



2024 Annual Report

CORPORATE INFORMATION

BOARD OF DIRECTORS

Patrick D. Walsh, Chairman of the Board
Chairman, Alcami Corporation

Thomas Haughey, Director
Retired General Counsel and Secretary, Par
Pharmaceutical Companies, Inc.

Nikhil Lalwani, Director
President and Chief Executive Officer, ANI
Pharmaceuticals, Inc.

Matthew J. Leonard, R.Ph., Director
Senior Vice President, Global Access and Value, Pfizer, Inc.

Antonio R. Pera, Director
Retired President, Par Pharmaceutical Companies, Inc.

Muthusamy Shanmugam, Director
Head of Research & Development and Chief
Operating Officer of NJ Operations, ANI
Pharmaceuticals, Inc.

Renee P. Tannenbaum, Pharm.D., Director
Strategic Advisor to Biopharmaceutical and Device
Companies

Jeanne A. Thoma, Director
Retired President and Chief Executive Officer of SPI
Pharma, Inc.

EXECUTIVE OFFICERS

Nikhil Lalwani
President and Chief Executive Officer

Stephen P. Carey
Senior Vice President, Finance and Chief Financial Officer

Meredith W. Cook
Senior Vice President, General Counsel and
Corporate Secretary

Krista Davis
Senior Vice President and Chief Human Resources
Officer

Chad Gassert
Senior Vice President, Corporate Development &
Strategy

Ori Gutwerg
Senior Vice President, Generics

Christopher Mutz
Senior Vice President, Head of Rare Disease

Muthusamy Shanmugam
Head of Research & Development and Chief
Operating Officer of NJ Operations

Thomas Rowland
Senior Vice President, Head of Established Brands

CODE OF ETHICS

We have adopted a corporate Code of Ethics that applies to all of our directors, officers and employees. A copy of the Code of Ethics is accessible through the "Investor Relations-Governance-Governance Documents" section of our website at www.anipharmaeaceuticals.com

CORPORATE HEADQUARTERS

210 Main Street West
Baudette, Minnesota 56623
Phone: (218) 634-3500

COMMERCIAL HEADQUARTERS

500 Alexander Park Drive
Princeton, NJ 08540
Phone: 609-759-1810

COMMON STOCK TRADING

The Company's common stock trades on the Nasdaq Global Market under the symbol "ANIP".

ANNUAL MEETING OF STOCKHOLDERS

The Company's Annual Meeting of Stockholders will be held virtually at 9 a.m. ET on May 22, 2025 via webcast through the link: www.virtualshareholdermeeting.com/ANIP2025

INVESTOR RELATIONS

For additional information, please contact Investor Relations at IR@anipharmaeaceuticals.com

INDEPENDENT AUDITORS

EisnerAmper LLP
111 Wood Avenue South
Iselin, NJ 08830
Phone: (732) 243-7000

TRANSFER AGENT

Continental Stock Transfer & Trust Company
1 State Street, 30th Floor
New York, NY 10004
Phone: (800) 509-5586
www.continentalstock.com

LEGAL COUNSEL

Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, NJ 08540
Phone: (609) 919-6600

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-K

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

For the fiscal year ended December 31, 2024

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

For the transition period from _____ to _____.

Commission file number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

58-2301143

(State or other jurisdiction of incorporation or organization)

(I.R.S. Employer Identification No.)

210 Main Street West

Baudette, Minnesota

(Address of principal executive offices)

56623

(Zip Code)

(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 | Name of each exchange on which registered |
|--|----------------|---|
| Common Stock, par value \$0.0001 per share | ANIP | The Nasdaq Global Market |

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer

☒

Accelerated filer

☐

Non-accelerated filer

☐

Smaller reporting company

☐

Emerging growth company

☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 28, 2024 was \$1.2 billion (based upon the last reported sale price of \$63.68 per share on June 30, 2024, on The Nasdaq Global Market).

As of February 21, 2025, 21,762,646 shares of common stock and 10,864 shares of Class C Special stock of the registrant were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the definitive proxy statement for the registrant's 2025 annual meeting of stockholders to be filed within 120 days after the end of the period covered by this Annual Report on Form 10-K are incorporated by reference into Part III of this Annual Report on Form 10-K.

ANI PHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

For the Year Ended December 31, 2024

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In this annual report, references to “ANI Pharmaceuticals,” “ANI,” the “Company,” “we,” “us,” and “our” refer, unless the context requires otherwise, to ANI Pharmaceuticals, Inc., a Delaware corporation, and its consolidated subsidiaries.

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

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

- Our approved products, including Cortrophin Gel, ILUVIEN and YUTIQ, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability;
- 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;
- We may fail to realize the benefits expected from our acquisition of Alimera and the combined company may not perform as we or the market expects;
- The limited number of suppliers for our API could result in lengthy delays in production if we need to change suppliers;
- Several of the products we have acquired cannot be manufactured in our facilities and we must secure and maintain qualified and compliant contract manufacturers. Noncompliance by these contract manufacturers or our inability to find qualified contract manufacturers could result in us being unable to commercialize these products; Several of our products are manufactured and/or packaged by single-sourced third parties, which we cannot control and could result in us being unable to market and distribute products;
- We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business;
- Failure to comply with data protection laws and regulations could subject us to government enforcement actions, private litigation and/or adverse publicity, which could negatively affect our operating results and business;
- Our Medicaid rebate accruals have increased and continue to increase due to our acquisitions and subsequent sales of branded products and authorized generics of branded products;
- Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions;
- We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products;
- Production at any or all of our three current manufacturing facilities could be interrupted, which could cause us to fail to deliver product on a timely basis;
- We rely on third parties to assist with our clinical trials. If these parties do not perform or are non-compliant, it could negatively impact the clinical trial and potential of regulatory approval; further, we may be required to audit or redo previously completed trials or recall already-approved commercial products;
- Clinical trials for our products may not generate the outcomes we expect, may take longer or be more costly to complete than we anticipate;
- We may be adversely affected by the expiration of patents that protect key aspects of our products in the near- to medium-term;
- Inability to protect our intellectual property in the U.S. and foreign countries could negatively affect sales of our branded products;

- If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are material to our business;
- Our success is largely dependent upon certain key employees, including members of our senior management, the loss of whom could adversely affect our operations;
- We rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology could harm our ability to operate the business effectively;
- We are involved in and may become involved in legal proceedings from time to time, which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources;
- We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums;
- The obligations and liabilities of Alimera, some of which may be unanticipated or unknown, may be greater than we have anticipated, which may diminish the value of Alimera to us;
- Our operations in an international market subject us to additional regulatory oversight both in the international market and in the U.S., as well as, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results;
- Our operations, including those resulting from our acquisition of Alimera, and its international operations, will subject us to political and economic risks, increase our exposure to potential liability under anti-corruption, trade protection, tax, and other laws and regulations;
- Future acquisitions and investments could disrupt our business and harm our financial position and operating results;
- Pharmaceutical product quality standards are steadily increasing on all products, and if we cannot meet these standards, we may be required to discontinue marketing and/or recall products from the market;
- Federal and state false claims litigation brought against us by private individuals and the government could result in civil and criminal penalties, damages, fines and other related actions;
- The use of legal, regulatory, and legislative strategies by competitors could result in increased costs to develop and market our products, delay new product introductions and reduce profit potential;
- Third-party payer actions may prevent us from effectively marketing our products or cause us to decrease pricing;
- Healthcare reform legislation could have a material adverse effect on our business, financial position, and operating results;
- Public health outbreaks, epidemics, or pandemics (such as COVID-19) have adversely affected and may in the future adversely affect our business;
- The continuing trend toward consolidation of customer groups could result in declines in the sales volume and prices of our products, and increased fees charged by customers;
- The Food and Drug Administration (“FDA”) does not provide guidance on safety labeling for products that are marketed without approved New Drug Applications (“NDAs”) or Abbreviated New Drug Applications (“ANDAs”), which could increase our potential liability with respect to failure-to-warn claims for these products;
- Four of our products are marketed without approved NDAs or ANDAs and we can offer no assurances that the FDA will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected;
- If the Drug Enforcement Administration (“DEA”) does not approve supply of the API we need to manufacture our controlled substances, we may be unable to manufacture controlled substances, which would eliminate our revenue on these products;
- Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods;
- Our indebtedness and liabilities could limit the cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operation;
- To service our indebtedness, we will be required to generate a significant amount of cash;
- Our New Credit Agreement contain restrictive and financial covenants and if are not in compliance with these covenants, our outstanding indebtedness under this facility could be accelerated and the lenders could terminate their commitments under the facility;
- Certain risks relating to our 2.25% Convertible Senior Notes due 2029 and related capped call transactions; and
- Raising additional funds by issuing additional equity securities may cause dilution to our current stockholders. Raising additional funds by entering into additional credit or other borrowing facilities or issuing debt may subject us to covenants and other requirements that may restrict our operations.

NOTE REGARDING TRADEMARKS

Cortenema®, Purified Cortrophin® Gel, Inderal® LA, ILUVIEN®, Inderal® XL, InnoPran XL®, Kionex®, Lithobid®, Reglan®, SOVUNA®, Vancocin®, Veregen®, and YUTIQ® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries. Cortrophin-Zinc™ is a trademark owned by ANI Pharmaceuticals, Inc. and its consolidated subsidiaries pending registration. Atacand® and Atacand HCT® are the property of AstraZeneca AB and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Arimidex® and Casodex® are the property of AstraZeneca UK Limited and are licensed to ANI Pharmaceuticals, Inc. for U.S. sales of those products. Oxistat® is the property of Fougera Pharmaceuticals Inc. and licensed to ANI Pharmaceuticals, Inc. for U.S. sales of Oxistat® Lotion.

PART I

Item 1. Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, “ANI,” the “Company,” “we,” “us,” or “our”) is a diversified bio-pharmaceutical company committed to its mission of “Serving Patients, Improving Lives” by developing, manufacturing, and commercializing innovative and high-quality therapeutics.

On September 16, 2024, the Company completed its previously announced acquisition of Alimera Sciences, Inc., a Delaware corporation pursuant to the terms of the Agreement and Plan of Merger (the “Merger Agreement”), dated as of June 21, 2024, by and among the Company, Alimera and ANIP Merger Sub INC., a Delaware corporation and wholly-owned subsidiary of the Company. Pursuant to the Merger Agreement, Merger Sub merged with and into Alimera, with Alimera surviving the merger as a wholly-owned subsidiary of the Company. In connection with the acquisition, the Company added two new products, ILUVIEN® and YUTIQ®, both of which are indicated for the treatment of certain chronic retinal diseases (see Note 3 “Business Combination” in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

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, and the building was ultimately sold in March 2024. 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 (see Note 4 “Restructuring Canada Operations” in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K). 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.

On August 13, 2024, the Company entered into a credit agreement with JPMorgan Chase Bank, N.A., as administrative agent, and the financial institutions party thereto as lenders, (the “New Credit Agreement”) which provides for aggregate principal commitments consisting of (i) a senior secured delayed-draw term loan facility in an aggregate principal amount of \$325.0 million, and (ii) a senior secured revolving credit facility in an aggregate commitment amount of \$75.0 million, which may be used for revolving credit loans, swingline loans and letters of credit.

On September 16, 2024, ANI drew the full \$325.0 million of New Credit Agreement principal, with proceeds used to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the acquisition. As of December 31, 2024, the revolving credit facility remains undrawn, and \$75.0 million is available for borrowing, subject to the satisfaction of certain conditions. The New Credit Agreement and the revolving credit facility mature on September 16, 2029.

On August 13, 2024, the Company completed an offering of \$316.25 million aggregate principal amount of the Company's Convertible Senior Notes due 2029 (the “Notes”). The Notes are due September 1, 2029, unless earlier repurchased, redeemed, or converted. After deducting the initial purchasers’ discounts and commissions of approximately \$9.5 million, but before deducting the Company’s offering expenses, the net proceeds to the Company from the offering of the Notes was approximately \$306.8 million. In connection with the offering of Notes, on August 7, 2024 and August 8, 2024, the Company entered into capped call transactions with certain financial institutions (“Capped Calls”). After payment of the cost of entering into the Capped Calls transactions, of approximately \$40.6 million, the Company used the remainder of the net proceeds from the Notes offering, together with cash on hand, to repay the Company’s existing senior secured credit agreement with Truist Bank, dated as of November 19, 2021.

In May 2023, through a public offering, the Company 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.

We have a commercial portfolio of 125 products with a wide variety of indications and a robust portfolio of pipeline products as of December 31, 2024. This portfolio is the result of internal research and development, acquisitions of businesses, acquisitions of Abbreviated New Drug Applications (“ANDAs”), New Drug Applications (“NDAs”), product rights, and entry into agreements to obtain the distribution rights for various products.

