193	4.6 years
Total Definite-Lived Intangible Assets	496,708	(320,464)	176,244	496,708	(307,499)	189,209	4.3 years
Indefinite-Lived Intangible Assets:							
In process research and development	19,800	—	19,800	19,800	—	19,800	Indefinite
Total Intangible Assets, net	$ 516,508	$ (320,464)	$ 196,044	$ 516,508	$ (307,499)	$ 209,009	

(1) Weighted average amortization period as of March 31, 2024.

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

Amortization expense for definite-lived intangibles was $13.0 million and $12.8 million for the three months ended March 31, 2024 and 2023, respectively.

No impairment losses were recognized in the three months ended March 31, 2024 and 2023.

Indefinite-lived intangible assets other than goodwill include primarily IPR&D projects. IPR&D intangible assets represent the fair value of technology acquired in a business combination or asset acquisition for which the technology projects are incomplete but have substance or alternative future use. When an IPR&D project is completed (generally upon receipt of regulatory approval), then the IPR&D will be accounted for as a definite-lived intangible asset.

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

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

(in thousands)		
2024 (remainder of the year)	$	37,862
2025		47,592
2026		34,107
2027		25,140
2028		18,359
2029 and thereafter		13,184
Total	$	176,244

9. MEZZANINE AND STOCKHOLDERS’ EQUITY

Stockholders’ Equity

Authorized shares

The Company is authorized to issue up to 33.3 million shares of common stock with a par value of $ 0.0001 per share, 0.8 million shares of class C special stock with a par value of $0.0001 per share, and 1.7 million shares of undesignated preferred stock with a par value of $ 0.0001 per share at March 31, 2024.

There were 21.4 million and 21.0 million shares of common stock issued and outstanding as of March 31, 2024, respectively, and 20.7 million and 20.5 million shares of common stock issued and outstanding as of December 31, 2023, respectively.

Class C Special Stock

There were 11 thousand shares of class C special stock issued and outstanding as of March 31, 2024 and December 31, 2023. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock is exchangeable, at the option of the holder, for one share of common stock, at an exchange price of $90.00 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of our assets upon liquidation, dissolution, or winding-up the Company.

The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption, or sinking fund rights.

Mezzanine Equity

PIPE Shares

Concurrently with the execution of the Merger Agreement, and as financing for a portion of the acquisition, on March 8, 2021, the Company entered into an Equity Commitment and Investment Agreement with Ampersand 2020 Limited Partnership (the "PIPE Investor"), pursuant to which the PIPE Investor purchased 25,000 shares of Series A Convertible Preferred Stock (the "PIPE Shares"), for a purchase price of $ 1,000 per share and an aggregate purchase price of $25.0 million on November 19, 2021. The PIPE Shares are classified as mezzanine equity because the shares are mandatorily redeemable for cash upon a change in control, an event that is not solely within the Company's control.

The PIPE Shares accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and will also participate, on a pro-rata basis, in any dividends that may be declared with respect to our common stock. The PIPE Shares are convertible into common shares at the conversion price of $41.47 (i) beginning two years after their issuance date, at the election of ANI (in which case the PIPE Investor must convert all of the PIPE Shares), if the volume-weighted average price of the common stock for any 20 trading days out of 30 consecutive trading days exceeds 170% of the conversion price, and (ii) at any time after issuance, at the election of the PIPE Investor. As of March 31, 2024, the PIPE shares are currently convertible into a maximum of 602,901 shares of common stock.

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

There were 25,000 shares of Series A convertible preferred stock outstanding as of March 31, 2024.

10. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. As of March 31, 2024, we had 0.1 million shares of common stock available under the ESPP. Under the ESPP, participants can purchase common shares of the Company's stock at a 15% discount on the lowest share price on the first day of the purchase period or the last day of the purchase period.

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

(in thousands)	Three Months Ended March 31,	
	2024	2023
Selling, general, and administrative	$ 139	$ 72
Cost of sales	30	12
Research and development	11	7
Total	$ 180	$ 91

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 its stockholders at the 2022 Annual Meeting of Stockholders (the “Annual Meeting”) held on April 27, 2022. During the 2023 Annual Meeting of Stockholders held on May 23, 2023, stockholders approved an amendment of the 2022 Plan (the “2023 Stock Plan Amendment”). The 2023 Stock Plan Amendment increased the shares authorized for issuance under the 2022 Plan by 750,000 additional shares. As of March 31, 2024, 0.4 million shares of common stock were available for issuance under the 2022 Plan.

Stock Options: Outstanding stock options to purchase shares of common stock are granted to employees and consultants generally vest over a period of four years and have 10-year contractual terms. Outstanding stock options granted to non-employee directors generally vest over a period of one to four years and have 10-year contractual terms.

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

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

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

Performance-Based Restricted Stock Units:

February 28, 2023 Performance-Based Restricted Stock Units Grant

Awards may also be issued in the form of Performance Stock Units (“PSUs”). PSUs represent the right to receive an amount of cash, a number of shares of common stock or a combination of both, contingent upon the achievement of specified performance objectives during a specified performance period. PSUs granted to date vest over a three-year performance period. On February 28, 2023, as part of the Company's equity compensation program, we granted PSUs to certain executives. Of these PSUs, 50% were market performance-based restricted stock units (“MPRSUs”), vesting of which is contingent upon the Company meeting certain total shareholder return (“TSR”) levels as compared to a select peer group over the over three years starting January 1, 2023. The MPRSUs are also subject to the recipient’s continued employment or service through December 31, 2025. The MPRSUs cliff vest at the end of the three-year period and have a maximum potential to vest at 200% (83,942 shares, net of forfeitures) based on TSR performance. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized straight-line over the vesting term. The estimated grant date fair value per share of the MPRSUs was $68.65 and was calculated using a Monte Carlo simulation model. These MPRSUs are included at 100% of the estimate number of shares at the end of the three-year performance period and are reflected under “Granted” in the table below.

The other 50% of the PSUs were performance based restricted stock units (“PRSUs”), vesting of which is contingent upon the Company meeting certain adjusted non-GAAP year-on-year EBITDA growth rates over the over three years starting January 1, 2023. The PRSUs are also subject to the recipient’s continued employment or service through December 31, 2025. The PRSUs cliff vest at the end of the three-year period and have a maximum potential to vest at 200% (83,942 shares, net of forfeitures) based on adjusted non-GAAP year-on-year EBITDA growth rates. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized straight-line over the vesting term. The Company analyzed progress on the performance goals to assess the likelihood of achievement. The estimated grant date fair value per share of the PRSUs was $41.84 based on the closing price of the stock on the date of grant. These PRSUs are included at 100% of the estimated number of shares at the end of the three-year performance period and are reflected under “Granted” in the table below.

February 14, 2024 Performance-Based Restricted Stock Units Grant

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

The estimated grant date fair value per share of the MPRSUs was $ 85.65 and was calculated using a Monte Carlo simulation model. These MPRSUs are included at 100% of the estimate number of shares at the end of the three-year performance period and are reflected under “Granted” in the table below.

The estimated grant date fair value per share of the PRSUs was $ 56.10 based on the closing price of the stock on the date of grant. These PRSUs are included at 100% of the estimated number of shares at the end of the three-year performance period and are reflected under “Granted” in the table below.

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

(in thousands)	**Three Months Ended March 31,**	
	2024	**2023**
Selling, general, and administrative	$ 6,232	$ 3,908
Research and development	272	200
Cost of sales	250	139
Total	$ 6,754	$ 4,247

A summary of stock option (including Inducement Grants), RSA, and PSU activity under the 2022 Plan and Inducement Grants during the three months ended March 31, 2024 and 2023 is presented below:

(in thousands)	Options	PSUs	RSAs
Outstanding at December 31, 2022	907	—	1,141
Granted	3	85	520
Options Exercised/RSAs Vested	(5)	—	(235) (1)
Forfeited	(16)	—	(28)
Expired	—	—	—
Outstanding at March 31, 2023	889	85	1,398
Outstanding at December 31, 2023	689	84	1,351
Granted	—	74	542
Options Exercised/RSAs Vested	(31)	—	(335) (2)
Forfeited	—	—	(5)
Expired	—	—	—
Outstanding at March 31, 2024	658	158	1,553

(1) Includes 85 thousand shares purchased from employees to cover employee income taxes related to income earned upon vesting of restricted stock. The shares purchased are held in treasury and the $3.5 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

(2) Includes 129 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 $8.7 million total purchase price for the shares is included in Treasury stock in our accompanying unaudited interim condensed consolidated balance sheets.

11. INCOME TAXES

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

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. As of March 31, 2024, a valuation allowance was recorded against consolidated net deferred tax assets of $0.4 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

The Company uses a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. The Company has not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements. The Company recognizes interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; the Company did not have any such amounts accrued as of March 31, 2024 and December 31, 2023. The Company is subject to taxation in various U.S. jurisdictions, Canada, and India and all of its income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

For interim periods, the Company recognizes an income tax expense (benefit) based on our estimated annual effective tax rate, calculated on a worldwide consolidated basis, expected for the entire year. The interim annual estimated effective tax rate is based on the statutory tax rates then in effect, as adjusted for estimated changes in estimated permanent differences and excludes certain discrete items whose tax effect, when material, are recognized in the interim period in which they occur. These changes in permanent differences and discrete items result in variances to the effective tax rate from period to period. The Company's estimated annual effective tax rate changes throughout the year as our on-going estimates of pre-tax income, and changes in permanent differences are revised, and as discrete items occur. Global Intangible Low-Taxed Income ("GILTI"), as defined in the Tax Cuts and Jobs Act of 2017, generated from our Canadian and Indian operations is subject to U.S. taxes, with certain defined exemptions, thresholds and credits. For financial reporting purposes the Company has elected to treat GILTI inclusions as a period cost.

For the three months ended March 31, 2024, the Company recognized a n income tax expense of $7.1 million. The Company's effective tax rate was 28.1% after discrete items f or the three months ended March 31, 2024. The effective tax rate differed from the federal statutory rate of 21% primarily due to state taxes, stock based compensation, tax on the sale of the Oakville, Ontario manufacturing site, and recording of a withholding tax liability on the proceeds of the sale.

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

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

12. COMMITMENTS AND CONTINGENCIES

Operating Leases

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

Government Regulation

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

Unapproved Products

Four products, Esterified Estrogens and Methyltestosterone ("EEMT"), Opium Tincture, Thyroid Tablets, and Hyoscyamine are marketed without approved NDAs or ANDAs. If the FDA took enforcement action against the Company, the Company may be required to seek FDA approval for the group of products or withdraw them from the market. During the three months ended March 31, 2024, net revenues from commercial sales of these products for these products totaled $4.1 million.

On December 27, 2023, the Company acquired from Alvogen, Inc. the rights to Hyoscyamine for total cash consideration of $ 2.0 million, which product was launched commercially in February 2024. Contract manufacturing revenues for Hyoscyamine, for three months ended March 31, 2024 and 2023 were $0.1 million and $0.6 million, respectively.

During the three months ended March 31, 2023, unapproved products consisted of only EEMT and Opium Tincture, and net revenues from these products totaled $3.7 million.