Strategy

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

Our strategy is driven by the following key growth drivers:

Building a successful Rare Disease and Brands Segment

We have spent significant time, effort and resources in establishing and expanding our Rare Disease and Brands segment which consists of Rare Disease and Brands portfolio of products. We plan to continue to expand our Rare Disease business, through a combination of organic growth and acquisition. While we 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.

The acquisition of Alimera is anticipated to strengthen our Rare Disease business and expand our footprint beyond the U.S. with the addition of Alimera’s direct marketing operations located in Germany, the United Kingdom, Portugal, and Ireland, as well as its partnerships in other countries in Europe, Asia, and the Middle East. ILUVIEN and YUTIQ are a durable franchise with high barriers to genericization which the Company believes have a clear role for patients in need of alternative therapeutic options. ANI sees the potential to unlock significant additional growth for the ILUVIEN and YUTIQ franchise through commercial synergies and execution.

Purified Cortrophin® Gel

We acquired the NDAs for Purified Cortrophin® Gel (Repository Corticotropin Injection USP) (“Cortrophin Gel”) and Cortrophin-ZincTM in January 2016 and executed long-term supply agreements with a supplier of our primary raw material for corticotrophin API, a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin Gel fill/finish contract manufacturer. On October 29, 2021, the FDA approved the Company’s Supplemental New Drug Application (“sNDA”) for Cortrophin Gel 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 adrenocorticotrophic hormone (“ACTH”), also known as purified corticotropin. On January 24, 2022, we announced the commercial launch of Cortrophin Gel in the U.S. as our foundational Rare Disease asset.

Throughout 2023 and 2024, we continued to build and invest in our Rare Disease 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-mL vial of Cortrophin Gel, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares.

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

ILUVIEN and YUTIQ

ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg, was developed in the U.S. and internationally for the treatment of diabetic macular edema (“DME”), a leading cause of severe vision loss and blindness, and certain international markets for chronic non-infectious uveitis affecting the posterior segment of the eye (“NIU-PS”). Alimera acquired exclusive commercialization rights to YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg, in May 2023 from EyePoint Pharmaceuticals, Inc. (“EyePoint”) for the treatment and prevention of NIU-PS worldwide except for Europe, the Middle East, Africa, (known as ILUVIEN in Europe, the Middle East and Africa) and certain Asian countries including China. ILUVIEN and YUTIQ are state-of-the-art sustained release intravitreal implants that respectively help patients maintain vision longer and reduce disease recurrence. ILUVIEN is being evaluated as baseline therapy in naïve or near naïve patients with early DME in combination with the current standard of care, anti-vascular endothelial growth factor (“VEGF”) therapy in the NEW DAY clinical trial. YUTIQ is being further studied in the SYNCHRONICITY clinical trial, a prospective, open-label clinical trial evaluating the safety and efficacy of YUTIQ for the treatment and prevention of chronic NIU-PS and related intraocular inflammation.

Both ILUVIEN and YUTIQ treat patients by delivering a continuous microdose of the corticosteroid fluocinolone acetonide (“FAC”) in the eye, for up to 36 months. ILUVIEN was developed internally by Alimera and initially to treat DME, a disease of the retina that affects individuals with Type 1 or Type 2 diabetes and can lead to severe vision loss and blindness. ILUVIEN is sold to treat DME only in the U.S. YUTIQ is sold to treat NIU-PS only in the U.S. In certain European and Middle Eastern countries, ILUVIEN is approved and commercialized to treat DME and to prevent relapse in recurrent NIU-PS, an inflammatory disease of the uveal tract, which is comprised of the iris, ciliary body and choroid, that can lead to severe vision loss and blindness. We also have rights to commercialize ILUVIEN for NIU-PS in Africa.

ILUVIEN and YUTIQ are both intravitreal implants that are inserted into the back of the patient’s eye in non-surgical procedures employing devices with 25-gauge needles, which allow for a self-sealing wounds. “Intravitreal” refers to the space inside the eye behind the lens that contains the jelly-like substance called vitreous. The implants, which are non-bioerodible, provide consistent delivery as a result of their constant surface area, permitting elution of FAC to the vitreous. We call this CONTINUOUS MICRODOSING™. This delivery mechanism provides lower daily and aggregate exposure to corticosteroids than any other intraocular dosage forms currently available, which we believe mitigates the typical risks associated with corticosteroid therapy. CONTINUOUS MICRODOSING delivery makes ILUVIEN and YUTIQ the only approved drug therapies for DME and NIU-PS that are designed to deliver consistent daily therapeutic levels of corticosteroid and reduce the recurrence of DME and uveitis for up to three years. Other therapies that physicians currently use to treat DME, such as anti-VEGF treatments and other corticosteroids, are acute (short-acting) therapies that provide a higher initial daily dose but then rapidly decline, requiring frequent reinjection by the physician to maintain an effective dose or reestablish the therapeutic effect after the disease has recurred.

FAC is a non-proprietary corticosteroid and the active compound in ILUVIEN (0.19mg) and YUTIQ (0.18mg). We believe that corticosteroids provide the best option in the treatment of DME and NIU-PS because they reduce the inflammatory aspects of both diseases. ILUVIEN and YUTIQ deliver continuous daily sub-microgram levels of FAC in in vivo release kinetic studies for up to 36 months. ILUVIEN and YUTIQ are the only single injection therapies available to treat retinal diseases consistently every day for up to three years, which may allow patients to see better, longer, with fewer injections.

NEW DAY Clinical Trial

We believe that ILUVIEN continues to be underutilized in the treatment of DME and should be used much earlier in patients suffering from DME. With the NEW DAY clinical trial, we intend to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME by comparing ILUVIEN to the current standard of care, anti-VEGF therapy.

In July 2020, Alimera announced the initiation of our NEW DAY clinical trial, a multicenter, single masked, randomized, controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its advantages over using the current standard of care of repeat anti-VEGF injections. The NEW DAY clinical trial was fully enrolled with 300 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U.S. We expect to share the clinical trial data in the second half of 2025.

Patients who meet the entry criteria have been randomized to receive either an ILUVIEN intravitreal implant or five injections of intravitreal aflibercept 2 mg at four-week intervals for the first 16 weeks as a loading dose. After the initial 16-week period, both treatment arms will be evaluated every four weeks and receive supplemental intravitreal injections of aflibercept 2 mg only as needed. Criteria for supplemental treatment is set by protocol and will be identical in both treatment arms. The planned treatment period in the trial is 18 months. Once the treatment period is concluded, patients will be given the option to participate in an open label extension trial for up to 42 months.

The primary outcome measure for the NEW DAY clinical trial is the mean number of supplemental aflibercept injections needed during the trial between treatment groups. Key secondary endpoints include mean best corrected visual acuity (“BCVA”) score over time up to 18 months, time to first supplemental treatment, retinal thickness amplitude on optical coherence tomography (“OCT”), and diabetic retinopathy scores. In addition, the trial will collect patient-reported outcome measures to evaluate the effect on patients’ quality of life and level of functioning. Exploratory endpoints will include neuronal functional measures and OCT imaging measures of retinal nerve layer thickness.

SYNCHRONICITY Clinical Trial

The SYNCHRONICITY clinical trial is a multicenter, open label trial evaluating YUTIQ in chronic inflammation. The SYNCHRONICITY clinical trial currently has enrolled 110 patient eyes in approximately 25 sites around the U.S. Patients who meet the entry criteria receive YUTIQ as an intravitreal injection in the designated study eye. The treatment period is 36 months, with data capture for this clinical trial being the first 24 months of YUTIQ drug treatment.

The primary outcome measure for the SYNCHRONICITY clinical trial is the mean change from baseline in BCVA letter score in the study eye measured by EDTRS at Month 6 and the mean change from baseline central subfield thickness at Month 6. Key secondary endpoints include time to recurrence of non-infectious inflammation in the study eye, presence of vascular leakage at Months 1, 3, 6, 12, 18, and 24, proportion of subjects with resolution of macular edema at Months 1, 3, 6, 12, 18, and 24, mean change from baseline in BCVA letter score at Day 14 and at Months 1, 3, 12, 18, and 24, and mean change from baseline in CST at Months 1, 3, 12, 18, and 24. We expect to share the preliminary topline results of the SYNCHRONICITY clinical trial data in the first half of 2025.

Brands

We have grown our brands portfolio of product offerings through acquisition. We have acquired the NDAs for and market Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, InnoPran XL, Oxistat, and Veregen. We are innovating in our go-to-market strategy through creative partnerships and a sales force for these products.

Strengthening our Generics 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 acquisition of Novitium in 2021 included its portfolio of commercial and pipeline generic products, manufacturing and development facilities and expert workforce. The Novitium acquisition significantly increased our generic pharmaceutical research and development and manufacturing capabilities. We have begun to increase our focus on niche lower competition opportunities such as injectables, Paragraph IV, and competitive generic therapy (“CGT”) designation filings. Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses. During 2023, we acquired two ANDAs and one pipeline product from the Chapter 7 Trustee for the estates of Akorn Holding Company and certain of its affiliates, acquired an ANDA and registered patents and pending patent applications from Slayback Pharma Limited Liability Company, and acquired additional ANDAs and product rights for two products in the second half of 2023. During 2022, we completed an asset acquisition of four ANDAs from Oakrum Pharma, including two that were commercial at the time of acquisition.

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.

Competitive Generic Therapy

The FDA Reauthorization Act of 2017 (“FDARA”) created a new pathway by which the FDA may, at the request of the applicant, designate a drug with “inadequate generic competition” as a competitive generic therapy (“CGT”). At the request of the applicant, the FDA may also expedite the review of an ANDA for a drug designated as a CGT. Under the CGT pathway, the FDA provides a statutory provision for a 180-day exclusivity period for certain first to market applicants whose ANDA received a CGT designation. Our Novitium subsidiary has developed a strong track record of obtaining CGT approvals and we expect to continue to develop generic drugs under the CGT pathway.

Products

A complete list of our generic and branded pharmaceutical products and descriptions is posted on our website, www.anipharmaceuticals.com.

Manufacturing, Suppliers, and Raw Materials

Several of our key products, including injectables, softgel capsules, and Cortrophin Gel, as well as ILUVIEN and YUTIQ, are products that are currently manufactured and supplied by third parties, in some cases as a single source. We expect our reliance on third party manufacturers to increase in the future as we receive approvals for new products to be manufactured through our collaboration arrangements, and as we seek additional growth opportunities outside of the capabilities of our current manufacturing facilities.

For instance, our supply agreement for YUTIQ (the "YUTIQ Supply Agreement") with EyePoint has an initial term of two years through May 2025. On February 27, 2025, the Company received written notice of non-renewal from EyePoint of the YUTIQ Supply Agreement, effective May 31, 2025. The Company has submitted a Prior Approval Supplement ("PAS") to the FDA seeking to add YUTIQ's indication of chronic NIU-PS to the ILUVIEN label. The Company expects FDA approval of the PAS in the second quarter of 2025 and plans to market ILUVIEN for chronic NIU-PS in addition to its current indication of DME in the U.S. For reference, ILUVIEN is already approved and marketed for DME and NIU-PS outside the U.S., including in 17 European countries and the Middle East. In order to support the transition to ILUVIEN, in July 2024, the Company extended its partnership with Alliance Medical Products, Inc., a subsidiary of Siegfried Holding AG ("Siegfried"), its long-term supplier for ILUVIEN, through 2029, and contracted with Siegfried to upgrade equipment on the existing manufacturing line and significantly expand capacity through the addition of a second manufacturing line.

We require a supply of quality raw materials, including API, and components to manufacture and package our pharmaceutical products. In order to manufacture certain of our products deemed controlled substances, we must submit a request to the DEA for a quota to purchase the amount of API needed for manufacture. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers.

We source the raw materials for our products from both domestic and international suppliers, which we carefully select. Generally, we qualify only a single source of API for use in each product due to the cost and time required to validate and qualify a second source of supply. Any change in one of our API suppliers must usually be approved through a PAS by the FDA. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we selectively choose suppliers based on various factors including quality, reliability of supply, and long-term financial stability.

Certain of the APIs for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections and customs delays. In addition, certain of our products are manufactured, packaged, or manufactured and packaged by third parties. Alimera did not have, and we do not have in-house manufacturing capability for and depend, and expect to continue to depend, exclusively on third-party contract manufacturers to manufacture and package ILUVIEN and YUTIQ.

The pharmaceutical industry in the U.S. is highly regulated by multiple U.S. government agencies, such as the FDA, the DEA, and the Centers for Medicare and Medicaid Services (“CMS”), as well as state and local government entities. As a result, we are subject to extensive and complex rules and regulations, which are subject to revision from time to time, including changes in the priorities and focus of presidential administrations on our industry, as occurred in January 2025, or when a U.S. Supreme Court ruling changes the scope of judicial deference to federal agency interpretations of law as occurred in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024). While we have experience with these regulations and changes, there can be no assurance that we will be able to fully comply with all applicable regulations or that our past compliance activities will be upheld by government agencies or U.S. Courts in the future.