Legal proceedings

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

Some of these matters with which we are involved are described below and in our 2023 Form 10-K, and unless otherwise disclosed, we are unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. We record accruals for loss contingencies to the extent we conclude it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

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

Furthermore, like many pharmaceutical manufacturers, we are periodically exposed to product liability claims. The prevalence of these claims could limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial condition, and operating results. Recent trends in the product liability and director and officer insurance markets is to exclude matters related to certain classes of drugs. Our policies have been subject to such exclusions which place further potential risk of financial loss on us.
Legal fees for litigation-related matters are expensed as incurred and included in the condensed consolidated statements of operations under the selling, general, and administrative expense line item.

Commercial Litigation

On December 3, 2020, class action complaints were filed against the Company on behalf of putative classes of direct and indirect purchasers of the drug Bystolic. On December 23, 2020, six individual purchasers of Bystolic, CVS, Rite Aid, Walgreen, Kroger, Albertsons, and H-E-B, filed complaints against the Company. On March 15, 2021, the plaintiffs in these actions filed amended complaints. All amended complaints were substantively identical. The plaintiffs in these actions alleged that, beginning in 2012, Forest Laboratories, the manufacturer of Bystolic, entered into anticompetitive agreements when settling patent litigation related to Bystolic with seven potential manufacturers of a generic version of Bystolic: Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, Watson, and various of their corporate parents, successors, subsidiaries, and affiliates. ANI itself was not a party to patent litigation with Forest concerning Bystolic and did not settle patent litigation with Forest. The plaintiffs named the Company as a defendant based on the Company's January 8, 2020 Asset Purchase Agreement with Amerigen. Under the terms of the 2020 Asset Purchase Agreement, Amerigen agreed to indemnify ANI for certain liabilities relating to Bystolic, including liabilities that arose prior to closing of the asset purchase. The complaints alleged that the 2013 patent litigation settlement agreement between Forest and Amerigen violated federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs alleged they paid higher prices as a result of delayed generic competition. Plaintiffs sought damages, trebled or otherwise multiplied under applicable law, injunctive relief, litigation costs and attorneys' fees. The complaints did not specify the amount of damages sought from the Company or other defendants and the Company. The cases were consolidated in the United States District Court for the Southern District of New York as In re Bystolic Antitrust Litigation, Case No. 20-cv-005735 (LJL). On April 23, 2021, the Company and other defendants filed motions to dismiss the amended complaints. On January 24, 2022, the court dismissed all claims brought by the plaintiffs without prejudice. The court granted the plaintiffs until February 22, 2022 to file amended complaints, which were filed in federal court in the Southern District of New York, on that date. The newly amended complaints contained substantially similar claims. On April 19, 2022, the Company and other defendants filed motions to dismiss the newly amended complaints. After full briefing and oral argument, on February 21, 2023, the court granted the Company and the defendants' motion to dismiss all actions with prejudice. Plaintiffs filed an appeal in the Second Circuit. Oral arguments were held on December 6, 2023 and a decision from the court is pending. ANI continues to dispute any liability in this matter.

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

On March 5, 2024, a complaint was filed against ANI by Acella Pharmaceuticals, LLC, in the United States District Court of Minnesota, asserting, among other things, false advertising under the Lanham Act, and unfair trade practices and false advertising under Minnesota law, relating to ANI's natural desiccated thyroid tablets USP. The complaint seeks injunctive relief, actual and consequential damages, disgorgement of profits, and attorneys' fees and costs. On April 16, 2024, ANI filed an answer to Acella's complaint, denying all claims, and asserting certain affirmative defenses, and counterclaims against Acella for false advertising of its thyroid product marketed as NP Thyroid® Tablets, under the Lanham Act, common law unfair competition and unfair and deceptive trade practices and false advertising under Minnesota and Georgia law. ANI seeks injunctive relief, compensatory damages, punitive damages and attorneys' fees and costs. ANI disputes any liability in this matter and intends to defend this lawsuit vigorously.

Patent Litigation

On November 21, 2023, a complaint was filed against Novitium and certain other defendants in the case of Harmony Biosciences, LLC, Bioprojet Societe Civile de Recherche and Bioprojet Pharma SAS v. AET Pharma US, Inc., Annora Pharma Private Limited, Novitium Pharma LLC, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited in the United States District Court for the District of Delaware, asserting, among other things, that Novitium's proposed pitolisant hydrochloride drug product, which is subject to Novitium's Abbreviated New Drug Application No. 218495, infringes U.S. Patent Nos. 8,207,197, 8,354,430 and 8,486,947. The complaint seeks damages, injunctive relief, attorneys' fees and costs. On January 29, 2024, Novitium filed its answer, denying all allegations and asserting counterclaims of non-infringement and invalidity. On February 16, 2024, plaintiffs filed their answer, denying Novitium's counterclaims and asserting certain affirmative defenses against Novitium. On April 15, 2024, the court consolidated Novitium's case and two other cases brought by plaintiffs against Lupin Limited et al, and MSN Pharms. Inc. et al., into one consolidated matter filed in C.A. No. 23-1286-JLH. The court also set a trial date of February 2026. Novitium disputes any liability in this matter.

Ranitidine Related Litigation

Federal Court Multi District Litigation

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

ANI and Novitium dispute any liability in this matter.

State Court Personal Injury Litigation

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

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

Pennsylvania. In September 2022, two complaints were filed naming Novitium as a defendant in Pennsylvania state court, Philadelphia County. On February 16, 2023, the Pennsylvania plaintiffs filed a consolidated long-form complaint against the generic defendants, Plaintiffs v. Actavis, et. al. Civil Action No. 1364. The long-form complaint names Novitium as a defendant. The long form complaint asserts causes of action for negligence, failure to warn, negligent storage and transportation, breach of express warranties, breach of implied warranties, negligent misrepresentation, fraud, strict products liability, wrongful death and survivor actions, and loss of consortium. The complaint includes a prayer for punitive damages. The generic defendants filed their preliminary objections to Plaintiffs' consolidated long-form generic complaint on March 20, 2023. The court dismissed all claims related to failure to warn/design defects on preemption grounds. The court also sustained the generics' preliminary objections relating to the counts of strict liability-design defect and breach of implied warranty to the extent Pennsylvania substantive law applies, effectively dismissing the generic defendants from the case unless and until a non-resident plaintiff names a generic in a short form complaint. Out of an abundance of caution, however, the generics, including Novitium, all filed answers to the long form complaint in June 2023. In January 2024, plaintiffs filed short form complaints naming generic defendants, including Novitium in one complaint.

ANI and Novitium dispute any liability in these matters.

13. FAIR VALUE DISCLOSURES

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Facility bears an interest rate that fluctuates with the changes in SOFR and, because the variable interest rates approximate market borrowing rates available to us, we believe the carrying values of these borrowings approximated their fair values at March 31, 2024.

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

Money Market Funds

Money market funds are readily convertible into cash and the net asset value of each fund on the last day of the reporting period is used to determine its fair value. Money market funds are included in Cash and cash equivalents within the Consolidated Balance Sheet, and is classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. The Company does not adjust the quoted market price for such financial instruments. The fair value of the money market funds as of March 31, 2024 was approximately $174.3 million.

Interest Rate Swap

The fair value of the interest rate swap is estimated based on the present value of projected future cash flows using the SOFR forward rate curve (see Note 5). The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 5, the fair value of the interest rate swap was $7.7 million as of March 31, 2024, and was classified as a non-current asset.

CG Oncology Equity Securities

The Company currently holds 219,925 shares of common stock in CG Oncology (Nasdaq: CGON). The Company accounts for its investment in CG Oncology equity securities as an equity investment with a readily determinable fair value, as the securities are publicly traded on the NASDAQ. The fair value of the equity securities is based on its closing price on the NASDAQ and is classified within Level 1 of the fair value hierarchy because the equity securities are valued using quoted market prices. The Company does not adjust the quoted market price for such financial instruments. The fair value of the CG Oncology equity securities as of March 31, 2024 was approximately $9.7 million based on a closing market price of $43.90 on March 28, 2024. This amount is classified on the unaudited condensed consolidated statements of operations as Unrealized gain on investment in equity securities. Between 2013 and 2023, CG Oncology securities held by the Company were valued at zero under U.S. GAAP.

Contingent Consideration

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

The discounted cash flow method used to value this contingent consideration includes inputs which are classified as Level 3 inputs, as the inputs are not based on readily available market data.

Pursuant to the terms of the Agreement and Plan of Merger, dated as of March 8, 2021, on December 12, 2023, the Company paid $ 12.5 million of cash consideration to the Company Members, defined as the holders of Novitium ownership interests in the Agreement and Plan of Merger, as the holders of Novitium ownership interests, for the achievement of the "ANDA Filing Earn-Out," as defined in the Agreement (Note 14). Furthermore, on February 22, 2024, the Company paid $12.5 million to Company Members of Novitium upon the achievement of the "Gross Profit Earn-Out," as defined in the Agreement (Note 14).

The fair value of the contingent consideration was approximately $11.6 million and $24.0 million as of March 31, 2024 and December 31, 2023, respectively, and is reflected as a current and non-current accrued contingent consideration liability in the unaudited interim condensed consolidated balance sheets.

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

Payment Type	Valuation Technique	Unobservable Input	Assumptions
Profit-based milestone payments	Probability-weighted discounted cash flow	Discount rate	13.0%
		Projected fiscal year of payment	2025-2035
Product development-based milestone payments	Probability-weighted discounted cash flow	Discount rate	7.0% - 13.0%
		Probability of payment	100.0%
		Year of payment	2024

The following table presents the changes in contingent consideration balances classified as Level 3 for the three months ended March 31, 2024 and 2023:

	Three Months Ended March 31,	
(in thousands)	**2024**	**2023**
Beginning balance	$ 23,984	$ 35,058
Payment of Gross-Profit earn-out	(12,500)	—
Change in fair value	90	961
Ending balance	$ 11,574	$ 36,019

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

(in thousands) Description	Fair Value at March 31, 2024	Level 1	Level 2	Level 3
Assets				
Money Market Fund	$ 174,316	$ 174,316	$ —	$ —
Interest rate swap	$ 7,654	$ —	$ 7,654	$ —
CG Oncology - Investment in equity securities	$ 9,655	$ 9,655	$ —	$ —
Liabilities				
Contingent consideration	$ 11,574	$ —	$ —	$ 11,574

Description	Fair Value at December 31, 2023	Level 1	Level 2	Level 3
Assets				
Money Market Fund	$ 194,841	$ 194,841	$ —	$ —
Interest rate swap	$ 6,236	$ —	$ 6,236	$ —
Liabilities				
Contingent consideration	$ 23,984	$ —	$ —	$ 23,984

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

There are no financial assets or liabilities that are measured at fair value on a non-recurring basis.

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

There are no non-financial assets or liabilities that are measured at fair value on a recurring basis.

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

Long-lived assets, including property, plant, and equipment, right-of-use (“ROU”) assets, intangible assets, and goodwill, are measured at fair value on a non-recurring basis, and no such fair value impairment was recognized in the three months ended March 31, 2024 and 2023.

14. RELATED PARTY TRANSACTIONS

PIPE Shares

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

Novitium

In connection with the acquisition of Novitium, the Company entered into employment agreements with the two executives and founders of Novitium, Muthusamy Shanmugam, Head of R&D and COO of NJ Operations of ANI, and Chad Gassert, Sr. Vice President, Corporate Development and Strategy of ANI. Both serve as executive officers of the Company and Mr. Shanmugam also serves on the Company's board of directors. Mr. Shanmugam holds a minority interest in Scitus Pharma Services (“Scitus”), which provides clinical research services to Novitium, a majority interest in SS Pharma LLC (“SS Pharma”), which acquires and supplies API to Novitium, a minority interest in Nuray Chemical Private Limited (“Nuray”), which manufactured and supplied API to Novitium in prior periods, and a minority interest in SThree Chemicals Pvt Ltd (“SThree”), which acquires and supplies API to Novitium.

A summary of payments to related parties is presented below:

	Three Months Ended March 31,	
	2024	2023
Scitus Pharma Services	$ 501	$ 717
SS Pharma LLC	1,069	1,601
SThree Chemicals Pvt Ltd	386	—
	$ 1,956	$ 2,318

As of March 31, 2024, the outstanding balances due to Scitus, SS Pharma, and SThree were $ 0.4 million, $0.2 million, and $0.3 million respectively.

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

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

15. SEGMENT REPORTING

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

- **Generics, Established Brands, and Other** – Consists of operations related to the development, manufacturing, and marketing of generic and established brand pharmaceuticals, including those sold through traditional channels, contract manufactured products, product development services, royalties, and other.
- **Rare Disease** – Consists of operations related to the development, manufacturing and marketing of pharmaceuticals used in the treatment of patients with rare conditions. The rare disease segment currently consists of operations related to Cortrophin Gel.

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

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

Financial information by reportable segment is as follows:

(in thousands)	Three Months Ended March 31, 2024	2023
Net Revenues		
Generics, Established Brands, and Other	$ 100,493	$ 90,456
Rare Disease	36,937	16,330
Total net revenues	$ 137,430	$ 106,786
Segment earnings before interest, taxes, depreciation and amortization ("EBITDA") and reconciliation to income before income taxes		
Generics, Established Brands, and Other	$ 45,306	$ 38,828
Rare Disease	396	(1,251)
Depreciation and amortization	(14,686)	(14,700)
Corporate and other unallocated expenses [1]	(10,704)	(12,982)
Total operating income	20,312	9,895
Unrealized gain on investment in equity securities	9,655	—
Interest expense, net	(4,600)	(7,696)
Other expense, net	(32)	(34)
Income Before Income Tax Expense	$ 25,335	$ 2,165

[1] Includes expenses not directly allocated or attributable to a reporting segment, including certain management, legal, accounting, human resources, insurance, and information technology expenses, and are included in selling, general, and administrative expenses in our unaudited interim consolidated statement of operations. This amount also includes the gain on the sale of the Oakville, Ontario site, refer to Note 3 for further information.

Geographic Information

Operations are currently located in the United States and India. The Company has ceased operations at our Oakville, Ontario, Canada location as of March 31, 2023. The majority of the assets of the Company are located in the United States.

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

(in thousands)	Three Months Ended March 31,
Location of Operations	**2024**	**2023**
United States	$ 137,430	$ 106,221
Canada	—	565
Total Revenue	$ 137,430	$ 106,786

The following table depicts the Company's property, plant and equipment, net according to geographic location, which excludes the land and building at the Company's Canada facility, which was classified as held for sale as of December 31, 2023. These assets had a carrying value of approximately $8.0 million. The land and building at the Canada facility was sold on March 28, 2024, refer to Note 3. The Company's property, plant and equipment are as follows:

(in thousands)	March 31, 2024	December 31, 2023
United States	$ 46,905	$ 43,163
India	1,621	1,430
Total property and equipment, net	$ 48,526	$ 44,593

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following Management's Discussion and Analysis of Financial Condition and Results of Operations should be read in conjunction with the unaudited interim condensed consolidated financial statements and the accompanying notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, the audited consolidated financial statements and the accompanying notes thereto in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (the "2023 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 2023 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 2023 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 scaling up our Rare Disease business through the launch of our lead asset, Cortrophin Gel, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our U.S.-based manufacturing capabilities. Our three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, and one is located in East Windsor, New Jersey, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. We ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. We have fully completed the transition of the products manufactured or packaged in Oakville to one of our three U.S. based manufacturing sites. In February 2024, our Canadian subsidiary entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of $19.2 million Canadian Dollars, or approximately $14.2 million, based on the current exchange rate. The sale closed on March 28, 2024 (see Note 3).

Strategy

Our objective is to build a sustainable and growing biopharmaceutical company serving patients in need and creating long-term value for our investors. Our overall strategy is enabled by an empowered, collaborative, and purposeful team with high performance-orientation, Serving Patients, Improving Lives.

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

Building a successful Rare Disease platform

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

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

During 2021 and 2022, we invested significantly in leadership, expertise and infrastructure in the areas of commercialization of rare disease therapies and developed a launch strategy and commercial plan for this product. During this timeframe, we hired a significant number of new employees and assembled and trained our Rare Disease field force. On January 24, 2022, we announced the commercial launch of Cortrophin Gel in the U.S as our foundational Rare Disease asset.

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

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

Strengthening our Generics, Established Brands, and Other segment through continued investment in our generic research and development capability and increased focus on niche opportunities

We have grown our generics business through a combination of market share gains on existing products and new product launches. We have also successfully acquired numerous ANDAs through business and asset acquisitions. Our most recent business acquisition was Novitium, including its portfolio of commercial and pipeline generic products, manufacturing and development facilities and expert workforce. The Novitium acquisition significantly increased our generic pharmaceutical research and development and manufacturing capabilities. We have begun to increase our focus on niche lower competition opportunities such as injectables, Paragraph IV, and competitive generic therapy ("CGT") designation filings. Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses. During 2022, we completed an asset acquisition of four ANDAs from Oakrum Pharma, including two that were commercial at the time of acquisition. During 2023, we acquired two ANDAs and one pipeline product from the Chapter 7 Trustee for the estates of Akorn Holding Company and certain of its affiliates, acquired an ANDA and registered patents and pending patent applications from Slayback Pharma Limited Liability Company, and acquired additional ANDAs and product rights for two products in the second half of 2023.

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

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

Generic Product Development Considerations

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

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

Recent Developments

Restructuring

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

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

Product Launches

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

GENERAL

Impacts to our first quarter 2024 and 2023 results of operations, including to net revenues, operating expenses, interest and other expense, net, and income taxes are described below.

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

	Three Months Ended March 31,	
(in thousands)	**2024**	**2023**
Net Revenues	$ 137,430	$ 106,786
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	49,157	37,708
Research and development	10,511	5,924
Selling, general, and administrative	48,021	36,468
Depreciation and amortization	14,686	14,700
Contingent consideration fair value adjustment	90	961
Restructuring activities	—	1,130
Gain on sale of building	(5,347)	—
Operating Income	20,312	9,895
Unrealized gain on investment in equity securities	9,655	—
Interest expense, net	(4,600)	(7,696)
Other expense, net	(32)	(34)
Income Before Income Tax Expense	25,335	2,165
Income tax expense	7,128	726
Net Income	$ 18,207	$ 1,439

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

	Three Months Ended March 31,	
	2024	2023
Net Revenues	100 %	100 %
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	35.8 %	35.3 %
Research and development	7.6 %	5.5 %
Selling, general, and administrative	34.9 %	34.2 %
Depreciation and amortization	10.7 %	13.8 %
Contingent consideration fair value adjustment	0.1 %	0.9 %
Restructuring activities	— %	1.1 %
Gain on sale of building	(3.9)%	— %
Operating Income	14.8 %	9.2 %
Unrealized gain on investment in equity securities	7.0 %	— %
Interest expense, net	(3.3)%	(7.2)%
Other expense, net	(0.0)%	(0.0)%
Income Before Income Tax Expense	18.5 %	2.0 %
Income tax expense	5.2 %	0.7 %
Net Income	13.3 %	1.3 %

RESULTS OF OPERATIONS FOR THE THREE MONTHS ENDED MARCH 31, 2024 AND 2023

Net Revenues

(in thousands)	Three Months Ended March 31, 2024	2023	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 70,217	$ 63,713	$ 6,504	10.2 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	30,276	26,743	3,533	13.2 %
Generics, established brands, and other segment total net revenues	$ 100,493	$ 90,456	$ 10,037	11.1 %
Rare Disease Segment				
Rare disease pharmaceutical products	$ 36,937	$ 16,330	$ 20,607	126.2 %
Total net revenues	$ 137,430	$ 106,786	$ 30,644	28.7 %

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

Net revenues for the three months ended March 31, 2024 were $137.4 million compared to $106.8 million for the same period in 2023, an increase of 28.7%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $70.2 million during the three months ended March 31, 2024, an increase of 10.2% compared to $63.7 million for the same period in 2023, driven by increased volumes on the base business and the inclusion of 2023 launches and new product launches in 2024. From a product perspective, the increase was principally driven by revenues from year over year increases in products such as Colestipol, Nitrofurantoin, Lacosamide, and various other products tempered by a decrease in revenues of Meloxicam, Nebivolol, and Famotidine, among others.
- Net revenues for branded pharmaceutical products, royalties, and other pharmaceutical services were $30.3 million during the three months ended March 31, 2024, an increase of 13.2% compared to $26.7 million for the same period in 2023, driven by a net increase in volume.
- Net revenues of rare disease pharmaceutical products, which consists entirely of sales of Cortrophin Gel, were $36.9 million during the three months ended March 31, 2024, an increase of $20.6 million from $16.3 million for the same period in 2023. This increase was driven by increased volume in this third year of launch (product was launched in late January 2022).

In addition to the above, within our Generics, Established Brand, and Other segment, from time to time we have been successful in supplying incremental volume in markets that were experiencing supply chain disruptions for competing products. This factor favorably impacted the established brand portion of the segment in the current year period as compared to favorably impacting both the generic and established brand portion of the segment in the prior year period. Generally, when opportunities for volume and revenue upside related to our products arise in the marketplace, there is no assurance as to how long these favorable market conditions may persist.

Cost of Sales (Excluding Depreciation and Amortization)

(in thousands)	Three Months Ended March 31, 2024	2023	Change	% Change
Cost of sales (excluding depreciation and amortization)	$ 49,157	$ 37,708	$ 11,449	30.4 %

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

For the three months ended March 31, 2024, cost of sales increased to $49.2 million from $37.7 million for the same period in 2023, an increase of $11.4 million, or 30.4%. The increase is primarily due to a net increase in sales volumes of pharmaceutical products across all segments and a significant net increase in sales of products that bear a royalty payable, including Cortrophin Gel.

Cost of sales, as a percentage of net revenues, increased slightly from 35.3% to 35.8% for the three months ended March 31, 2024, compared to the same period in 2023, primarily due to a shift in product mix year over year.