Branded and Generic Pharmaceutical Products

The Drug Approval Process

Generally, prescription pharmaceutical products distributed in the U.S., whether branded or generic, must be approved by the FDA. All applications for FDA approval must contain information relating to product formulation, raw material suppliers, analytical testing, stability, manufacturing processes, packaging, labeling, and quality control. Information and data to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for their intended use is also required to be submitted. There are generally two types of applications used for obtaining FDA approval of new products.

An NDA is filed with the FDA when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system, or a new indication for an approved drug. To market a new drug in the U.S., a sponsor must generally complete nonclinical laboratory tests, animal studies and formulation studies under the FDA’s Good Laboratory Practice (“GLP”) regulations and other applicable laws or regulations; conduct clinical testing in humans pursuant to an investigational new drug application (“IND”); develop manufacturing processes to ensure the product’s identity, strength, quality, purity, and potency; successfully undergo an FDA inspection or remote regulatory assessment of the manufacturing facility or facilities where the product is produced to assess compliance with current good manufacturing practices (“cGMP”); and receive FDA approval of the NDA.

Clinical trials involve the administration of an investigational product to human subjects under the supervision of qualified investigators. The trials must be conducted in accordance with protocols detailing objectives, safety parameters, effectiveness criteria, human subject protections, and statistical analysis plans. To ensure that clinical trials are conducted ethically and safely, sponsors must file a protocol for each trial with the FDA as part of their IND along with diversity action plans when applicable. Additionally, all research participants or their legally authorized representatives must provide written informed consent prior to participating in a clinical trial, which is then reviewed and approved by an institutional review board (“IRB”). The FDA may order the temporary or permanent discontinuation of, or impose conditions on the conduct of, a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to clinical trial patients. An IRB also may require the clinical trial to be halted for failure to comply with the IRB’s requirements or if the trial poses an unexpected serious harm to human subjects.

The purpose of the clinical trials is to generate enough data to provide statistically significant evidence of clinical efficacy and safety of the product candidate for approval. These trials are well-controlled and are intended to establish the overall risk-benefit profile of the product candidate and provide an adequate basis for physician labeling. The FDA typically requires that an NDA include data from two adequate and well-controlled clinical trials, but sometimes approval may be based upon a single adequate and well-controlled clinical trial plus confirmatory evidence or a single large multicenter trial without confirmatory evidence. Clinical trials must be registered with and clinical trial data must be disclosed to a publicly-available government database, or be subject to potential FDA enforcement action.

Abbreviated New Drug Application (“ANDA”)—An ANDA is filed when approval is sought to market a generic equivalent of a drug approved under an NDA.

The ANDA development process is generally less time-consuming and less complex than the NDA development process. It typically does not require new preclinical and clinical studies, because it relies on the studies establishing safety and efficacy conducted for the branded drug approved through the NDA process. The ANDA process, however, typically requires one or more bioequivalence studies to show that the ANDA drug is bioequivalent to the previously approved reference listed drug (“RLD”).

The Drug Price Competition and Patent Term Restoration Act of 1984 (the “Hatch-Waxman Act”) provides that generic drugs may enter the market after the approval of an ANDA, which requires (1) that bioequivalence to the branded product be demonstrated through clinical studies or in vitro studies, or be self-evident, and (2) either the expiration, invalidation or circumvention of any patents or the end of any other relevant market exclusivity periods related to the branded drug. Accordingly, generic products generally provide a safe, effective, and cost-efficient alternative to users of branded products. Growth in the generic pharmaceutical industry has been driven by the increased market acceptance of generic drugs, as well as the number of branded drugs for which patent terms and/or other market exclusivities have expired.

Generic products are generally commercialized after the expiration of patent protection for the branded product and after the end of a period of non-patent market exclusivity. In addition to patent exclusivity, the holder of the NDA may be entitled to a period of non-patent market exclusivity, during which the FDA cannot approve an application for a generic product. Also, if the NDA drug is a new chemical entity (“NCE”), the FDA may not approve an ANDA for a generic product for up to five years following approval of the NDA for the NCE. If an NDA drug is not an NCE, but the holder of the NDA conducted or sponsored clinical trials (that are not bioequivalence studies) essential to approval of the NDA or a supplement thereto, the FDA may not approve a generic equivalent to the NDA drug for three years. Certain other periods of exclusivity may be available if the branded drug is indicated for treatment of a rare disease, is an antibiotic, or is studied for pediatric indications.

In order to obtain FDA approval of NDAs and ANDAs, our manufacturing procedures and operations must conform to FDA requirements and guidelines, generally referred to as cGMP. The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, the standards around which are continuously changing and evolving. As a result, we must consistently monitor and comply with these changes. Our facilities, procedures, operations, and testing of products are subject to periodic inspection by the FDA, the DEA, and other authorities. In addition, the FDA conducts drug pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with NDA and ANDA specifications, cGMP and other FDA regulations. Our suppliers are subject to similar regulations and periodic inspections.

Hatch-Waxman Act for Drugs

Section 505 of the Federal Food, Drug, and Cosmetic Act (“FDCA”) sets forth three types of drug applications that may be submitted to the FDA for marketing authorization for a new drug. Under section 505(b)(1), sponsors may file an NDA which must contain full reports of investigations of safety and efficacy. Under section 505(b)(2), sponsors may file an NDA with full reports of investigations of safety and efficacy but may include at least some of the information required for approval from investigations that were not conducted by or for the applicant and relying, in part, on the FDA’s prior findings of safety and efficacy for an existing product, or published literature.

Under section 505(j), the ANDA approval pathway allows an abbreviated approval process for a generic version of an approved drug by which a manufacturer scientifically demonstrates that its duplicate product performed in the same manner as an existing approved drug (the “RLD”), by measuring the time it takes the duplicate (or “generic”) drug to reach the bloodstream in healthy volunteers and thereby demonstrating “bioequivalence” to the RLD. An approved ANDA provides marketing authority for a generic drug product that has the same active ingredients, dosage form, strength, route of administration, labeling, performance characteristics and intended use as a previously approved product.

The ANDA or 505(b)(2) NDA approval generally cannot be made effective until all of the RLD’s FDA-listed patents have expired, except where the ANDA or 505(b)(2) NDA applicant challenges a listed patent through a paragraph IV certification. Upon submission of an ANDA or 505(b)(2) NDA that references an RLD with listed patents, an applicant must certify to the FDA that at least one of the following criteria are met – (1) no patent information has been submitted to the FDA; (2) such patent has expired; (3) the date on which such patent expires; or (4) such patent is invalid or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. Alternatively, the applicant may elect to submit a “section viii” statement certifying that its proposed label does not contain any language regarding the RLD’s patented method-of-use.

If the ANDA or 505(b)(2) NDA applicant has provided a paragraph IV certification to the FDA, the applicant must also notify NDA and patent holders of the certification, who may then initiate a patent infringement lawsuit. If the suit is filed within 45 days of receipt of the certification, the FDA is subject to a 30-month stay such that the ANDA or 505(b)(2) NDA approval does not become effective until the earlier of (i) 30 months from the patent or application owner’s receipt of the notice of the paragraph IV certification, (ii) the expiration of the patent, (iii) when the infringement case concerning each such patent is decided in the applicant’s favor or settled, or (iv) such shorter or longer period as may be ordered by a court. It is common for the NDA holder or patent owner(s) to sue for patent infringement, thereby initiating a 30 month stay and delaying approval of the ANDA or 505(b)(2) NDA for a significant period of time.

Orphan drug designation

The FDA may grant orphan drug designation to drugs intended to treat a “rare disease or condition,” which is defined as a disease or condition that affects fewer than 200,000 individuals in the U.S., or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making the drug available in the U.S. will be recovered from sales in the U.S. for that product. Orphan drug designation must be requested before submitting an application to FDA for marketing approval. When reviewing a request for orphan drug designation, FDA considers the mechanism of action of the drug to determine what distinct disease or condition the drug is intended to treat, diagnose or prevent. Whether a given medical condition constitutes a distinct disease or condition for the purpose of orphan-drug designation depends on a number of factors, assessed cumulatively, including, pathogenesis of the disease or condition; course of the disease or condition; prognosis of the disease or condition; and resistance to treatment. These factors are analyzed in the context of the specific drug for which designation is requested.

While an orphan drug designation does not shorten the regulatory review and approval process or convey any other advantage in the review process, it does provide opportunities for grant funding towards clinical trial costs, tax advantages, and FDA user-fee exemptions. Additionally, if a product with orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances.

Post-approval Requirements

After FDA approval of an NDA or ANDA product is obtained, there are many post-approval requirements that must be met. These include registering the manufacturing establishment and listing the product with the FDA, reporting and keeping records of any adverse reactions or production problems, providing updated safety and efficacy information to the agency, drug shortage and manufacturing volume reporting, and complying with advertising and promotional labeling regulations. Additionally, FDA may approve an NDA with post-marketing study requirements, meaning that additional clinical trials must be conducted after approval in order to further monitor the drug’s safety and efficacy.

The FDA has the authority to require a Risk Evaluation and Mitigation Strategy (“REMS”) for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. A REMS may include, but is not limited to, elements such as medication guides, patient package inserts, communication plans to educate healthcare providers of the product’s risks, patient registries, or limitations on who can prescribe or dispense it. A REMS imposes numerous compliance obligations on the NDA and ANDA manufacturers. We currently participate in the Opioid Analgesic REMS for our Oxycodone Hydrochloride Oral Solution, Oxycodone Capsules and Levorphanol Tartrate Tablets commercial products, among others.

The Prescription Drug Marketing Act (“PDMA”) regulates the distribution of a manufacturer’s prescription drug samples and requires a compliance program governing the storage, security, distribution and recordkeeping of samples, as well as monitoring for loss or theft. The Drug Supply Chain Security Act (“DSCSA”) requires manufacturers and their trading partners, such as repackagers, wholesale distributors, dispensers, and third-party logistics providers, to implement interoperable electronic product tracking and tracing technology at the package level to identify and trace certain prescription drugs as they are distributed in the United States. Products subject to the DSCSA must only be transferred to appropriately licensed purchasers. ANI started manufacturing serialization-compliant products in November 2018. The DSCSA also establishes product verification, investigation, quarantine, disposition and notification responsibilities related to counterfeit, diverted, stolen, fraudulent and intentionally adulterated products that would result in serious adverse health consequences or death to humans. See **“Risk Factors — We are subject to federal, state, and local laws and regulations, and complying with these may cause us to incur significant additional costs.”**

Drug Advertising, Marketing and Promotion

The FDA regulates the marketing, labeling, advertising, and promotion of products that are placed on the market. Manufacturers must adhere to strict guidelines when promoting their products; all statements regarding a product must be consistent with its approved labeling and truthful and non-misleading in nature. Additionally, manufacturers may only promote their product for approved indications outlined by the FDA. All claims made about a product should also be adequately substantiated with evidence of both benefits and risks associated with use in order to ensure fair balance between them.

Physicians may prescribe drugs off-label but manufacturers cannot promote such uses unless they have been previously authorized by the FDA. Interactions between manufacturers and health care providers (“HCPs”) are governed by fraud and abuse laws, including anti-kickback provisions and the submission of claims for reimbursement. The federal Anti-Kickback Statute (“AKS”) is a criminal statute that prohibits, among other things, knowingly and willfully offering, paying, soliciting, or receiving remuneration directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs, in whole or in part. The term “remuneration” has been interpreted broadly by the Office of Inspector General of the U.S. Department of Health and Human Services and the courts to include anything of value including arrangements between pharmaceutical industry members on the one hand and prescribers, purchasers and formulary managers on the other. The Beneficiary Inducement Civil Monetary Penalties Law imposes similar restrictions on interactions between the pharmaceutical industry and federal healthcare program beneficiaries. There are certain statutory exceptions and regulatory safe harbors to the AKS protecting some common activities from prosecution, but they are drawn narrowly, and practices that involve remuneration that may be alleged to be intended to induce or reward prescribing, purchases, or recommendations may be subject to scrutiny.

The Patient Protection and Affordable Care Act, of 2010, as amended, (the “ACA”) modified the intent requirement under the AKS to a stricter standard, such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it to have committed a violation. In addition, the ACA also provided that a violation of the AKS is grounds for the government or a whistleblower to assert that a claim for reimbursement submitted to a federal healthcare program for payment of items or services resulting from such violation constitutes a per se false or fraudulent claim for purposes of the federal civil False Claims Act (“FCA”).