During the three months ended March 31, 2024, we purchased approximately 25% of our raw material inventory from one supplier. During the three months ended March 31, 2023, no single vendor represented more than 10% of our raw material inventory purchases.

Other Operating Expenses, net

(in thousands)	Three Months Ended March 31, 2024	2023	Change	% Change
Research and development	$ 10,511	$ 5,924	$ 4,587	77.4 %
Selling, general, and administrative	48,021	36,468	11,553	31.7 %
Depreciation and amortization	14,686	14,700	(14)	(0.1)%
Contingent consideration fair value adjustment	90	961	(871)	(90.6)%
Restructuring activities	—	1,130	(1,130)	(100.0)%
Gain on sale of building	(5,347)	—	(5,347)	100.0 %
Total other operating expenses, net	$ 67,961	$ 59,183	$ 8,778	14.8 %

For the three months ended March 31, 2024 , other operating expenses, net increased to $68.0 million from $59.2 million for the same period in 2023, an increase of $8.8 million, or 14.8%, primarily as a result of the following factors:

- Research and development expenses increased from $5.9 million to $10.5 million, an increase of $4.6 million or 77.4%, primarily due to expenses related to a FDA filing fee for a 505(b)(2) for one product of approximately $2.0 million, and a higher level of activity associated with ongoing and new projects in the three months ended March 31, 2024.
- Selling, general, and administrative expenses increased from $36.5 million to $48.0 million, an increase of $11.6 million, or 31.7%, due to increased employment related costs, continued investment in our Rare Disease segment sales and marketing activities, legal expenses, as well as an overall increase in activities required to support the growth of our business.
- Depreciation and amortization expense was $14.7 million for the three months ended March 31, 2024 , compared to $14.7 million for the same period in 2023, a nominal decrease of approximately $14.0 thousand year-over-year.

- We recognized losses of $0.1 million and $1.0 million in the three months ended March 31, 2024 and 2023, respectively, for the contingent consideration fair value adjustment. The change in the fair value adjustment during the three months ended March 31, 2024 is primarily related to changes in the anticipated timing of cash flows (i.e., moving closer to the anticipated payment dates of the consideration for the third milestone) and fluctuations in the discount rates, offset by adjustments recorded upon payment of the Gross Profit Earn-Out during the first quarter. Additionally, the fair value measurement adjustment in the three months ended March 31, 2024 is related to only the third milestone, whereas the fair value adjustment at March 31, 2023 related to all three milestones.
- We recognized restructuring activities expenses of $1.1 million in the three months ended March 31, 2023. In 2023 costs included severance and other employee benefits costs of $0.2 million, $0.7 million of accelerated depreciation costs and $0.2 million for other miscellaneous costs accrued in 2022. There were no restructuring expenses recognized in the three months ended March 31, 2024.
- We recognized a gain related to the sale of the former Oakville, Ontario manufacturing site of approximately $5.3 million during the three months ended March 31, 2024. There was no comparable sale in the three months ended March 31, 2023.

Other Income (Expense), net

	Three Months Ended March 31,			
(in thousands)	2024	2023	Change	% Change
Unrealized gain on investment in equity securities	$ 9,655	$ —	$ 9,655	(100.0)%
Interest expense, net	(4,600)	(7,696)	3,096	(40.2)%
Other expense, net	(32)	(34)	2	(5.9)%
Total other income (expense), net	$ 5,023	$ (7,730)	$ 12,753	(165.0)%

For the three months ended March 31, 2024, we recognized total other income of $5.0 million as compared to total other expense of $7.7 million for the same period in 2023, an increase of $12.8 million.

The increase in Unrealized gain on investment in equity securities of approximately $9.7 million is due to the recognition of our investment of CG Oncology upon their January 2024 IPO and the subsequent mark to market to fair value of equity securities held in CG Oncology as of the balance sheet date. There was no comparable gain on investment in the three months ended March 31, 2023.

Interest expense, net for the three months ended March 31, 2024 consists primarily of interest expense on borrowings under our Term Facility of approximately $8.5 million and amortization of deferred debt issuance costs of approximately $0.6 million, offset by dividend income earned on our money market funds and interest earned on our cash balances of approximately $2.8 million, the effects of the interest rate swap of approximately $1.6 million, and interest capitalized into construction in progress. The decrease in interest expense is primarily related to the increase in the dividend income and interest income earned on our larger cash balances during the current period, as interest expense on borrowing under our Term Facility and amortization of deferred debt issuance costs are consistent with the three months ended March 31, 2023.

Income Tax Expense

(in thousands)	Three Months Ended March 31, 2024	2023	Change	% Change
Income tax expense	$ 7,128	$ 726	$ 6,402	881.8 %

Income tax expense consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance.

For the three months ended March 31, 2024 , we recognized an income tax expense of $7.1 million. The Company's effective tax rate was 28.1% after discrete items for the three months ended March 31, 2024 . The effective tax rate differed from the federal statutory rate of 21% primarily due to state taxes, stock based compensation, tax on the sale of the Oakville, Ontario manufacturing site, and recording of a withholding tax liability on the proceeds of the sale.

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

LIQUIDITY AND CAPITAL RESOURCES

Debt Financing

On November 19, 2021, the Company, as borrower, entered into a credit agreement (the "Credit Agreement") with Truist Bank and other lenders, which provides for credit facilities consisting of (i) a senior secured term loan facility in an aggregate principal amount of $300.0 million (the "Term Facility") and (ii) a senior secured revolving credit facility in an aggregate commitment amount of $40.0 million, which may be used for revolving credit loans, swingline loans and letters of credit (the "Revolving Facility," and together with the Term Facility, the "Credit Facility"). The Credit Facility is secured by substantially all our assets and the assets of our domestic subsidiaries. As of March 31, 2024, $3.0 million of principal of the loan was recorded as current borrowings in the condensed consolidated balance sheet. As of March 31, 2024, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

Equity Financing

In May 2023, through a public offering, we completed the issuance and sale of 2,183,545 shares of ANI common stock, resulting in net proceeds after issuance costs of $80.6 million. The proceeds are intended to be used to in-license, acquire or invest in additional businesses, technologies, products or assets, to fund our commercialization efforts, including, but not limited to, sales and marketing and consulting expenses related thereto, and for general corporate purposes.

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

Cash Flows

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

	Three Months Ended March 31,	
(in thousands)	**2024**	**2023**
Operating Activities	$ 18,269	$ 21,424
Investing Activities	$ 8,933	$ (2,353)
Financing Activities	$ (19,726)	$ (4,548)

Net Cash Provided by Operations

Net cash provided by operating activities was $18.3 million for the three months ended March 31, 2024, compared to net cash provided by operating activities of $21.4 million during the same period in 2023, a change of $3.2 million. The decrease in cash provided by operating activities was driven by net income in the current year period due to increased sales and gross profit offset by non-recurring transactions such as gain on the sale of the Oakville, Ontario manufacturing site, the gain on investment of equity securities as well as significant fluctuations in our assets and liabilities due to increased activities.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the three months ended March 31, 2024 was $8.9 million, principally due to the proceeds received from the sale of the Oakville, Ontario manufacturing site in March 2024 of approximately $13.5 million offset by capital expenditures of approximately $4.6 million. Net cash used in investing activities for the three months ended March 31, 2023 was $2.4 million, principally due to $2.3 million of capital expenditures.

Net Cash Used in F inancing Activities

Net cash used in financing activities for the three months ended March 31, 2024 was $19.7 million, principally resulting from $12.5 million paid to the Company Members of Novitium, $8.7 million of treasury stock purchased related to restricted stock vests, $0.8 million maturity payments on the Term Facility, and $0.4 million convertible preferred stock dividends paid, offset by $2.6 million from proceeds from stock option exercises and ESPP purchases. Net cash used in financing activities for the three months ended March 31, 2023 was $4.5 million, primarily resulting from $3.5 million of treasury stock purchased in relation to restricted stock vests, $0.8 million maturity payments on the Term Facility, and $0.4 million convertible preferred stock dividends paid.

CRITICAL ACCOUNTING ESTIMATES

A summary of our significant accounting policies is included in Part II, Item 8. Consolidated Financial Statements, Note 1, *Description of Business and Summary of Significant Accounting Policies*, in our Annual Report on Form 10-K for the year ended December 31, 2023. Certain of our accounting policies are considered critical, as these policies require significant, difficult or complex judgments by management, often requiring the use of estimates about the effects of matters that are inherently uncertain. There have been no material changes to our critical accounting estimates since the 2023 Form 10-K.

CONTRACTUAL OBLIGATIONS

As of March 31, 2024, our contractual obligations have not changed materially from the amounts reported in our 2023 Form 10-K.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of March 31, 2024. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were effective at the reasonable assurance level. In designing and evaluating our disclosure controls and procedures, we recognize that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, during the quarter ended March 31, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Part II — OTHER INFORMATION

Item 1. Legal Proceedings

Please refer to Note 12, *Commitments and Contingencies*, in the unaudited interim condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q, which is incorporated into this item by reference.

Item 1A. Risk Factors

In addition to the other information set forth in this report, please carefully consider the factors described under the heading “Risk Factors” in our most recent Annual Report on Form 10-K for the fiscal year ended December 31, 2023 in Part I, Item 1A. The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that our management currently deems to be immaterial, also may adversely affect our business, financial condition, and/or operating results.

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

Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

There were no repurchases of equity securities pursuant to a repurchase plan or program during the three months ended March 31, 2024.

Period	Total Number of Shares Purchased(1)	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or approximate dollar value) of Shares that may yet be Purchased Under the Plans or Programs
January 1 - January 31, 2024	3,320	$ 56.74	—	$ —
February 1 - February 29, 2024	49,066	$ 66.47	—	$ —
March 1 - March 31, 2024	76,630	$ 68.00	—	$ —
Total	129,016	$ 67.13	—	

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

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Our directors and executive officers may from time to time enter into plans or other arrangements for the purchase or sale of our common stock that are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or may represent a non-Rule 10b5-1 trading arrangement under the Exchange Act. During the quarter ended March 31, 2024, no such plans or other arrangements were adopted or terminated.

Item 6. Exhibits

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

INDEX TO EXHIBITS

Exhibit No.	Description
10.1	Assignment and Technology Transfer Agreement between Bio Sante Pharmaceuticals, Inc. and Cold Genesys , Inc., dated as of November 15, 2010
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, Rule 13(a)-14(a)/15d-14(a).
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following financial information from this quarterly report on Form 10-Q for the fiscal quarter ended March 31, 2024 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).

*In accordance with SEC Release 33-8238, Exhibit 32.1 is being furnished and not filed.

SIGNATURES

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

ANI Pharmaceuticals, Inc. (Registrant)

Date: May 10, 2024

By: /s/ Nikhil Lalwani

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

Date: May 10, 2024

By: /s/ Stephen P. Carey

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

Exhibit 10.1

[***] Certain information contained in this document has been omitted based on a court order.

ASSIGNMENT AND TECHNOLOGY TRANSFER AGREEMENT
between

BIOSANTE PHARMACEUTICALS, INC.

and

COLD GENESYS, INC.