The FCA imposes civil liability on individuals or entities that knowingly submit, or cause to be submitted, false or fraudulent claims for payment to the government or avoid, decrease, or conceal an obligation to pay money to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. The civil FCA has been used to assert liability on the basis of kickbacks and other improper referrals, improperly reported government pricing metrics such as Best Price or Average Manufacturer Price, improper use of Medicare provider or supplier numbers when detailing a provider of services, improper promotion of off-label uses not expressly approved by the FDA in a product’s label, and allegations as to misrepresentations with respect to products, contract requirements, and services rendered. Intent to deceive is not required to establish liability under the civil FCA. Rather, a claim may be false for deliberate ignorance of the truth or falsity of the information provided or for acts in reckless disregard of the truth or falsity of that information. The FCA also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the FCA. These suits, also known as qui tam actions, may be brought, with only a few exceptions, by any private citizen who has material information of a false claim that has not yet been previously disclosed. If the government decides to intervene in a qui tam action and prevails in the lawsuit, the individual will share in the proceeds from any damages, penalties or settlement funds. If the government declines to intervene, the individual may pursue the case alone. The civil FCA provides for treble damages and a civil penalty for each false claim, such as an invoice or pharmacy claim for reimbursement. FCA liability may further be imposed for known Medicare or Medicaid overpayments, for example, overpayments caused by understated rebate amounts, that are not refunded within 60 days of discovering the overpayment, even if the overpayment was not caused by a false or fraudulent act. In addition, a civil judgment for violating the FCA may result in exclusion from federal health care programs, suspension and debarment from government procurement programs, and refusal of orders under existing government contracts.

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) also created federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, a healthcare benefit program, regardless of whether the payor is public or private, in connection with the delivery or payment for healthcare benefits; knowingly and willfully embezzling or stealing from a healthcare benefit program; willfully obstructing a criminal investigation of a healthcare offense; and knowingly and willfully falsifying, concealing, or covering up by any trick or device a material fact, or making any materially false statements, in connection with the delivery of, or payment for, healthcare benefits, items, or services relating to healthcare matters. Additionally, the ACA amended the intent requirement of certain of these criminal statutes under HIPAA so that a person or entity no longer needs to have actual knowledge of the statute, or the specific intent to violate it, to have committed a violation.

In addition, as part of the ACA, the federal government enacted the Physician Payment Sunshine Act. Manufacturers of drugs and biologics for which payment is available under Medicare, Medicaid, or the Children’s Health Insurance Program (with certain exceptions) are required to annually report to CMS certain payments and other transfers of value made to or at the request of HCPs that are covered recipients as well as principal investigators and research institutions at teaching hospitals for clinical trials. Failure to submit required information may result in civil monetary penalties. If not preempted by this federal law, several states currently also require reporting of marketing and promotion expenses, as well as gifts and payments to HCPs and organizations.

Most states have adopted laws similar to each of the above federal laws, which may be broader in scope and apply to items or services reimbursed by any third-party payor, including commercial insurers. Certain state laws regulate sponsors' use of prescriber-identifiable data and require implementation of commercial compliance programs, compliance with the pharmaceutical industry's voluntary compliance guidelines, and applicable compliance guidance promulgated by the federal government. State laws may also restrict payments or the provision of other items of value made to HCPs and other potential referral sources; impose restrictions on marketing practices; or require sponsors to track and report information related to payments, gifts, and other items of value to HCPs. Such laws typically impose significant civil monetary penalties for each instance of reporting noncompliance. See **"Risk Factors — We may become subject to federal and state false claims litigation brought by private individuals and the government."**

Controlled Substances

The DEA regulates certain drug products containing controlled substances, pursuant to the U.S. Controlled Substances Act ("CSA"). Certain of our products contain significant components that are classified as controlled substances. CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security, and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored, and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts, and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, we must submit a request to the DEA for a quota to purchase the amount of API needed to manufacture certain of our products deemed controlled substances. Without approved quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are dependent upon the DEA to approve quotas large enough to support our continued manufacture of our controlled substances at commercial levels. See **"Risk Factors — We are entirely dependent on periodic approval by the DEA for the supply of the API needed to manufacture our controlled substances. An inability to obtain such approvals would reduce or eliminate our revenues for our controlled substances, and could have a material adverse effect on our business, financial position, and operating results. In addition, we are subject to strict regulation by the DEA and are subject to sanctions if we are unable to comply with related regulatory requirements."**

Unapproved Products

Four of our products, EEMT, Opium Tincture, Thyroid Tablets, and Hyoscyamine, are marketed without approved NDAs or ANDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. We continue to believe that, so long as we comply with applicable manufacturing standards, the FDA will continue to operate on a risk-based approach and will not take action against us. However, we can offer no assurance that the FDA will continue to follow this approach or that it will not take a contrary position with any individual product or group of products. See **"Risk Factors — Four products, which together comprised less than 10% of our total revenue in 2024, are marketed without approved NDAs or ANDAs and we can offer no assurances that the FDA will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected."**

Pharmaceutical Coverage, Pricing, and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost of our products. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Sales of our products will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, such products. The process for determining whether a payor will provide coverage for a product is separate from the process for setting the price or reimbursement rate that the payor will pay for the product if coverage is approved. Decisions regarding whether to cover any of our products, the extent of coverage and amount of reimbursement to be provided are made on a plan-by-plan basis. No uniform policy for coverage and reimbursement exists in the U.S., and coverage and reimbursement can differ significantly from payor to payor. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular condition.

The containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Under the United States federal Budget Control Act of 2011, the failure of the Joint Select Committee on Deficit Reduction to reach required deficit reduction goals triggers automatic reimbursement reduction under Medicare and other government programs. Currently, All fee-for-service Medicare items and services on claims, including drugs, are subject to the 2% sequestration cut through fiscal year 2032. The payment reduction is taken from the calculated payment amount after the approved amount is determined and the deductible and coinsurance are applied. The Inflation Reduction Act of 2022 ("IRA") became law on August 22, 2022. Among other things, it requires manufacturers of selected drugs to negotiate discounted prices with the Secretary of the Department of Health and Human Services to set the maximum reimbursement for such drugs under Medicare Part D. Failure to reach an agreement can subject manufacturers to an excise tax and loss of coverage for such drugs under Medicare. In addition, the IRA amended the Medicare Part D plan design to eliminate the coverage gap phase of the benefit beginning on January 1, 2025. Manufacturers desiring Medicare Part D coverage of their branded drugs and biologics must participate in the new Manufacturer Discount Program and pay a rebate of 10% of the reimbursement in the initial phase of the benefit and 20% in the catastrophic phase of the benefit. The company does participate in the Manufacturer Discount Program ensure Medicare Part D coverage of our products but results in lower profitability when such drugs are dispensed to Medicare Part D beneficiaries.

Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved product(s). Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products, less favorable coverage policies and reimbursement rates may be implemented for other company products and/or for the products in the future. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. Furthermore, restrictions or conditions on coverage imposed by Medicare, Medicaid or other government programs may result in similar restrictions or conditions being adopted or imposed by private payors. The implementation of cost containment measures or other healthcare reforms may prevent the generation of revenue, attainment of profitability, or commercialization of products. In addition, it is possible that there will be further legislation or regulation that could harm the business, financial condition and results of operations.

Medicaid/Medicare

Medicaid and Medicare, both of which are U.S. federal health care programs administered by CMS, are major payors of pharmaceutical products, including those we produce.

Medicaid is administered by the states and jointly funded by the federal and state governments. Its focus is on low-income populations. State drug coverage policies under Medicaid may vary significantly state by state. The Patient Protection and Affordable Care Act (“PPACA”), as amended by the Health Care and Education and Reconciliation Act of 2010, together known as the Affordable Care Act (“ACA”), originally required states to expand their Medicaid programs to individuals with incomes up to 138% of the federal poverty level. Although the United States Supreme Court in 2011 made the Medicaid expansion optional, many states have expanded their Medicaid programs.

The ACA also made changes to Medicaid law that has negatively impacted our business. Pharmaceutical manufacturers that want their drug products covered by state Medicaid programs must enter into a rebate agreement with CMS and pay rebates to state Medicaid agencies on utilization of their drugs dispensed to Medicaid beneficiaries. The ACA raised the rebate percentages for both generic and branded pharmaceuticals effective January 1, 2010. The basic rebate is currently 13% of the average manufacturer price for sales of Medicaid-reimbursed products marketed under ANDAs. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of 23.1% of the average manufacturer price or the difference between the average manufacturer price and the “best price” (as defined in the Medicaid statute) during a specific period. In addition, there is an additional rebate if the average manufacturer price of the drug is rising faster than inflation. Since passage of ACA in 2010, Medicaid rebates have been capped at average manufacturer price per unit. However, beginning January 1, 2024 pursuant to the American Rescue Plan of 2021, Medicaid rebates will no longer be capped at average manufacturer price. As a result we could end up paying substantially higher Medicaid rebates on certain products.

Medicare is run by the federal government and is largely focused on the elderly and disabled. The Medicare Modernization Act of 2003 (“MMA”) created Medicare Part D to provide voluntary prescription drug coverage for Medicare beneficiaries. The MMA has increased coverage of pharmaceuticals, which has benefited the pharmaceutical industry for both brands and generic drugs. The ACA made some changes to Part D to make it easier for Medicare beneficiaries to obtain drugs, such as reducing coinsurance amounts. The ACA also required pharmaceutical companies to provide discounts to Medicare Part D beneficiaries for the cost of branded prescription drugs. The ACA created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D. Under the Medicare Coverage Gap Discount Program, any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a “generic,” is subject to the discount requirement. Certain of our products, while marketed as “generics,” are sold under approved NDAs and, therefore, are subject to the discount requirement.

The IRA was signed into law on August 16, 2022. The IRA brings sweeping changes to Medicare coverage and reimbursement for prescription drugs that could negatively impact us and other pharmaceutical manufacturers. Of note, beginning January 1, 2025, the IRA alters the current structure of the Medicare Part D standard benefit by eliminating the coverage gap. The IRA reduces a beneficiary’s out-of-pocket maximum to \$2,000 beginning in 2025. The existing coverage gap discount program for pharmaceutical manufacturers has been replaced by a new manufacturer discount program effective in January 2025. Under the new program, manufacturers will provide a 10% discount off the negotiated price for applicable drugs (branded drugs and biologics manufactured by companies that have Part D discount agreements) after the deductible is satisfied through the initial coverage phase of the benefit. In the catastrophic phase, manufacturers will provide a 20% discount off negotiated price. Any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a “generic,” is subject to the manufacturer discount requirement. We currently expect that this will increase discounts due on Medicare Part D utilization of our drug products. ANI has qualified as a Specified Manufacturer, and is therefore eligible for the specified manufacturer discount phase in for patients covered under the Low Income Subsidy program for applicable drugs marketed as of August 16, 2022.

In addition to restructuring the Medicare Part D benefit, under the IRA, CMS will negotiate directly with manufacturers the price that Medicare will pay for certain high-cost drugs via establishment of the Drug Price Negotiation Program (or the “Program”). The Program will apply to drugs administered or dispensed under both Medicare Parts B and D, although for the first two years of the Program, only Medicare Part D qualifying drugs will be impacted. The Program officially began in 2023 with CMS selecting 10 drugs for direct price negotiation from a list of drugs representing the highest Medicare Part D spend. The newly negotiated prices for the first tranche of Part D drugs will not be applicable until 2026. CMS will select up to an additional 15 drugs for price negotiation for initial price applicability year 2027 by February 1, 2025. If a manufacturer of a selected drug does not negotiate a Maximum Fair Price (“MFP”) with the CMS, the manufacturer must pay an excise tax of 65 to 95% of Medicare utilization based on the prior year or withdraw all manufacturer drug products from coverage under Medicare and Medicaid. Manufacturers that agree on an MFP, but do not honor it, will be subject to civil monetary penalties equal to 10 times the amount of the product dispensed or administered that year, as well as the difference between the reimbursed price and the MFP. Even if a manufacturer’s drug is not selected for negotiation under the Program, its Medicare coverage could be impacted as a drug with a MFP automatically receives placement on Part D plan formularies and could usurp coverage of another therapeutic alternative in the same class of drugs as the general rule is that Medicare Part D plan formularies have at least 2 drugs per each therapeutic class outside of the 6 protected classes. While none of our drug products have currently been selected for negotiation, we continue to monitor the process for potential impact to our business. The Program and resulting excise tax have been challenged as unconstitutional in various lawsuits including cases brought by the National Infusion Center Association, Global Colon Cancer Association, and Pharmaceutical Research and Manufacturers of America. In the event that the Program and resulting excise tax are struck down as unconstitutional, the Medicare Part D marketplace could be disturbed by insurers exiting the Medicare Part D market and premiums increasing. If this occurs, it could negatively impact reimbursement and coverage for our self-administered drugs.

Lastly, the IRA imposed additional rebates on manufacturers including ANI to the extent certain drug pricing metrics are rising faster than inflation. These new inflation rebates are similar to those imposed on manufacturers under Medicaid and could result in additional rebates due from us on Medicare utilization of our products. Inflation rebates are accruing on Medicare Part D utilization from October 1, 2022 and on Medicare Part B utilization of drugs from January 1, 2023 forward though the CMS has deferred collection of such rebates until 2025.

Payment or reimbursement of prescription therapeutics by Medicaid or Medicare requires manufacturers to submit certified pricing information to CMS. The Medicaid Drug Rebate statute requires manufacturers to calculate and report price points, which are used to determine Medicaid manufacturer rebate payments shared between the states and the federal government and Medicaid payment rates for ANI products. For products paid under Medicare Part B, manufacturers must also calculate and report their Average Sales Price, which is used to determine the Medicare Part B payment rate. For certain products, the Veterans Health Care Act (the “VHCA”) requires manufacturers to calculate and report to the Department of Veterans Affairs (“VA”) a different price called the Non-Federal Average Manufacturer Price, which is used to determine the maximum price that can be charged to certain federal agencies, referred to as the Federal Ceiling Price (“FCP”). Like the Medicaid rebate amount, the FCP includes an inflation penalty. A Department of Defense regulation requires manufacturers to provide this discount on products dispensed by retail pharmacies when paid by the TRICARE Program. The VHCA also requires manufacturers participating in the Medicaid program to enter into Federal Supply Schedule contracts with the VA through which their products must be sold to certain federal agencies at FCP. This necessitates compliance with applicable federal procurement laws and regulations, including submission of commercial sales and pricing information, and subjects companies to contractual remedies as well as administrative, civil, and criminal sanctions. In addition, the VHCA requires sponsors participating in Medicaid to agree to provide different mandatory discounts to certain Public Health Service grantees and other safety net hospitals and clinics under the 340B program based on the sponsor’s reported Medicaid pricing information. The 340B program has its own regulatory authority to impose sanctions for non-compliance, adjudicate overcharge claims against sponsors by the purchasing entities, and impose civil monetary penalties for instances of overcharging. These price reporting requirements create risk of submitting false information to the government, potential FCA liability and exclusion from certain of these programs.

Most of our products are covered by Medicaid and Medicare. Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions. Any determination that we have failed to comply with those obligations could subject us to penalties and sanctions, and we could be subject to federal or state false claims litigation.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. Certain states have formed Prescription Drug Affordability Boards that have the authority to set reimbursement and/or drug pricing in the state. We expect that additional state and federal health care reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments and/or third party payors or purchasing customers in certain states pay for health care products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

Patents, Trademarks, and Licenses

Our success depends in part on our and our licensors' ability to obtain and maintain proprietary protection for our key branded products or any future products or product candidates, technology and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. Because we license certain intellectual property relating to ILUVIEN from third parties, we depend on their ability to obtain and maintain such protection. Where we have conducted our own research, our policy is to seek to protect our proprietary position by, among other methods, filing U.S. and foreign patent applications related to our proprietary technology, inventions and improvements that are important to the development of our business. We also rely on trade secrets, know-how, continuing technological innovation and in-licensing opportunities to develop and maintain our proprietary position.

As of December 31, 2024, we owned two U.S. patents as well as pending patent applications relating to Cortrophin Gel. In addition, as a result of the Alimera acquisition, in September 2024, we acquired rights to two U.S. utility patents covering ILUVIEN and YUTIQ and foreign counterparts to an expired U.S. design patent covering the ILUVIEN injector. We license one utility patent right relating to the YUTIQ injector from EyePoint. Pursuant to an amended and restated license agreement (the "New Collaboration Agreement") with EyePoint, our ILUVIEN-related patent rights are only for diseases of the human eye in Europe, the Middle East and Africa, and for diseases of the human eye excluding uveitis in the rest of the world. Pursuant to a product rights agreement ("Product Rights Agreement") entered into with EyePoint in May 2023, these rights have been expanded to include uveitis worldwide except for China and certain other countries in Asia.

U.S. utility patents generally have a term of 20 years from the date of filing. The utility patent rights relating to ILUVIEN that EyePoint licensed to us include one U.S. patent that will expire in August 2027. An additional licensed patent relating to the YUTIQ injector will expire in January 2028.

In addition to Cortrophin Gel, ILUVIEN and YUTIQ, we own the trademark names for most of our branded products, including Cortenema, Cortrophin-Zinc, Inderal LA, Inderal XL, InnoPran XL, Kionex, Lithobid, SOVUNA, Reglan, Vancocin, and Veregen. We license the trademark names for Atacand, Atacand HCT, Arimidex, Casodex, Oxistat. With the exception of a license for patent technology for Inderal XL, InnoPran XL, and Veregen, we do not license any patents associated with these products. Further, patent protection and market exclusivity for some of these branded products have expired, with the exception of the Veregen product, which has three patents. One patent expired in 2022 and the remaining two patents expire in 2025 and 2026. Therefore, we consider the trademark names to be of material value and we act to protect these rights from infringement. However, our business is not dependent upon any single trademark. Trademark protection continues in some countries as long as used, and in other countries, as long as registered. Registration is for fixed terms and may be renewed indefinitely. We believe that sales of our branded products have benefited and will continue to benefit from the value of the product name. We also recently acquired certain patents and patent applications relating to baclofen and a patent was granted on our hydrochlorothiazide product.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our and our licensor's success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology we develop. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before such product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Distribution Agreements

In addition to selling products under our own NDAs and ANDAs, we enter into marketing and distribution agreements with third parties in which we sell products under ANDAs or NDAs owned or licensed by these third parties. These products are sold under our own label.

Customers

Our customers purchase and distribute our products. Our customers include major national wholesalers. Our products are sold by major retail pharmacy chains, distributors, national mail order houses, as well as group purchasing organizations.

In recent years, the wholesale distributor network for pharmaceutical products has been subject to increasing consolidation, which has increased the concentration of our wholesale customers. In addition, the number of retail market chains and, in particular, the number of independent drug stores and small chains, has decreased as retail consolidation has occurred, also increasing the concentration of our retail customers. As a result of this trend toward consolidation, a smaller number of companies each control a larger share of pharmaceutical distribution channels. For the years ended December 31, 2024 and 2023, approximately 64% and 70% of our net revenues were attributable to four customers, respectively. For the year ended December 31, 2022, three customers accounted for approximately 59% of our net revenues. In addition, as noted below, our customers also distribute our products. The loss of any of these customers, including in their role as distributors, could have a material adverse effect on our business.

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.

In the Rare Disease business, specifically for Cortrophin Gel, there is a limited distribution network and a select group of specialty pharmacies which can dispense product to appropriate patients. We contract and engage with the largest health insurance payers across the appropriate channels and classes of trade. For ILUVIEN and YUTIQ, our sales personnel focus on physician offices, clinics, pharmacies and hospitals in the U.S. and in European countries where we seek to engage end users to purchase our products.

Consistent with industry practice, we maintain a return policy that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. See "Management's Discussion and Analysis of Results of Operations and Financial Condition—Critical Accounting Estimates" for a discussion of our accruals for chargebacks, rebates, returns, and other allowances.

Sales, Marketing, and Distribution

We market, sell, and distribute our products in the United States and internationally. Our products are distributed through the following channels:

- **Wholesalers.** We conduct business with the three major wholesalers in the United States: Cencora, Inc., Cardinal Health, and McKesson.
- **Retail Market Chains.** We conduct business with all the major retail chains in the United States which includes CVS, Rite Aid, Kroger, Walmart, and Walgreens.
- **Distributors and Specialty Pharmacies.** We have contracts with several major distributors and specialty pharmacies in the United States, including Anda, Smith Drug Company, Morris Dickson, CVS Caremark, Accredo, OptumRx, and CuraScript. We also have various agreements with international distributors for our ILUVIEN product.
- **Group Purchasing Organizations.** We have contracts with group purchasing organizations in the United States, such as ClarusONE, Walgreens Boots Alliance Development Group, Red Oak Sourcing, Econdisc, Optisource, Rx Sourcing Strategies, The Premier Group, Topco, The Buyer's Consortium, Managed Health Care Associates Inc., Asembia, Premier Inc, and Kaiser Permanente.
- **Specialty Pharmacies.** In our Rare Disease and Brands segment we contract with specialty pharmacies.
- **Hospitals, Clinics, and Physicians.** In our Rare Disease and Brands segment, specifically for ILUVIEN and YUTIQ, we contract with certain hospital systems, clinics, and physician offices.

Competition

Certain of our products face limited competition due to complexities in formulation, active pharmaceutical ingredient sourcing, materials handling and manufacturing, and regulatory hurdles. Nevertheless, we compete with numerous other pharmaceutical companies, including large, global pharmaceutical manufacturers capable of addressing these complexities and hurdles with respect to products that we currently produce and products that are in our pipeline. In addition, our products are subject to competition from other generic products and non-prescription alternative therapies.

Our brands portfolio of pharmaceutical products currently face competition from generic products and we expect them to continue to face competition from generic products in the future. In order to launch a generic product, a manufacturer must apply to the FDA for an ANDA showing that the generic product is therapeutically equivalent to the RLD. (See "Government Regulation.")

The primary means of competition among generic drug manufacturers are pricing, contract terms, service levels, and reliability. To compete effectively, we seek to consistently produce high-quality, reliable, and effective products. We also establish active working relationships with each of our customers, continually gather important market information in order to respond successfully to requests for proposals, maintain sufficient inventories to assure high service levels, and work to reduce product costs by sourcing and qualifying alternative suppliers whenever possible.

Over the past several years, the pharmaceutical industry has experienced significant consolidation, particularly in distribution channels and among generic and brand drug companies.

The wholesale distributor network for pharmaceutical products has been subject to increasing consolidation, which has increased the concentration of our wholesale customers. In addition, the number of retail market chains and, in particular, the number of independent drug stores and small chains, has decreased as retail consolidation has occurred, also increasing the concentration of our retail customers. As a result of this trend toward consolidation, a smaller number of companies each control a larger share of pharmaceutical distribution channels, which results in pricing pressure on our business and can result in a shift in sales to our competitors.

In addition, consolidation among pharmaceutical companies has created opportunities by reducing the number of competitors. However, as competitors grow larger through consolidation, so do their resources. Larger competitors may be able to aggressively decrease prices in order to gain market share on certain products and may have resources that would allow them to market their products more effectively to potential customers.

Our sales can also be impacted by new studies that indicate that a competitor's product has greater efficacy than one of our products. If competitors introduce new products with therapeutic or cost advantages, our products can be subject to progressive price reductions and/or decreased volume of sales.

Principal competitors for the Generic pharmaceutical markets in which we do business include, but are not limited to:

- Amneal Pharmaceuticals, Inc., Apotex Inc., Aurobindo Pharma, Camber Pharmaceuticals Inc., Hikma Pharmaceuticals plc, Lupin Pharmaceuticals, Inc., Rising Pharmaceuticals, Inc., Strides Pharma Inc., Sun Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Viatris Inc., and Zydus Pharmaceuticals USA.

The principal competitor for Cortrophin Gel is Acthar[®] Gel marketed by Mallinckrodt Pharmaceuticals.

The principal competitors for ILUVIEN and YUTIQ are:

DME Competitors

- Eylea[®] (aflibercept) 4 mg and Eylea[®] HD (aflibercept) 8 mg, marketed by Regeneron in the U.S. and by Bayer in the EEA; Vabysmo[®] (faricimab-svoa), marketed by Genentech; Avastin[®] (bevacizumab), Lucentis[®] (ranibizumab injection), marketed by Genentech (Roche) in the U.S. and Novartis in the rest of the world; Ozurdex[®] (dexamethasone intravitreal implant), marketed by Allergan, an AbbVie company.

NIU-PS Competitors

- Ozurdex[®] (dexamethasone intravitreal implant), marketed by Allergan, an AbbVie company; Xipere[®] (triamcinolone acetonide injectable suspension 40 mg/ml) marketed by Bausch & Lomb; Retisert[®], marketed by Bausch and Lomb; Humira[®] (adalimumab), marketed by AbbVie.

Product Liability

Product liability litigation represents an inherent risk to all firms in the pharmaceutical industry. We utilize traditional third-party insurance policies with regard to our product liability claims. Such insurance coverage at any given time reflects current market conditions, including cost and availability, when the policy is written.

Human Capital

As of January 2025, we have 897 employees, of which 720 are located in the United States, 112 in India, 28 in the United Kingdom, 18 in Germany, 11 in Portugal, 8 in Ireland, and 1 in Canada. We also utilize agency resources as well as a small number of part-time and consultant resources to meet our operational needs and our turnover is in line with similar businesses in our industry and locations.