Dated as of November 15, 2010

ASSIGNMENT AND TECHNOLOGY TRANSFER AGREEMENT

This Assignment and Technology Transfer Agreement ("Agreement") is by and between BioSante Pharmaceuticals, Inc., organized and existing under the laws of Delaware doing business at 111 Barclay Boulevard, Suite 280, Lincolnshire, Il 60069 ("BioSante"), and Cold Genesys, Inc. organized and existing under the laws of California doing business at 2 Narbonne, Newport Beach, Ca 92660 ("Cold Genesys"). (BioSante and Cold Genesys are hereinafter also individually referred to as "Party" and collectively referred to as the "Parties").

RECITALS

WHEREAS, BioSante owns certain targeted oncolytic virus technology (OVT), including its targeted CG0070 adenovirus clinical program;

WHEREAS, BioSante and BioValley International, Inc. entered into a Confidential Disclosure Agreement, dated February 3, 2010 related to the targeted OVT technology;

WHEREAS, BioSante and BioValley International, Inc. entered into a Non-binding Memorandum of Understanding, effective June 23, 2010, to memorialize in writing certain terms and conditions in a MOU to assist BioValley International, Inc in seeking potential corporate partners and or any necessary financing to acquire the BioSante Technology;

WHEREAS, BioValley International Inc. assigned its entire right, title and interest under the MOU to Cold Genesys on October 7, 2010;

WHEREAS, Cold Genesys wishes to acquire the entire right, title and interest to BioSante's targeted OVT technology;

WHEREAS, the Parties now wish to enter into a definitive agreement to memorialize the sale of the OVT technology to Cold Genesys, and

THEREFORE, in consideration of the mutual promises, covenants and agreements set forth herein, and for other good and valuable consideration, the receipt and adequacy of which is hereby acknowledged, the Parties agree as follows:

ARTICLE 1

DEFINITIONS

1.1 Definitions. The following terms, as used in this Agreement, have the following meanings. All other capitalized terms used herein shall have the meaning as provided in the body of this Agreement:

"Acquisition Fee" shall have the meaning as indicated in Section 3.1(a).

"Affiliate" means, with respect to any Person, any other Person that, directly or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control

with, such Person, and the term “control” (including the terms “controlled by” and “under common control with”) means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of such Person, whether through ownership of voting securities, by contract or otherwise.

“BioSante BioMaterials” means all CG0070-related biological reagents owned by BioSante listed in Appendix A, which includes any GMP viral stocks, Master Cell Banks, Master Viral Stocks, production vectors, any and all OVT-related chemical compounds and formulations, chemical or biological solutions, gene, nucleic acid or amino acid sequence information, genetic or protein libraries, DNA, RNA, proteins, enzymes, antibodies, probes, plasmids, vectors, expression vectors and systems, cells, cell lines, cell banks, cell cultures, transformed hosts, tissues and other biological materials or information pertaining thereto together with any and all progeny, mutants and replications of such materials, and any and all constituents and derivatives of such materials, software, designs, formulae, procedures, methods, screening and selection processes and technologies, assays, analytical tests, techniques, ideas, know-how, research and development and technical data, programs, tools, specifications, processes, apparatus currently in BioSante’s possession.

“BioSante Documentation” means all clinical, regulatory, and manufacturing documentation owned by BioSante related to the preclinical and clinical development for CG0070 listed in Appendix B, including any IND filing, case report forms (CRFs), and Certificates of Analysis for reagents, recordings, graphs, drawings, reports, analyses, and other writings describing or embodying the above (whether in tangible or electronic form) currently in BioSante’s possession.

“BioSante Know-how” means the rights associated with trade secrets, know-how and all other rights in or to confidential business or technical information related to the CG0700 development program currently in BioSante’s possession.

“BioSante Patents” means the patent and patent applications listed in Appendix C and if not listed in Appendix C, should include all patents and patent applications held by BioSante related to CG0070 and OVT-related chemical compounds, if any, and including any continuations, continuations-in-part, divisionals, substitutions, reissues, renewals, extensions or modifications for any of the foregoing, and all foreign counterparts thereof.

“BioSante Technology” means the BioSante BioMaterials, the BioSante Documentation, BioSante Know-how and the BioSante Patents.

“Disclosing, Party” shall have the meaning as indicated in Section 5.1

“Effective Date” of this Agreement means the date the last Party hereto executed the Agreement.

“Governmental Authority” means any federal, national, supranational, state, provincial, local or other government, governmental, regulatory or administrative authority, agency or commission or any court, tribunal, or judicial or arbitral body of competent jurisdiction.

"Indemnitees" shall have the meaning as indicated in Section 6.3.

"Licensed Field" means the use and sale of oncolytic adenoviral products incorporating the BioSante Technology for any and all indications, including cancer.

"Liens" means any security interest, pledge, hypothecation, mortgage, lien, encumbrance, other than any assignment of license of the BioSante Patents.

"Net Sales" shall mean gross sales revenues and fees billed by Cold Genesys, its Affiliates or Sublicensees from the sale of Licensed Products less (i) trade discounts allowed, refunds, returns and recalls, (ii) sales taxes and other governmental charges and duties (including value added tax) actually paid, and (iii) provisions for uncollectible accounts determined in accordance with generally accepted accounting principles, consistently applied to all products of the selling party. Except as set forth in Section 4.6, in the event that Cold Genesys or any of its Affiliates or Sublicensees sells a Licensed Product in combination with another drug as part of a combination product (as such drug is defined in the marketing application to the FDA), the Net Sales for purposes of royalty payments shall be calculated by multiplying the Net Sales of that combination by the fraction A/A+B, where A is Company's then gross selling price of the Licensed Product sold separately and B is the lowest, then-current fair market gross selling price of the other drug sold separately, provided that no deduction shall be made for costs for drugs not defined in the marketing application, provided further that in no event shall the Net Sales be reduced below an amount equal to the product of the number of combinations sold multiplied by Cold Genesys's then selling price for the Licensed Product if sold on a stand-alone basis, and provided further that any drug that is not an FDA-approved, therapeutically active, stand-alone product (even if noted in the marketing application) in its own right shall be disregarded in respect to this definition.

"OVT Products" means CG0700, any derivatives thereof and any product whose manufacture, use or sale would, but for the assignment to be granted under Section 2.1 of this Agreement, infringe a Valid Claim of a BioSante Patent.

"Person" means any individual, corporation, partnership, firm, joint venture, association, joint-stock company, limited liability company, limited liability partnership, labor union, trust, unincorporated organization, governmental body or other entity.

"Phase 2 Clinical Trial" shall mean a human clinical trial conducted in patients and designed to indicate a statistically significant level of efficacy for a product in a desired indication, as well as to obtain some information of the dosage regimen required, in accordance with 21 C.F.R. 312.21(b) as may be amended from time to time, or any foreign equivalent thereof

"Proprietary Information" shall have the meaning as indicated in Section 5.11

"Receiving Party" shall have the meaning as indicated in Section 5.1.

"Reimbursement Payment" shall have the meaning as indicated in Section 3.1(b).

"Subscription Agreement" shall have the meaning as indicated in Section 3.6.

"Sublicensee" means any third party (other than an Affiliate) to whom Cold Genesys has granted the right to develop, manufacture and sell Licensed Products, with respect to Licensed Products made and sold by such third party.

"Sublicensing Fees" means any amounts received, whether in cash, equity, credit, or other property or combination thereof, related to granting a license or sublicense, or sale of the BioSante Technology to a third party to develop OVT Products.

"Territory" means worldwide.

"Taxes" shall have the meaning as indicated in Section 3.7.

"Third Party" means any Person other than a Party or their respective Affiliates.

"Valid Claim" shall mean a claim of an issued or unexpired patent which has not been held unpatentable, invalid or unenforceable by a court or other governmental agency of competent jurisdiction and has not been admitted to be invalid or unenforceable through re-issue, re-examination or disclaimer.

ARTICLE II

ASSIGNMENT AND TRANSFER OF RIGHTS AND TECHNOLOGY

2.1 Assignment of Intellectual Property Rights and BioSante Technology. Subject to the terms and conditions of this Agreement (including without limitation full payment under Article III), BioSante, on behalf of itself and its Affiliates, hereby sells, assigns and transfers to Cold Genesys all entire right title and interest and to the BioSante Patents and the BioSante Know-how.

2.2 Patent Assignment Agreement. Contemporaneously with the execution of this Agreement, the Parties shall execute a "Patent Assignment Agreement" in a form substantially similar to that attached hereto as Exhibit I to document the transfer of the BioSante Patents. Cold Genesys shall have sole responsibility, at its sole cost and expense, to file the Patent Assignment Agreement and any forms or documents as required to record the assignment of the BioSante Patents from BioSante to Cold Genesys with the United States Patent & Trademark Office and any applicable foreign equivalents. As of the Effective Date, as between the Parties, Cold Genesys shall be solely responsible for maintaining (including prosecution and payment of all fees) and enforcing the assigned BioSante Patents.

2.3 Transfer of the Ownership of BioSante BioMaterials and BioSante Documentation. In connection with the assignment above in Section 2.1, BioSante shall provide and/or deliver to Cold Genesys:

(a) BioSante BioMaterials. On the Effective Date, BioSante shall transfer the ownership of, at Cold Genesys's sole cost and expense, the BioSante BioMaterials to a location of Cold Genesys's choice. As of the Effective Date, as between the Parties, Cold Genesys shall be solely responsible for controlling, maintaining and storing the BioSante BioMaterials at its sole cost and expense. Upon Cold Genesys's written request, BioSante agrees to temporarily maintain the BioSante BioMaterials at its present location, Pacific BioMaterials Management, Inc. in Fresno, Ca, on behalf of Cold Genesys, and at Cold Genesys's sole cost and expense, at the current rate of four hundred and seventy five US dollars ($475) per month for up to a period of three (3) months.

(b) BioSante Documentation. On the Effective Date, BioSante shall transfer the ownership of, to Cold Genesys, at Cold Genesys's sole cost and expense, the BioSante Documentation to a location of Cold Genesys's choice. As of the Effective Date, as between the Parties, Cold Genesys shall be solely responsible for controlling, maintaining and storing the BioSante Documentation at its sole cost and expense.

(c) BioSante Patents. Within ten (10) business days after the Effective Date, BioSante agrees to provide to Cold Genesys: (a) copies of all of its patent files of the patents and of the pending patent applications constituting BioSante Patents and the names and addresses of counsel who are currently involved in the prosecution thereof, and (b) copies of other relevant documents, if any, in BioSante's possession that relate to the BioSante Patents, including the prosecution histories constituting the BioSante Patents. Cold Genesys shall be responsible for retaining present patent counsel or transfer of the responsibility for oversight of the patents to another law firm or third party.

2.4 Excluded Assets; No Implied Licenses. Nothing contained in this Agreement shall be construed as conferring (i) any ownership rights to any intellectual property rights, technology or any other assets (whether tangible or intangible) owned or controlled by BioSante other than those expressly transferred under Article II of this Agreement, or (ii) any license rights, by implication, estoppel or otherwise, under any intellectual property rights owned or controlled by BioSante, other than as expressly transferred or granted in Article II of this Agreement.