Our Purpose and Core Values

Our human capital management strategy is guided by our purpose and core values. Our purpose is Serving Patients, Improving Lives. Our core values are Patient First, Teamwork, Innovation, Integrity & Compliance, Accountability & Transparency, and Commitment to Excellence. We believe that our purpose and core values provide clarity, a shared language, and ultimately create what is distinctive about our company and our culture. We are motivated to bring our best to ANI every day by the patients we serve, the people we work with, the direct impact we have on the work, and the learning, growth and development opportunities we provide.

Culture, Engagement, and Diversity, Equity, and Inclusion

We believe that attracting, retaining, and promoting engagement for talented employees is critical to the success of our business, and we take pride in our values, culture, and communities. We are committed to creating a diverse, equitable, and inclusive work environment within all levels of the business. As of the end of 2024, approximately 42% of our workforce identified as female and approximately 58% identified as male. In the same period, approximately 45% of our workforce identified as a person of color or indigenous person, with approximately 55% identifying as white.

Furthermore, we do not tolerate discrimination or harassment of any kind against anyone, or the use of child or forced labor. We value employee input, and conduct focus groups and survey employees on specific topics (e.g. approximately 30% of our employees participated in a benefits and wellness survey in 2024). We offer ongoing training and career development to all employees, both through curriculum developed internally, and through external resources (e.g. LinkedIn Learning). Together, we own our culture and participate in ongoing open dialogue as we strive for continued growth.

At ANI, we believe that no one should go without medicines that they need. In December 2022, we formed the ANI Rare Disease Patient Assistance Program, Inc. (“ANI PAP”) for the purpose of providing certain medicine for free to patients in the United States who do not have prescription drug or health insurance coverage and who, without assistance, cannot afford their medicine. In addition, ANI has provided patient-related financial support to nonprofit organizations that are aligned with ANI’s mission to address unmet needs. Our charitable contributions support initiatives and programs that advance medical care or patient care within the Company’s therapeutic areas of focus.

Total Rewards

ANI’s Total Rewards Philosophy is grounded in pay for performance and seeks to provide compensation and benefits that are competitive within the pharmaceuticals industry, as well as competitive with local employers for jobs of a cross-industry nature. We pay fair and competitive salaries, short-term incentives, and long-term incentives that are informed by external market rates and internal equity. We recognize and reward employee performance, productivity, and alignment with ANI’s Core Values. We believe that a holistic rewards strategy should also go beyond compensation and benefits to consider elements such as wellness, recognition, and purpose. We support flexible and remote working arrangements throughout the business, as we are able.

Health and Safety Management and Training

We are committed to the safety and health of our employees, patient-customers, and the public. It is critical within our mission to ensure we keep our employees and customers safe while accomplishing our business goals. ANI has established a health and safety program with a focus on continuous improvement and employee engagement. ANI personnel are encouraged to take corrective actions where appropriate and to communicate concerns to management with a “see something, say something” approach. We recognize and reward personnel for contributing to the safety system within our working environment. The overall program continually evolves to reflect regulatory changes and compliance standard industry best practices. As part of onboarding new employees, we provide health and safety training and periodic training programs to maintain and improve employee awareness of safety issues. The goal of the safety training programs is to ensure that our staff are well informed on the subject matters and have the appropriate tools to make sound health and safety decisions in our day-to-day operations.

Environmental Stewardship and Sustainability

ANI is committed to Serving Patients, Improving Lives, both directly through our high-quality products, and through our environmental stewardship and sustainability practices. We strive to minimize waste and emissions, promote reuse and recycling, and conserve resources. We continue to increase our efforts and have formed an Environmental, Social, and Governance (“ESG”) Steering Committee to oversee cross-functional initiatives. The ESG Steering Committee reports to our Board of Directors through our Nominating and Governance Committee and is committed to providing progress updates at least twice per year.

Available Information

We file annual, quarterly and current reports, proxy statements and other information required by the Securities Exchange Act of 1934, as amended (the “Exchange Act”), with the Securities and Exchange Commission (“SEC”). We make available free of charge on our website (www.anipharma.com) our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and any amendments to those filings as soon as reasonably practicable after such material is electronically filed with or furnished to the SEC. Also posted on our website in the “Investors – Corporate Governance” section are our Corporate Governance Guidelines, Code of Ethics and the charters for the Audit and Finance, Compensation, and Nominating and Corporate Governance Committees. Information on, or accessible through, our website is not a part of, and is not incorporated into, this report or any other SEC filing. Copies of our SEC filings or corporate governance materials are available without charge upon written request to Investor Relations, c/o ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota, 56623.

Item 1A. Risk Factors

Risk Factor Summary

Investing in our common stock involves a high degree of risk. You should carefully consider all information in this Annual Report on Form 10-K prior to investing in our common stock. These risks are discussed more fully in the section titled “Risk Factors.” These risks and uncertainties include, but are not limited to, the following:

- Our approved products, including Cortrophin Gel, ILUVIEN and YUTIQ, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability;
- 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;
- We may fail to realize the benefits expected from our acquisition of Alimera and the combined company may not perform as we or the market expects;
- The limited number of suppliers for our API could result in lengthy delays in production if we need to change suppliers;
- Several of the products we have acquired cannot be manufactured in our facilities and we must secure and maintain qualified and compliant contract manufacturers. Noncompliance by these contract manufacturers or our inability to find qualified contract manufacturers could result in us being unable to commercialize these products; Several of our products are manufactured and/or packaged by single-sourced third parties, which we cannot control and could result in us being unable to market and distribute products;
- We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business;
- Failure to comply with data protection laws and regulations could subject us to government enforcement actions, private litigation and/or adverse publicity, which could negatively affect our operating results and business;
- Our Medicaid rebate accruals have increased and continue to increase due to our acquisitions and subsequent sales of branded products and authorized generics of branded products;
- Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions;
- We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products;
- Production at any or all of our three current manufacturing facilities could be interrupted, which could cause us to fail to deliver product on a timely basis;
- We rely on third parties to assist with our clinical trials. If these parties do not perform or are non-compliant, it could negatively impact the clinical trial and potential of regulatory approval; further, we may be required to audit or redo previously completed trials or recall already-approved commercial products;
- Clinical trials for our products may not generate the outcomes we expect, may take longer or be more costly to complete than we anticipate;
- We may be adversely affected by the expiration of patents that protect key aspects of our products in the near- to medium-term;
- Inability to protect our intellectual property in the U.S. and foreign countries could negatively affect sales of our branded products;
- If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are material to our business;
- Our success is largely dependent upon certain key employees, including members of our senior management, the loss of whom could adversely affect our operations;
- We rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology could harm our ability to operate the business effectively;
- We are involved in and may become involved in legal proceedings from time to time, which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources;
- We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums;
- The obligations and liabilities of Alimera, some of which may be unanticipated or unknown, may be greater than we have anticipated, which may diminish the value of Alimera to us;
- Our operations in an international market subject us to additional regulatory oversight both in the international market and in the U.S., as well as, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results;
- Our operations, including those resulting from our acquisition of Alimera, and its international operations, will subject us to political and economic risks, increase our exposure to potential liability under anti-corruption, trade protection, tax, and other laws and regulations;

- Future acquisitions and investments could disrupt our business and harm our financial position and operating results;
- Pharmaceutical product quality standards are steadily increasing on all products, and if we cannot meet these standards, we may be required to discontinue marketing and/or recall products from the market;
- Federal and state false claims litigation brought against us by private individuals and the government could result in civil and criminal penalties, damages, fines and other related actions;
- The use of legal, regulatory, and legislative strategies by competitors could result in increased costs to develop and market our products, delay new product introductions and reduce profit potential;
- Third-party payer actions may prevent us from effectively marketing our products or cause us to decrease pricing;
- Healthcare reform legislation could have a material adverse effect on our business, financial position, and operating results;
- Public health outbreaks, epidemics, or pandemics (such as COVID-19) have adversely affected and may in the future adversely affect our business;
- The continuing trend toward consolidation of customer groups could result in declines in the sales volume and prices of our products, and increased fees charged by customers;
- The Food and Drug Administration (“FDA”) does not provide guidance on safety labeling for products that are marketed without approved New Drug Applications (“NDAs”) or Abbreviated New Drug Applications (“ANDAs”), which could increase our potential liability with respect to failure-to-warn claims for these products;
- Four of our products are marketed without approved NDAs or ANDAs and we can offer no assurances that the FDA will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected;
- If the Drug Enforcement Administration (“DEA”) does not approve supply of the API we need to manufacture our controlled substances, we may be unable to manufacture controlled substances, which would eliminate our revenue on these products;
- Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods;
- Our indebtedness and liabilities could limit the cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operation;
- To service our indebtedness, we will be required to generate a significant amount of cash;
- Our New Credit Agreement contain restrictive and financial covenants and if are not in compliance with these covenants, our outstanding indebtedness under this facility could be accelerated and the lenders could terminate their commitments under the facility;
- Certain risks relating to our 2.25% Convertible Senior Notes due 2029 and related capped call transactions; and
- Raising additional funds by issuing additional equity securities may cause dilution to our current stockholders. Raising additional funds by entering into additional credit or other borrowing facilities or issuing debt may subject us to covenants and other requirements that may restrict our operations.

The following are significant factors known to us that could materially harm our business, financial position, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward-looking statement made in this report. The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may adversely affect our business, financial position, and operating results. If any of these risks actually occur, our business, financial position, and operating results could suffer significantly. As a result, the market price of our common stock could decline and investors could lose all or part of their investment.

Risks Related to our Business

Our approved products, including Cortrophin Gel, ILUVIEN and YUTIQ, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability and we may face substantial competition from competitors that discover, develop or commercialize competing products before or more successfully than we do, which could have a material adverse effect on our business, financial position, and operating results.

The development and commercialization of new drugs is highly competitive, and the commercial success of our products or any of our future products or product candidates will depend on several factors, including our ability to differentiate any such products or product candidates from our competitors’ current or future products, including the creation of generic competitive products. We seek to develop, license, or acquire products that we can commercialize at levels of market acceptance that would allow us to recoup our costs, grow market share, and achieve profitability. However, we face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to our current products and to any future products or product candidates that we may develop or commercialize in the future.

Even if we are able to obtain regulatory approvals for our pharmaceutical products, if we fail to predict accurately demand for such products, or our competitors more effectively develop competitive products, that have few or less severe adverse side effects and have higher rates of acceptance by physicians, our business, financial position, and operating results could be adversely affected. Levels of market acceptance for our products could be impacted by several factors, including but not limited to:

- our products' pricing relative to that of our competitors;
- our marketing effectiveness relative to that of our competitors;
- timing of our market entry;
- our ability to market our products effectively to the retail level; and
- acceptance of our products by government and private formularies.

Some of these factors are outside of our control and, if any arise, our profitability, business, financial position, and operating results could be materially adversely affected.

Cortrophin Gel is our first rare disease pharmaceutical product. To the extent our ongoing and continuing efforts to commercialize this product are unsuccessful, our business, financial condition and results of operations will be negatively impacted.

On October 29, 2021, we received approval from the FDA for our Cortrophin Gel product 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. We have devoted significant time and money to the development of this product since we acquired the rights to the product in 2016. We have invested and continue to invest significantly in the commercialization of this product in the U.S, including building out a sales force and developing a patient support program, with a full-scale launch in January 2022. In October 2023, we announced FDA approval and commercial availability of a 1-mL vial of Cortrophin Gel, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares. The ability for us to generate significant net product revenues from our Cortrophin Gel products will depend upon our ability to successfully sell the product and numerous other factors, including:

- successfully establishing and maintaining effective sales, marketing, and distribution systems in jurisdictions in which Cortrophin Gel is approved for sale;
- successfully establishing and maintaining manufacturing capabilities with our third-party suppliers and CMOs and manufacturing adequate commercial quantities of Cortrophin Gel at acceptable cost and quality levels, including maintaining current good manufacturing practice ("cGMP") and quality systems regulation standards required by various regulatory agencies;
- broad acceptance of Cortrophin Gel by physicians, patients, and gaining market access share in the healthcare community;
- the acceptance of pricing and placement of Cortrophin Gel on payers' formularies and the associated tiers;
- effectively competing with the only other competitor that has an approved adrenocorticotrophic hormone ("ACTH") therapy product on the market, as well as other products that are in development or may be developed in the future as a treatment option;
- continued demonstration of safety and efficacy of Cortrophin Gel in comparison to competing products or treatment options;
- our ability to comply with ongoing regulatory obligations and continued regulatory review which may result in significant additional expense and may require labeling changes based on new safety information, post-market studies or clinical trials to evaluate safety risks related to the use of Cortrophin Gel; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims.