2.5 Technical Assistance. Except as provided under Sections 2.2 & 2.3, neither Party shall be required to provide the other Party with any technical assistance or to furnish the other Party with, or obtain on their behalf, any documents, materials or other information or BioSante Technology.

2.6 No Assumption of Liabilities. Notwithstanding anything herein to the contrary, neither party shall not assume any liability of the other Party, including, without limitation, any such liability relating to any fact, circumstance, occurrence, condition, act or event or omission occurring prior to the Effective Date.

2.7 Insolvency. Notwithstanding anything herein to the contrary, should Cold Genesys become insolvent or cease to exist as an on-going business entity, within 12 months from the Effective Date of this Agreement, Cold Genesys agrees to assign its entire right, title and interest in any remaining BioSante Technology to BioSante or its successor. Cold Genesys will have the sole right to choose what portions of BioSante Technology need to be maintained or being used

during this period and the remaining BioSante Technology will pertain only to those remaining portions in an “as is” condition.

ARTICLE III

COMPENSATION

3.1 Initial Payments. In exchange and consideration for the rights and BioSante Technology transferred hereunder in Sections, 2.1, 2.2 and 2.3, Cold Genesys shall pay BioSante:

(a) a one-time, non-refundable acquisition fee of fifty thousand US dollars ($50,000) (“Acquisition Fee”) upon the Effective Date; and

(b) a one-time, non-refundable payment to reimburse BioSante for actual fees and costs related to filing, prosecuting or maintaining the BioSante Patents from June 23, 2010, the Effective Date of the MOU, to the Effective Date of this Agreement in the amount of forty thousand six hundred and ninety one dollars and twenty cents ($40,691.20) composed of thirty eight thousand five hundred five ($38,505) in costs and fees plus two thousand one hundred eighty six dollars and twenty cents ($2,186.20) in patent annuities. (“Reimbursement Payment”).

3.2 Sublicensing Fees. Cold Genesys, and its Affiliates, shall pay to BioSante thirty percent (30%) of any Sublicensing Fees received from any Sublicensee should Cold Genesys or its Affiliates license or sell the BioSante Technology to a Third Party prior to completion of a Phase 2 Clinical Trial.

3.3 Running Royalties. Cold Genesys, its Sublicensees and its Affiliates, shall pay to BioSante running royalties in the amount of five percent (5%) on Net Sales of CG0070 in the Territory; and two percent (2%) on Net Sales of other OVT Products for an approved therapy derived all or in part from the BioSante Technology. In the event that other royalties are due after successful development of the BioSante Technology, royalty payments to BioSante shall be adjusted such that total royalty payments for CG0070 five percent (5%) or other OVT Products two percent (2%) not exceed a total of five percent (5%) and two percent (2%), respectively; however, the royalty due to BioSante shall not be reduced to less than 2.5% and 1% respectively.

3.4 Payment Terms. All payments paid under this Agreement shall be non-refundable. All fees shall be paid by Cold Genesys to BioSante by electronic transfer of immediately available funds to:

Name of Payee: BioSante Pharmaceuticals, Inc.
Address: 111 Barclay Boulevard, Suite 280, Lincolnshire, IL 60069
Bank: Bank of America
Account Name: BioSante Pharmaceuticals, Inc.
ABA Routing No: 026009593
Account No: 5800975699

3.5 Board Representation on Cold Genesys. Within thirty (30) days from the Effective Date, Cold Genesys shall adopt a resolution appointing a BioSante representative to serve on Cold Genesys's Board of Directors. BioSante's percentage of representation shall never fall below its percent ownership in Cold Genesys. Cold Genesys shall indemnify and hold harmless BioSante and the BioSante representative(s) for any acts, errors and omissions that occur while performing duties or services on behalf of and as a member of the Cold Genesys' Board of Directors, and within one (1) year from the Effective Date, shall obtain and maintain adequate directors and officers insurance as a company of similar size in the industry.

3.6 Subscription Agreement. Contemporaneously with the execution of this Agreement, Cold Genesys shall execute a "Subscription Agreement" in a form substantially similar to that attached hereto as Exhibit II to transfer to BioSante a nineteen and nine tenths percent (19.9%) ownership position in Cold Genesys. BioSante's ownership position in Cold Genesys shall not be reduced below 18.7% for the first twelve (12) months after execution. If necessary, Cold Genesys shall issue additional shares to BioSante to prevent subsequent dilution as set forth in this Section. Cold Genesys agrees to provide to BioSante financial reports due twenty (20) days after the end of each calendar quarter of a given year in order for BioSante to comply with Securities and Exchange Commission reporting regulations and rules.

3.7 Taxes. Each Party shall be responsible for its own taxes (including without limitation any sales, use or value-added taxes), duties, tariffs or other similar charges ("Taxes") incurred in connection with each Party's performance under this Agreement. If Cold Genesys concludes, after consultation with BioSante, that Tax withholdings are required under applicable law with respect to any payments due BioSante hereunder, Cold Genesys shall withhold the required amount and pay it to the appropriate governmental authority. Any such Tax required to be withheld shall be an expense of and borne solely by BioSante. To the extent required by law, Cold Genesys shall pay Taxes deducted and withheld from payments payable hereunder to the appropriate governmental authorities on behalf of BioSante.

ARTICLE IV

REPRESENTATIONS AND WARRANTIES

4.1 General Warranties. Each Party represents and warrants to the other Party that:

(a) it has the power and authority to execute and delivery this Agreement and to perform the acts required of it hereunder; and

(b) the execution delivery and performance of this Agreement by such Party has been duly authorized by all requisite corporate action, and this Agreement constitutes such Party's legal, valid and binding obligation enforceable against it in accordance with its terms.

The execution, delivery and performance of the Agreement does not and will not (i) violate, conflict with or result in the breach of any provision of its certificate of incorporation, operating agreement or by laws, (ii) conflict with or violate any law, governmental regulation or governmental order applicable to it or any of its assets, properties or businesses or (iii) conflict

with, or result in any breach of, constitute default (or event which with the giving of notice or lapse of time, or both, would become a default) under, require any consent under, or give to others any rights pursuant to any contract, agreement, or arrangement by which it is bound.

4.2 Representations and Warranties by BioSante. BioSante represents and hereby warrants, as of the Effective Date:

(a) List of BioSante Patents. To best of BioSante's knowledge, Appendix C sets forth a true and complete list of all BioSante Patents as well as those related to CG0070 and any OVT-related chemical compounds, indicating for such item, as applicable, the application or registration number, date and jurisdiction of filing or issuance, and patent and application titles.

(b) Ownership. The BioSante Patents include all of the patents and patent applications owned or controlled by BioSante related to CG0070. BioSante exclusively owns all right, title and interest in and to each item of the BioSante Patents, free and clear of all Liens and owns all BioSante BioMaterials and BioSante Documentation. BioSante has not licensed these patents and patent applications to any third party.

(c) Infringement. To BioSante's knowledge, there is no action or claim pending, asserted or threatened against BioSante concerning any of the foregoing BioSante Technology, not has BioSante received any notification that a license under any Third Party's intellectual property rights related to the OVT technology may be required. To BioSante's knowledge, there is no action or claim pending, asserted ort threatened by BioSante against any Third Party concerning any of the foregoing BioSante Technology.

(d) Protection Measures. BioSante has taken commercially reasonable measures to maintain the confidentiality and value of all confidential or proprietary BioSante Technology.

4.3 Warranties Disclaimer. Except as otherwise set forth herein, (i) EACH PARTY ACKNOWLEDGES AND AGREES THAT ALL BIOSANTE TECHNOLOGY TRANSFERRED OR SERVICES PROVIDED HEREUNDER ARE PROVIDED WITHOUT ANY ADDITIONAL WARRANTIES WHATSOEVER, WHETHER EXPRESS, IMPLIED OR STATUTORY, WITH RESPECT THERETO, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTIES OF MECHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE ENFORCEABILITY OR NON-INFRINGEMENT, (ii) neither party makes any warranty or representation that any manufacture, use, importation, offer for sale or sale of any product or service covered by the BioSante Technology under this Agreement will be free from infringement of any patent or other intellectual property right of any Third Party, and (ii) BioSante does not make any warranty or representation as to the validity and/or scope of the BioSante Patents.

4.4 BioSante BioMaterials. The BioSante BioMaterials are experimental in nature and they are provided "AS IS." BIOSANTE MAKES NO REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE BIOMATERIALS, EITHER EXPRESS OR IMPLIED, AND SPECIFICALLY DISCLAIMS ANY IMPLIED WARRANTY OF NON-INFRINGEMENT, MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

ARTICLE V

CONFIDENTIAL INFORMATION

5.1 Confidentiality. Each Party acknowledges that it may obtain confidential, non-public information under this Agreement ("Proprietary Information") of the other Party. The Party receiving the Proprietary Information ("Receiving Party") of the other Party ("Disclosing Party") shall, at all times, both during the Term and for a period five (5) years after the initial disclosure of the applicable Proprietary Information, keep in confidence and trust all of the Disclosing Party's Proprietary Information received by it. The Receiving Party shall not use the Proprietary Information of the Disclosing Party other than as expressly permitted under the terms of this Agreement or by a separate written agreement. The Receiving Party shall take all reasonable steps to prevent unauthorized disclosure or use of the Disclosing Party's Proprietary Information and to prevent it from falling into the public domain or into the possession of unauthorized persons. The Receiving Party shall not disclose Proprietary Information of the Disclosing Party to any person or entity other than its officers, employees, consultants and permitted Sublicensees, who need access to such Proprietary Information in order to effect the intent of this Agreement and who have entered into written confidentiality agreements which protect the Proprietary Information of the Disclosing Party under no less protective terms as contained herein, or to its respective attorneys, auditors or bankers who will abide to the confidentiality provisions herein. The Receiving Party shall immediately give notice to the Disclosing Party of any unauthorized use or disclosure of Disclosing Party's Proprietary Information. Without in any way limiting the Disclosing Party's rights, in law or equity, against the Receiving Party or any Third Party, the Receiving Party agrees to provide reasonable assistance to the Disclosing Party to remedy such unauthorized use or disclosure of its Proprietary Information.

5.2 Exceptions. The obligations under Section 5.1 above shall not apply to the extent that the Proprietary Information is information which:

(a) is already known to the Receiving Party without an obligation of confidentiality at the time of disclosure, which knowledge the Receiving Party shall have the burden of proving;

(b) which knowledge the Receiving Party shall have the burden of proving;

(c) is, or, through no act or failure to act of the Receiving Party, becomes publicly known;

(d) is rightfully received by the Receiving Party from a Third Party without restriction on disclosure;

(e) is independently developed by the Receiving Party after the Effective Date without reference or access to the Proprietary Information of the Disclosing Party, which independent development the Receiving Party will have the burden of proving; or

(f) is approved for release by written authorization of the Disclosing Party.