If we do not achieve one or more of these factors, we could experience an inability to successfully commercialize Cortrophin Gel, which would negatively impact our business, financial condition and results of operations. In addition, sales of Cortrophin Gel could be negatively affected by discovery of previously unknown problems with the product, such as adverse events of unanticipated severity or frequency, problems with the facilities where the product is manufactured, or imposition of restrictions on Cortrophin Gel, including requiring withdrawal of the product from the market, by a regulatory agency if it disagrees with the promotion, marketing, or labeling of the product.

We may enter into new lines of business that offer new products and/or services and we may have limited experience in marketing such new products and/or services, which may subject us to additional risks.

From time to time, we may enter into new lines of business that offer new products and/or services. For example, in September 2024 we acquired Alimera, a global pharmaceutical company that specializes in the commercialization and development of ophthalmic retinal pharmaceuticals, which for us is a new line of business. Our lack of experience with or knowledge of such business or other new lines of business we may choose to enter, as well as external factors, such as competitive alternatives, potential conflicts of interest, either real or perceived, and shifting market preferences, may impact our implementation and operation of such new lines of business. Other risks of implementing new lines of business include:

- potential diversion of management's attention, available cash and other resources from our existing business;
- any determination by governmental agencies that any acquisition we undertake is anticompetitive in any relevant market;
- unanticipated liabilities or contingencies;
- compliance with new or increased regulatory burdens;
- potential damage to existing customer relationships, lack of customer acceptance or inability to attract new customers;
- the cost of developing an in-house sales and marketing organization, which would require significant expenditures, management resources, and time; and
- the inability to compete effectively in the new line of business.

Failure to successfully manage these risks in the implementation or acquisition of new lines of business or the offering of new products or services could have a material adverse effect on our reputation, business, results of operations and financial condition.

We depend on a limited number of suppliers for API. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. We may experience lengthy delays if we need to change an API supplier, which could have a material impact on business and results of operations.

Our ability to manufacture and distribute products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the U.S. During the year ended December 31, 2024, approximately 12%, of our raw material inventory purchases were from one domestic supplier. During the year ended December 31, 2023, no single vendor represented more than 10% of our raw material inventory purchases. During the year ended December 31, 2022 approximately 19%, of our raw material inventory purchases were from one domestic supplier. Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect our ability to manufacture and distribute our products and could result in legal liabilities that could materially affect our ability to realize profits or otherwise harm our business, financial, and operating results. We source the raw materials for our products from both domestic and international suppliers. Generally, we qualify only a single source of API for use in each product due to the cost and time required to validate and qualify a second source of supply. Any change in one of our API suppliers must usually be approved through a Prior Approval Supplement ("PAS") by the FDA. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we carefully select suppliers, based on various factors including quality, reliability of supply, and long-term financial stability. Certain of the API for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections.

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

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

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

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

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

We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business.

Many of our products are eligible for reimbursement under federal and state health care programs such as Medicaid, Medicare, TRICARE, and/or state pharmaceutical assistance programs, and as a result, certain U.S. federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are, and will be, applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business.

The domestic and foreign laws that may affect our ability to operate include, but are not limited to: (i) the U.S. Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, as a means of inducing, or in exchange for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) U.S. federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other federal healthcare program payers that are false or fraudulent; (iii) new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; (iv) the U.S. Physician Payments Sunshine Act, which among other things, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually information related to certain "payments or other transfers of value" made to physicians, physician assistants, advanced practice nurses and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, and similar state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; (v) the government pricing rules applicable to the Medicare and Medicaid programs, the 340B Drug Pricing Program, the U.S. Department of Veterans Affairs program, the TRICARE program, and state price transparency reporting laws; and (vi) state and foreign law equivalents of each of the above U.S. laws, such as anti-kickback and false claims laws which may apply to items or services. Defense of litigation claims and government investigations can be costly, time-consuming, and distract management, and it is possible that we could incur judgments, settlements, deferred or non-prosecution agreements, or corporate integrity agreements that would require us to change the way we operate our business. We are committed to conducting the sales and marketing of our products in compliance with the healthcare fraud and abuse laws, but certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and/or criminal sanctions.

Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that govern our activities, such as federal and state anti-kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn and construed by the courts. While we manage our business activities to comply with these statutory provisions, due to their breadth, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the DOJ, the Office of Inspector General at the U.S. Department of Health and Human Services, and other agencies have increased their enforcement activities with respect to the manufacturing, sales, marketing, research and similar activities of pharmaceutical companies in recent years, and many pharmaceutical companies have been subject to government investigations related to these practices. A determination that we are in violation of these and/or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacturing and/or distribution activities, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. Any of these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows.

If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity, which could negatively affect our operating results and business.

We are subject to data protection laws and regulations. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information and/or genetic privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health related and other personal information. In California, the California Consumer Privacy Act (“CCPA”) establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The California Privacy Rights Act currently in effect, significantly amends the CCPA. Virginia, Colorado, Utah, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business, and similar laws are under consideration in other states. These laws and regulations are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. The obligations to comply with the CCPA and evolving legislation may involve, among other things, updates to our notices and the development of new processes. We may be subject to fines, penalties, or private actions in the event of non-compliance with such laws.

In addition, we may obtain health information from third parties (e.g., healthcare providers who prescribe our product) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, (collectively, “HIPAA”). HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses, as well as their “business associates”—certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of a covered entity. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.

Further at the federal level, the Federal Trade Commission (“FTC”) also sets expectations for failing to take appropriate steps to keep consumers’ personal information secure, or failing to provide a level of security commensurate to promises made to individual about the security of their personal information (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5(a) of the Federal Trade Commission Act (“FTC Act”). The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers’ personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions.

EU Member States and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation (GDPR) imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted laws that impose restrictions and obligations similar to the GDPR. The obligations and restrictions under the GDPR and Switzerland’s laws concern, in particular, in some instances the consent of the individuals to whom the personal data relate, the processing details disclosed to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the EEA or Switzerland, contracting requirements (such as with clinical trial sites and vendors), and security breach notifications, as well as substantial potential fines, in some cases up to 4% of annual global turnover, for breaches of the data protection obligations. Data protection authorities from the different EU Member States and the EEA may interpret the GDPR and applicable related national laws differently which could effectively result in requirements additional to those currently understood to apply under the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EU. When processing personal data of subjects in the EU, we have to comply with applicable data protection and electronic communications laws. In particular, as we rely on service providers processing personal data of subjects in the EU, we have to enter into suitable contract terms with such providers and receive sufficient guarantees that such providers meet the requirements of the applicable data protection laws, particularly the GDPR which imposes specific and relevant obligations. Enforcement by EU and U.K. regulators is active, and failure to comply with the GDPR or applicable Member State law may result in substantial fines.

Legal mechanisms to allow for the transfer of personal data from the EEA or U.K. to the U.S. may impact our ability to transfer personal data or otherwise may cause us to incur significant costs to do so legally. On July 16, 2020, the European Court of Justice ruled that the Privacy Shield is an invalid data transfer mechanism and confirmed that the Standard Contractual Clauses (“SCCs”) remain valid. If companies are relying on the SCCs as their transfer mechanism to transfer personal information from the EEA to the U.S. (or to other jurisdictions not recognized as adequate by the EU), they must be incorporated into new and existing agreements within prescribed timeframes. The U.K. adopted versions of their own SCCs. Updating agreements to incorporate these new SCCs for the EEA and U.K. may require significant time and resources to implement, including through adjusting our operations, conducting requisite data transfer assessments, and revising our contracts. Companies that have not taken steps to demonstrate that their SCCs and personal data recipients in the U.S. or other non-adequate jurisdictions are suitable to receive the personal data may be subject to enforcement actions by competent authorities in the EU for failure to comply with related data privacy rules.

Additionally, the European Commission adopted a draft adequacy decision for the EU-U.S. Data Privacy Framework, which reflects the assessment by the European Commission of the U.S. legal framework. The draft decision concludes that the U.S. ensures an adequate level of protection for personal data transferred from the EU to U.S. companies. After an approval process, the European Commission is expected to adopt the final adequacy decision, which will allow data to flow freely from the EU to the U.S.

If we or our distributors fail to comply with applicable data privacy laws concerning, or if the legal mechanisms we or our distributors rely upon to allow, the transfer of personal data from the EEA or Switzerland to the U.S. (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions, including an order to stop transferring the personal data outside of the EEA and significant penalties against us. Moreover, our business could be adversely impacted if our ability to transfer personal data out of the EEA or Switzerland to the U.S. is restricted, which could adversely impact our operating results. Failure to comply with data protection laws and regulations could result in unfavorable outcomes, including increased compliance costs, delays or impediments in the development of new products, increased operating costs, diversion of management time and attention, government enforcement actions and create liability for us (which could include civil, administrative, and/or criminal penalties), private litigation and/or adverse publicity that could negatively affect our operating results and business.

Our anticipated revenue growth and profitability, if achieved, is dependent upon our ability to develop, license or acquire, and commercialize new products on a timely basis in relation to our competitors’ product introductions, and to address all regulatory requirements applicable to the development and commercialization of new products. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results.

Our future revenues and profitability are dependent upon our ability to successfully develop, license or acquire, and commercialize pharmaceutical products in a timely manner. Product development is inherently risky and time-consuming. Likewise, product licensing involves inherent risks, including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to the supply of product meeting specifications and terms such as license scope or termination rights. The development and commercialization process also requires substantial time, effort, and financial resources. Additionally, we have entered profit-sharing or royalty arrangements with third parties in which we sell products under ANDAs or NDAs owned or licensed by these third parties. Under these agreements, we pay these third parties a specified percentage of the gross profit earned on sales of the products, and such percentages in certain cases increase as additional gross profit is earned. Any increases in these percentages would impact our future profitability. We may not be successful in commercializing products on a timely basis, if at all, which could adversely affect our business, financial position, and operating results.

The FDA must approve any new prescription product before it can be marketed in the U.S. The process of obtaining regulatory approval to manufacture and market branded and generic pharmaceutical products is rigorous, time consuming, costly, and largely unpredictable. We may be unable to obtain requisite approvals on a timely basis for branded or generic products that we may develop, license, or acquire. Moreover, if we obtain regulatory approval for a drug, we may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which in turn could restrict the potential market for the drug. Also, for products pending approval, we may obtain raw materials or produce batches of inventory. In the event that regulatory approval is denied or delayed, we could be exposed to the risk of any such inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect our product introduction plans, business, financial position, and operating results.

The approval process for generic pharmaceutical products often results in the FDA granting simultaneous final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces a generic firm to face immediate competition when it introduces a generic product into the market. Additionally, further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to branded products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle. As a result, we could be unable to grow or maintain market share with respect to our generic pharmaceutical products, which could have a material adverse effect on our ability to market that product profitably and on our business, financial position, and operating results.

Furthermore, if we are unable to address all regulatory requirements applicable to the development and commercialization of new products in a timely manner, our product introduction plans, business, financial position, and operating results could be materially adversely affected.

The FDA regulates and monitors all promotion and advertising of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require a company to change current practices and prevent unlawful activity in the future.

Our Medicaid rebate accruals have increased and continue to increase due to our acquisitions and subsequent sales of branded products and authorized generics of branded products, and the estimates on which our accruals are based are subject to change. Any such change could have a material adverse effect on our business, financial position, and operating results.

Our Medicaid rebate accruals have increased significantly due to our acquisitions and subsequent sales of branded products and authorized generics of branded products. We accrue for these rebates at the time of sale based on our estimates of the amount of our product that will be prescribed to Medicaid beneficiaries. The resulting accruals are significant, and as Medicaid utilization trends change, we may need to change our estimates accordingly. We cannot guarantee that actual results will not differ from our estimates. In addition, the Patient Protection and Affordable Care Act (“PPACA”) included a significant expansion of state Medicaid programs. As more individuals become eligible for coverage under these programs, Medicaid utilization of our products could increase, resulting in a corresponding increase in our rebate payments. Increases in Medicaid rebate payments could decrease our revenues from product sales, which in turn could adversely affect our business, financial position, and operating results.

Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions. Any such change could have a material adverse effect on our business, financial position, and operating results.

Our accruals for the rebates under the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions. We accrue for these rebates at the time of sale based on our estimates of the amount of product that will be prescribed to patients in the Medicare Coverage Gap Discount program, which is primarily for the benefit of persons aged 65 years and over. As we acquire and launch additional products, many of which, are often used by patients in the 65 and older age range, our estimates of these rebates have grown. Increases in Medicare Coverage Gap Discount rebates, and legislative changes to the Medicare Coverage Gap Discount Program, could decrease our revenues from product sales, which in turn could adversely affect our business, financial position, and operating results.

We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products. Failure to successfully introduce products into the market could have a material adverse effect on our business, financial position, and operating results.