5.3 Disclosure to Government Agencies. Nothing in this Agreement shall prevent the Receiving Party from disclosing Proprietary Information to the extent the Receiving Party is legally compelled to do so by any governmental investigative or judicial agency pursuant to proceedings over which such agency has jurisdiction; provided, however, that as soon as reasonably possible and, in any event, prior to any such disclosure, the Receiving Party shall (a) assert the confidential nature of the Proprietary Information to the agency; (b) if legally permissible, immediately notify the Disclosing Party in writing of the agency's order or request to disclose; and (c) cooperate fully with the Disclosing Party in protecting against any such disclosure and/or obtaining a protective order narrowing the scope of the compelled disclosure and protecting its confidentiality.

ARTICLE VI

INDEMNITY OBLIGATIONS: LIMITATION OF LIABILITY

6.1 Indemnification by Cold Genesys. Cold Genesys shall indemnify, defend, and hold harmless BioSante and its Affiliates and their respective directors, board members, officers, employees, agents and independent contractors and their respective successors, heirs and assigns from and against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses) arising from a third party claim arising out of any theory of liability (including actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) concerning any product, process, or service made, used , sold, imported or performed, only after the date of this agreement by Cold Genesys, pursuant or any right or licensed transferred or granted to Cold Genesys under this Agreement, except for any claims resulting from or as a result of any misrepresentations, acts, omissions, negligence or willful misconduct by BioSante.

6.2 Indemnification by BioSante. BioSante shall indemnify, defend, and hold harmless Cold Genesys and its Affiliates and their respective directors, board members, officers, employees, agents and independent contractors and their respective successors, heirs and assigns from and against any liability, damage, loss, or expense (including reasonable attorneys' fees and expenses) arising from a third party claim arising out of any theory of liability (including actions in the form of tort, warranty, or strict liability and regardless of whether such action has any factual basis) concerning a breach of any of the representations or warranties made herein or any acts or omissions of BioSante related to the BioSante Technology.

6.3 Procedures. In the event that any Party entitled to indemnification under Section 6.1 or 6.2 (an "Indemnitee") is seeking such indemnification Indemnitee agrees to provide the indemnifying party with prompt written notice of any claim, suit, action, demand, or judgment for which indemnification is sought under this Agreement. The indemnifying party agrees, at its own expense, to provide attorneys reasonably acceptable to Indemnitee to defend against any such clam. The Indemnitee shall cooperate fully with The indemnifying party in such defense and will permit The indemnifying party to conduct and control such defense and the disposition of such claim, suit, or action (including all decisions relative to litigation, appeal, and settlement); provided, however, that any Indemnitee shall have the right to retain its own counsel

if representation of such Indemnitee by the counsel retained by the indemnifying party would be inappropriate because of actual or potential differences in the interests of such Indemnitee and any other party represented by such counsel. Such counsel retained by an Indemnitee may participate in the defense and disposition of such claim; provided that the indemnifying party is allowed to conduct and control such defense and disposition. The indemnifying party agrees to keep the Indemnitee informed of the progress in the defense and disposition of such claim and to consult with the Indemnitee with regard to any proposed settlement; provided that The indemnifying party shall not dispose of or settle any such claim in any manner which results in an admission of liability or an agreement to make payments by Indemnitee, or otherwise adversely affects Indemnitee's rights or interests, without the Indemnitee's prior written consent.

6.4 Limitation of Liability. EXCEPT FOR A BREACH OF THE INDEMNIFICATION OBLIGATIONS UNDER Section 6 , IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INDIRECT, INCIDENTAL OR PUNITIVE DAMAGES OR LOST PROFITS, HOWEVER CAUSED AND BASED ON ANY THEORY OF LIABILITY (INCLUDING NEGLIGENCE) ASINING IN ANY WAY OUT THIS AGREEMENT, WHETHER SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

ARTICLE VII
MISCELLANEOUS

7.1 Additional Actions and Documents. Each of the Parties hereby agrees to use its reasonable best efforts to take or cause to be taken such further actions, to execute, acknowledge, deliver and file or cause to be executed, acknowledged, delivered and filed such further documents and instruments, and to use best efforts to obtain such consents, as may be necessary or as may be reasonably requested to fully effectuate the purposes, terms and conditions of this Agreement, whether at or after the Effective Date.

7.2 Notices. All notices and other communications under this Agreement shall be in writing and shall be deemed given (a) when delivered personally by hand (with written confirmation of receipt); (b) when sent by facsimile (with written confirmation of transmission); or (c) one business day following the day sent by overnight courier (with written confirmation of receipt), in each case at the following addresses and facsimile numbers (or to such other address or facsimile number as a Party may have specified by notice given to the other Party pursuant to this provision):

If to BioSante, to:

BioSante Pharmaceuticals, Inc.
111 Barclay Boulevard, Suite 280
Lincolnshire, Illinois 60069
Facsimile: (847) 478-8013
Attention: President & CEO

If to Cold Genesys, to:

Cold Genesys, Inc.
2 Narbonne
Newport Beach, California 92660
Facsimile:
Attention: Chief Executive Officer

7.3 Entire Agreement; Amendments and Waivers. This Agreement (including all appendices, exhibits, schedules and other attachments) represents the entire understanding and agreement between the Parties hereto with respect to the subject matter hereof and supersedes all prior negotiations and drafts of the Parties with regard to the transactions contemplated herein and therein. This Agreement can be amended, supplemented or changed, and any provision hereof can be waived, only by written instrument making specific reference to this Agreement signed by the Party against whom enforcement of any such amendment, supplement, modification or waiver is sought. No action or nonaction taken pursuant to this Agreement, including without limitation, any investigation by or on behalf of any Party, shall be deemed to constitute a waiver by the Party taking such action or nonaction of compliance with any representation, warranty, covenant or agreement contained herein. The waiver by any Party hereto of a breach of any provision of this Agreement shall not operate or be construed as a further or continuing waiver of such breach or as a waiver of any other or subsequent breach. No failure on the part of any Party to exercise, and no delay in exercising, any right, power or remedy hereunder shall operate as a waiver thereof, nor shall any single or partial exercise of such right, power or remedy by such Party preclude any other or further exercise thereof or the exercise of any other right, power or remedy.

7.4 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of New York applicable to contracts made and performed in such state, without giving effect to its principles of conflicts of law.

7.5 Binding Effect; Assignment. This Agreement shall be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns. Nothing in this Agreement shall create or be deemed to create any Third Party beneficiary rights in any Person not a party to this Agreement. No assignment or transfer of this Agreement or of any rights or obligations hereunder may be made by Cold Genesys directly or indirectly (by operation of law or otherwise), except to Affiliates, without the prior written consent of BioSante and any attempted assignment without the required consent shall be void.

7.6 Good Faith Performance. The Parties agree to cooperate fully to work in good faith and mutually to assist each other in the performance of this Agreement. In this regard, the Parties will meet and consult to seek to resolve any problems and disputes under this Agreement.

7.7 Severability. If any term or other provision of this Agreement is invalid, illegal, or incapable of being enforced by any law or public policy, all other terms or provisions of this Agreement shall nevertheless remain in full force and effect so long as the economic or legal substance of the transactions contemplated hereby is not affected in any manner materially

adverse to any Party. Upon such determination that any term or other provision is invalid, illegal, or incapable of being enforced, the Parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the Parties as closely as possible in an acceptable manner in order that the transactions contemplated hereby are consummated as originally contemplated to the greatest extent possible.

7.8 Counterparts; Language. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of this Agreement and all of which, when taken together, will be deemed to constitute one and the same agreement. This Agreement shall be drafted in English only.

7.9 No Agency. Nothing in this Agreement shall be construed as establishing a joint venture or an agency relationship between the Parties. Neither Party shall have, or shall represent that it has, any power, right or authority to bind the other Party to any obligation or liability.

7.10 Rules of Construction. This Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the Party drafting or causing any instrument to be drafted. The words “hereof, “herein” and “hereunder” and words of similar import when used in this Agreement will refer to this Agreement as a whole (including any annexes, exhibits and schedules to this Agreement) and not to any particular provision of this Agreement, and section and subsection references are to this Agreement unless otherwise specified. The words “include”, “including”, or “includes” when used herein shall be deemed in each case to be followed by the words “without limitation” or words having similar import. The word “knowledge” when used in this Agreement will refer to actual knowledge of the Party without additional inquiry. The headings in this Agreement are included for convenience of reference only and will not limit or otherwise affect the meaning or interpretation of this Agreement. The meanings given to terms defined herein will be equally applicable to both the singular and plural forms of such terms.

7.11 Force Majeure. Neither Party shall be liable hereunder by reason of any failure or delay in the performance of its obligations hereunder on account of strikes, shortages, riots, insurrection, fires, flood, storm, explosions, acts of God, war, governmental action, labor conditions, earthquakes, material shortages or any other causes that are beyond the reasonable control of such Party.

[SIGNATURE PAGES FOLLOW]

IN WITNESS WHEREOF, the Parties have caused this Technology and Intellectual Property Agreement to be duly executed as of the date first above written.

COLD GENESYS, INC.

By: /s/ Alex Yeung, M.D.
Name: Alex Yeung, M.D.
Title: Chief Executive Officer

IN WITNESS WHEREOF, the Parties have caused this Technology and Intellectual Property Agreement to be duly executed as of the date first above written.

BIOSANTE PHARMACEUTICALS, INC.

By: /s/ Stephen M. Simes
Name: Stephen M. Simes
Title: President & CEO

[BIOSANTE'S SIGNATURE PAGE TO THE TECHNOLOGY AND INTELLECTUAL PROPERTY AGREEMENT COLD GENESYS'S SIGNATURE PAGE FOLLOWS

APPENDIX A

LIST OF BIOSANTE BIOMATERIALS

[***]

APPENDIX B

LIST OF BIOSANTE DOCUMENTATION

Bar Code	Class	Document Description
590614633	Clinical Research	CRFs
590614639	Clinical Research	CRFs
590614638	Clinical Research	CRFs
590614640	Clinical Research	CRFs
590614634	Clinical Research	CRFs
590614629	Clinical Research	CRFs
590614507	Clinical Research	ICF binders
590614508	Clinical Research	Misc Ref. Binders
590432893	Clinical Research	Misc Ref. Binders
590432777	Clinical Research	Study Files
590432776	Clinical Research	Study Files/Site files
590432775	Clinical Research	Site Files
590432778	Clinical Research	Site Files
590432780	Clinical Research	Site Files
590432779	Clinical Research	Site Files
590432774	Clinical Research	CSR Master Binders
590432773	Clinical Research	CRFs and Pharmacy Binder
590433504	Toxicology	Biodistrib. Mice/Multi-dose
511645176	Regulatory	Health Canada Docs
590433680	Regulatory	All corresp; Amend 1-18
590433678	Regulatory	Amendments 19-43
590433679	Regulatory	Amendments 44-50
590610818	Manufacturing	Lot History File Box 1
590610819	Manufacturing	Lot History File Box 2
590610820	Manufacturing	Lot History File Box 3; stab & DDM
590610955	Manufacturing	Lot History File Box 7; ‘04 –’08
590610956	Manufacturing	Lot History File Box 6; ‘05 –’08
590610957	Manufacturing	Lot History File Box 5; 5% DDM
590610958	Manufacturing	QC/FP release; tox; lot release
590457501	Manufacturing	Tech trans. Records; Hela-S3 adhere/serum free; DDM method

APPENDIX C

LIST OF BIOSANTE PATENTS

	Case No	Application No.	Patent No.	Status	Country	File Date	Expiry Date	Invention Title
1	CELL120/0	63450/98	744725	Granted	AU	03-Mar-1998	03-Mar-2018	Adenovirus Vectors Containing Heterologous Transcription Regulatory Elements and Methods of Using Same
2	CELL120/0	2283231	2283231	Granted	CA	03-Mar-1998	03-Mar-2018	Adenovirus Vectors Containing Heterologous Transcription Regulatory Elements and Methods of Using Same
3	CELL120/0	09/033556	6432700	Granted	US	02-Mar-1998	02-Mar-2018	Adenovirus Vectors Containing Heterologous Transcription Regulatory Elements and Methods of Using Same
4	CELL120/0D	7010044.1		Pending	EP	21-May-2007		Adenovirus Vectors Containing Heterologous Transcription Regulatory Elements and Methods of Using Same
5	CELL120/0	10-538674		Pending	JP	03-Mar-1998		Adenovirus Vectors Containing Heterologous Transcription Regulatory Elements and Methods of Using Same
6	CELL122/1	59162/99	762940	Granted	AU	10-Sep-1999	10-Sep-2019	Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
7	CELL122/1D	2003252891	2003252891	Granted	AU	09-Oct-2003	10-Sep-2019	Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
8	CELL122/1	99946842.4	1112371	Granted	FR	10-Sep-1999	10-Sep-2019	Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
9	CELL122/1	99946842.4	69939478.3	Granted	DE	10-Sep-1999	10-Sep-2019	Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
10	CELL122/1	99946842.4	1112371	Granted	CH	10-Sep-1999	10-Sep-2019	Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
11	CELL122/1	99946842.4	1112371	Granted	UK	10-Sep-1999	10-Sep-2019	Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
12	CELL122/1	09/392822	6900049	Granted	US	09-Sep-1999	10-Sep-2018	Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
13	CELL122/1	2343135		Pending	CA	10-Sep-1999		Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof

14	CELL122/1	99812304.8		Pending	CN	10-Sep-1999		Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
15	CELL122/1	2000-570347		Pending	JP	10-Sep-1999		Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
16	CELL122/2	10/938227	7575919	Granted	US	09-Sep-2004	09-Sep-2019	Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
17	CELL122/3	2786010		Pending	US	18-Aug-2005		Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
18	CELL122/4	11/894,776		Pending	US	20-Aug-2007		Adenovirus Vectors Containing Cell Status-Specific Response Elements and Methods of Use Thereof
19	CELL123/1	99967776.8	1141363	Granted	FR	30-Dec-1999	30-Dec-2019	Target Cell-Specific Adenoviral Vectors Containing E3 and Methods of Use Thereof
20	CELL123/1	99967776.8	69936663.1	Granted	DE	30-Dec-1999	30-Dec-2019	Target Cell-Specific Adenoviral Vectors Containing E3 and Methods of Use Thereof
21	CELL123/1	99967776.8	1141363	Granted	UK	30-Dec-1999	30-Dec-2019	Target Cell-Specific Adenoviral Vectors Containing E3 and Methods of Use Thereof
22	CELL123/1	09/474699	6495130	Granted	US	29-Dec-1999	29-Dec-2019	Target Cell-Specific Adenoviral Vectors Containing E3 and Methods of Use Thereof
23	CELL123/2	10/226820	6991935	Granted	US	21-Aug-2002	29-Dec-2019	Target Cell-Specific Adenoviral Vectors Containing E3 and Methods of Use Thereof
24	CELL126/1	2001247648	2001247648	Granted	AU	21-Mar-2001	24-Mar-2020	Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site
25	CELL126/1	1920614.3	1266022	Granted	EP	21-Mar-2001	24-Mar-2020	Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site
26	CELL126/1	09/814351	6692736	Granted	US	21-Mar-2001	21-Mar-2021	Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site
27	CELL126/1	2404235		Pending	CA	21-Mar-2001		Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site
28	CELL126/1	1920614.3		Pending	FR	21-Mar-2001		Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site
29	CELL126/1	1920614.3		Pending	DE	21-Mar-2001		Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site
30	CELL126/1	2001-570809		Pending	JP	24-Sep-2002		Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site
31	CELL126/1	1920614.3		Pending	CH	21-Mar-2001		Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site
32	CELL126/1	1920614.3		Pending	UK	21-Mar-2001		Cell-Specific Adenovirus Vectors Comprising an Internal Ribosome Entry Site

33	CELL135/0	2234464	7001764	Granted	US	02-May-2002	10-Sep-2018	Compositions Comprising Tissue Specific Adenoviral Vectors
34	CELL138/0	-624654	7459154	Granted	US	26-Dec-2022	26-Dec-2022	Methods and Reagents for the Enhancement of Virus Transduction in the Bladder Epithelium
35	CELL138/1	10/743813	7267815	Granted	US	26-Dec-2022	26-Dec-2022	Methods and Reagents for the Enhancement of Virus Transduction in the Bladder Epithelium
36	CELL138/6	12/284734		Pending	US			Methods and Reagents for the Enhancement of Virus Transduction in the Bladder Epithelium
37	CELL138/0	2003299972		Pending	AU			Methods and Reagents for the Enhancement of Virus Transduction in the Bladder Epithelium
38	CELL138/0	3800237.4		Pending	EP			Methods and Reagents for the Enhancement of Virus Transduction in the Bladder Epithelium
39	CELL138/0	540732	540732	Granted	NZ	24-Dec-2023		Methods and Reagents for the Enhancement of Virus Transduction in the Bladder Epithelium
40	CELL138/0	2,510,903		Pending	CA			Methods and Reagents for the Enhancement of Virus Transduction in the Bladder Epithelium
41	CELL153/2	2574698		Pending	CA	22-Jan-2007		Addition of Transgenes into Adenoviral Vectors
42	CELL153/2	5791283.4		Pending	EP	23-Jan-2007		Addition of Transgenes into Adenoviral Vectors
43	CELL153/2	200580031943		Pending	CN	22-Mar-2007		Addition of Transgenes into Adenoviral Vectors
44	CELL153/2	2007-522731		Pending	JP	19-Jan-2007		Addition of Transgenes into Adenoviral Vectors
45	CELL153/2	11/181850		Pending	US	15-Jul-2005		Addition of Transgenes into Adenoviral Vectors

EXHIBIT I

DRAFT PATENT ASSIGNMENT

ASSIGNMENT

WHEREAS, BioSante Pharmaceuticals, Inc., organized and existing under the laws of the State of Delaware, and having an office at 111 Barclay Boulevard, Suite 280, Lincolnshire, Illinois 60069, ASSIGNOR, is the owner of the entire right, title and interest to the inventions disclosed in the patents and patent applications which are identified in Exhibit A;

and WHEREAS, Cold Genesys, Inc., organized and existing under the laws of the State of California, and having an office at 2 Narbonne, Newport Beach, California 92660, ASSIGNEE, is desirous of obtaining our entire right, title, and interest in, to and under the inventions and the patents and applications in Exhibit A:

NOW, THEREFORE, in consideration of the sum of One Dollar ($1.00), and other good and valuable consideration, the receipt of which is hereby acknowledged, the said ASSIGNOR, has sold, assigned, transferred and set over, and by these presents do hereby sell, assign, transfer and set over, unto the ASSIGNEE, its successors, legal representatives and assigns, its entire right, title and interest in, to and under the inventions, and the United States patents and patent application and all utility applications in Exhibit A, and all divisions, renewals, continuations thereof, all Patents of the United States which may be granted thereon, and all reissues or extensions thereof, and all applications for industrial property protection, including, without limitation, all applications for patent, utility models, and designs which may hereafter be filed for said invention in any country or countries foreign to the United States, together with the right to file such applications and the right to claim for the same the priority rights derived from said United States application under Patents Laws of the United States, the International Convention for the Protection of Industrial Property, or any other international agreement or domestic laws of the country in which any such application is filed, as may be applicable, and all forms of industrial property protection, including, without limitation, patents, utility models, inventors' certificates and designs which may be granted for said inventions in any country or countries foreign to the United States and all extensions, renewals, and reissues thereof;

AND ASSIGNOR HEREBY authorizes and requests the Commissioner for Patents and any Official of any country or countries foreign to the United States, whose duty it is to issue patents or other evidence or forms of industrial property protection on application asforesaid, to issue the same to said ASSIGNEE, its successors, legal representatives and assigns, in accordance with the terms of this instrument;

AND ASSIGNOR HEREBY covenants and agrees that it has the full right to convey the entire interest herein assigned, and that we have not executed, and will not execute, any agreement in conflict herewith;

AND ASSIGNOR HEREBY further covenants and agrees that it will communicate to said ASSIGNEE, its successors, legal representatives and assigns, any facts known to us respecting said invention, and testify in any legal proceeding, sign all lawful papers, execute all divisional, continuing, reissue and foreign applications, make all rightful oaths, and generally do everything possible to aid said ASSIGNEE, its successors, legal representatives and assigns, to obtain and enforce proper protection for said invention in all countries.

IN TESTIMONY WHEREOF, ASSIGNEE hereunto set its hands and seals the day and year set opposite our respective signatures.

Date: _____, 20___ __L.S.

BioSante Pharmaceuticals, Inc.
Stephen Simes
President & CEO

State of)

County of)

On _____, 20___ before me, a Notary Public, personally appeared Stephen Simes, personally known to me on the basis of satisfactory evidence to be the person whose named is subscribed to the within instrument and acknowledged to me that he/she executed the same in his/her authorized capacity, and that be his/her signature on the instrument, the person executed the instrument.

WITNESS my hand and official seal

__

IN WITNESS WHEREOF, the Parties have caused this Technology and Intellectual Property Agreement to be duly executed as of the date first above written.

BIOSANTE PHARMACEUTICALS, INC.

By: __
Name:
Title:

[BIOSANTE'S SIGNATURE PAGE TO THE TECHNOLOGY AND INTELLECTUAL PROPERTY AGREEMENT COLD GENESYS'S SIGNATURE PAGE FOLLOWS]

EXHIBIT II

DRAFT SUBSCRIPTION AGREEMENT

Exhibit 31.1

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

I, Nikhil Lalwani, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2024

/s/ Nikhil Lalwani

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

Exhibit 31.2

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

I, Stephen P. Carey, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 10, 2024

/s/ Stephen P. Carey

Stephen P. Carey

Senior Vice President, Finance and Chief Financial Officer
(principal financial and accounting officer)

Exhibit 32.1

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

In connection with the quarterly report on Form 10-Q of ANI Pharmaceuticals, Inc. (the "Company") for the quarterly period ended March 31, 2024 (the "Report") as filed with the Securities and Exchange Commission on the date hereof, the undersigned Chief Executive Officer and Chief Financial Officer of the Company hereby certify that, to such officer's knowledge:

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

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

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

Dated: May 10, 2024

/s/ Nikhil Lalwani

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

Dated: May 10, 2024

/s/ Stephen P. Carey

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

A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.