We conduct research and development primarily to enable us to manufacture and market approved products in accordance with applicable regulations. Research and development is expensive and time-consuming. As we seek to develop new products, or re-commercialize products that were previously approved, our research expenses will increase, potentially significantly, and we cannot be certain that we will recover our investment in a product, even if that product is commercialized. If we spend significant resources on research and development efforts and are not able to introduce new products, our business, financial position, and operating results may be materially adversely affected.

We produce the majority of our products in three manufacturing facilities. Production at any or all of these facilities could be interrupted, which could cause us to fail to deliver sufficient product to customers on a timely basis and have a material adverse effect on our business, financial position, and operating results.

Our internal manufacturing operations are currently based in three facilities. We have transitioned products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites. While these three facilities are sufficient for our current needs, the facilities are highly specialized and any damage to or need for replacement of all or any significant function of our facilities could be very costly and time-consuming and could impair or prohibit production and shipping. A significant disruption at any of the facilities, even on a short-term basis, whether due to a labor strike, adverse quality or compliance observation, vandalism, natural disaster, fire, storm or other environmental damage, or other events could impair our ability to produce and ship products on a timely basis and, among other consequences, could subject us to “failure to supply” claims from our customers, as discussed below. Although we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses because of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. Any of these events could have a material adverse effect on our business, financial position, and operating results.

Virtually all of our contracts for the supply of generic products to our customers contain “failure to supply” clauses which require us to reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product in the event we failed to deliver the requested quantity within a specified period of time. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements and can be far in excess of the revenue that we would otherwise have received on the sale of our own product. Therefore, our ability to produce and ship a sufficient quantity of product on a consistent basis is critical. Failure to deliver products could have a material adverse effect on our business, financial position, and operating results.

The NEW DAY clinical trial may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME, fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, take longer or be more costly to complete than we currently anticipate or fail to change physician prescribing practices.

We are conducting our NEW DAY clinical trial, which is a multicenter, single-masked, randomized, controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its potential advantages over the current standard of care of repeat anti-VEGF (aflibercept) injections. The NEW DAY clinical trial is fully enrolled as of May 2023 with 300 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U.S. The NEW DAY clinical trial may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME, fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, or take longer or be more costly to complete than we currently anticipate, and/or fail to change physician prescribing practices despite a successful result. The occurrence of any of these events could materially and adversely affect our business, financial condition and cash flows, and results of operations.

We rely on third parties to assist with our clinical trials. If these third parties do not perform as required or expected, or if they are not in compliance with FDA rules and regulations, our clinical trials may be extended, delayed or terminated, or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the products being tested in such trials. Further, we may be required to audit or redo previously completed trials or recall already-approved commercial products.

We rely on third parties, such as medical institutions, clinical investigators, and contract laboratories, to assist with our clinical trials. We are responsible for confirming that our trials are conducted in accordance with applicable regulations and that each of our clinical trials is conducted in accordance with our general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording, and reporting the results of clinical trials, to assure that data and reported results are accurate and that the clinical trial participants are adequately protected. Our reliance on these third parties does not relieve us of these responsibilities. If the third parties assisting us with our clinical trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA’s good clinical practice regulations, do not adhere to our protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical trials may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the products being tested in such trials. For our already-approved commercial products, we may be required to audit or redo previously completed trials or recall our products from the market, which could have a material adverse effect on our business, financial position, and operating results.

Clinical trials for our products may not generate the outcomes we expect, may take longer or be more costly to complete than we anticipate.

From time to time, we initiate or participate in clinical trials for our products and may in the future participate in clinical trials or studies for other products. The timing of patient enrollment in these trials, and related costs, can be unpredictable, and any such trials or studies may be more expensive or take longer than we expect, data may be inconclusive, or such studies and trials may fail to change physician prescribing practices.

Further, the outcome of continuing post-marketing clinical trials, such as NEW DAY and SYNCHRONICITY, may fail, take longer than anticipated to complete or, could produce negative results requiring us to submit reports to the FDA of adverse events involving the use of our products and we may be required to implement risk management programs, or discontinue product marketing as a result. In addition, ongoing post-approval drug safety surveillance of our products could result in the submission of adverse event reports to the FDA. In some cases, studies and safety surveillance programs have resulted, and in the future may result, in one or more of the following:

- product label changes including FDA-mandated Black Box warnings;
- risk management programs such as patient registries;
- reduced product sales due to concerns among patients and physicians; and
- discontinuance of product marketing.

These situations, should they occur with respect to any of our products, could have a material adverse effect on our business, financial position, and operating results.

Climate change concerns could disrupt our businesses, adversely affect client activity levels, adversely affect the creditworthiness of our counterparties, and damage our reputation.

Climate change may cause extreme weather events that, among other things, could damage our facilities and equipment, injure our employees, disrupt operations at one or more of our primary locations, negatively affect our ability to service and interact with our clients, and adversely affect the value of our assets. Any of these events may increase our costs including our costs to insure against these events.

Climate change may also have a negative impact on the financial condition of our clients, which may decrease revenues from those clients and increase the credit exposures to those clients. Additionally, our reputation and client relationships may be damaged as a result of our involvement, or our clients' involvement, in certain industries associated with causing or exacerbating, or alleged to cause or exacerbate, climate change. We also may be negatively impacted by any decisions we make to continue to conduct or change our activities in response to considerations relating to climate change. New regulations or guidance relating to climate change, as well as the perspectives of shareholders, employees, and other stakeholders regarding climate change, may affect whether and on what terms and conditions we engage in certain activities or offer certain products.

Risks Related to Our Intellectual Property

We may be adversely affected by the expiration of patents that protect key aspects of ILUVIEN and YUTIQ in the near-to medium-term.

The patent rights relating to ILUVIEN and YUTIQ licensed to us from EyePoint include one U.S. patent that will expire in August 2027, and has expired in the EU in October 2024, although extensions have been obtained or applied for through May 2027 in various EU countries. Otherwise, no patent term extension will be available for any of these U.S. patents, European patents or any of our licensed U.S. or European pending patent applications. After these patents expire in August 2027 in the U.S., we will not be able to block others from marketing FAc in an implant similar to ILUVIEN or YUTIQ.

We rely on patent, trademark and other intellectual property protection in the discovery, development, manufacturing and sale of our products. In particular, patent protection is, in the aggregate, important in our marketing of pharmaceutical products in the U.S. and most major markets outside of the U.S. Patents covering our products normally provide market exclusivity, which is important for the profitability of many of our products.

As patents for certain of our products expire, we will or could face competition from lower priced generic or biosimilar products. In general, the expiration or loss of patent protection for a product may allow market entry by substitute products that could significantly reduce sales for the original product in a short amount of time. If our competitive position is compromised because of generics, biosimilars or otherwise, it could have a material adverse effect on our business and results of operations. In addition, proposals emerge from time to time for legislation to further encourage the early and rapid approval of generic drugs or biosimilars. Any such proposals that are enacted into law could increase the negative effect of generic competition.

Inability to protect our intellectual property in the U.S. and foreign countries could negatively affect sales of our branded products.

We own the trademark names for most of our branded products, including, Cortenema, Purified Cortrophin Gel, Cortrophin-Zinc, ILUVIEN, Inderal LA, Inderal XL, InnoPran XL, Lithobid, Reglan, Vancocin, Veregen, and YUTIQ. We license the trademark names for Atacand, Atacand HCT, Arimidex, Casodex, and Oxistat. While we will seek to protect those trademarks through timely renewal in applicable jurisdictions, we may not be able to renew our trademarks in a timely manner or to prevent third parties from using our trademarks, which could have a material adverse effect on our business, financial position, and operating results.

If we fail to comply with our obligations in the agreements under which we license development or commercialization rights to products or technology from third parties, we could lose license rights that are material to our business.

Our licenses are material to our business, and we may enter into additional licenses in the future. We hold a license from EyePoint to intellectual property relating to ILUVIEN pursuant to the New Collaboration Agreement. Pursuant to the Product Rights Agreement with EyePoint, we also have the commercialization rights to YUTIQ in the entire world, except Europe, the Middle East and Africa as we had previously licensed from EyePoint rights to certain products, which included YUTIQ (known as ILUVIEN in Europe, the Middle East and Africa) for the prevention of relapse in recurrent NIU-PS in those territories. The Product Rights Agreement also excludes any rights to YUTIQ for the treatment and prevention of chronic NIU-PS in China and certain other countries and regions in Asia, which rights are subject to a pre-existing exclusive license between EyePoint Parent and Ocumension.

Our ability to pursue the development and commercialization of our products depends upon the continuation of our agreements with EyePoint. The New Collaboration Agreement imposes various commercialization, milestone payment, royalty payments, insurance and other obligations on us, including the right by EyePoint to audit. If we fail to comply with these obligations, EyePoint may have the right to terminate the license. Our license rights to EyePoint's proprietary insert technology utilized in ILUVIEN could revert to EyePoint in certain circumstances, including failure to cure contractual breaches and filing for bankruptcy protection. We have from time to time amended the New Collaboration Agreement, and we may again seek to do so in the future if the need arises.

If our license with EyePoint, or any other current or future material license agreement, were terminated, or if we were unable to amend the New Collaboration Agreement or resolve any dispute related to such agreement, we may be unable to market the applicable products, such as ILUVIEN, that may be covered by such license, which would materially and adversely affect our business, results of operations and future prospects.

We do not control the commercialization of ILUVIEN in China, East Asia and the Western Pacific, and receipt of the value we currently anticipate will depend on, among other factors, Ocumension's ability to further commercialize ILUVIEN in that region.

We have granted an exclusive license to Ocumension for the development and commercialization of our 0.19mg FAc intravitreal injection in China, East Asia and the Western Pacific. Our ability to receive aggregated potential sales milestone payments of up to \$89.0 million depend upon achievement by Ocumension of specified amounts of net sales of ILUVIEN in that region in the future. However, we cannot assure you as to the amount, if any, we might receive. If there are any adverse developments or perceived adverse developments with respect to Ocumension's ability to commercialize ILUVIEN in China, East Asia and the Western Pacific, we may not realize the value we currently anticipate from this license, which would harm our business and may cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- regulatory hurdles in China, including related to the ongoing COVID-19 pandemic or the geopolitical tensions between the U.S. and China;
- competition, whether from current competitors or new products developed by others in the future;
- claims relating to intellectual property;
- global economic conditions;
- disruptions in Ocumension's business;
- disappointing or lower than expected sales of ILUVIEN;
- disputes between Ocumension and us; or
- Ocumension deciding to modify, delay or halt its development and commercialization of ILUVIEN.

If our license with Ocumension were terminated, or if Ocumension is unable to sell our licensed product, we will not receive any milestone payments under our license agreement, and our future revenues may be materially lower than expected.

If we or our licensors are unable to obtain and maintain protection for the intellectual property incorporated into our products, the value of our technology and products will be adversely affected.

Our success depends largely on our ability or the ability of our licensors to obtain and maintain protection in the U.S. and other countries for the intellectual property incorporated into our products. The patent situation in the field of biotechnology and pharmaceuticals generally is highly uncertain and involves complex legal and scientific questions. We or our licensors may be unable to obtain additional issued patents relating to our technology. Our success will depend in part on the ability of our licensors to obtain, maintain (including making periodic filings and payments) and enforce patent protection for their intellectual property, in particular, those patents to which we have secured exclusive rights.

Under our license with EyePoint, EyePoint controls the filing, prosecution and maintenance of all patents. Our licensors may not successfully prosecute or continue to prosecute the patent applications to which we are licensed. Even if patents are issued in respect of these patent applications, we or our licensors may fail to maintain these patents, may determine not to pursue litigation against entities that are infringing upon these patents, or may pursue such litigation less aggressively than we ordinarily would. Without protection for the intellectual property that we own or license, other companies might be able to offer substantially identical products for sale, which could adversely affect our competitive business position and harm our business prospects. Moreover, FAc is an off-patent active ingredient that is commercially available in several forms, including the extended release ocular implant Retisert.

Even if issued, patents may be challenged, narrowed, invalidated or circumvented, which could limit our ability to stop competitors from marketing similar products or limit the length of term of patent protection that we may have for our products. In addition, our patents and our licensors' patents may not afford us protection against competitors with similar technology.

Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our commercialization of our current products or the development or regulatory approval of other product candidates.

Our current products or any future products or product candidates may infringe upon other parties' intellectual property rights that are protected by patents or patent applications. Third parties may now or in the future own or control these patents and patent applications in the U.S. and abroad. These third parties could bring claims against us or our collaborators that would cause us to incur substantial expenses or divert substantial employee resources from our business. If those claims are successful, we could be required to pay substantial damages or could be prevented from developing any future product candidates. Further, if a patent infringement suit were brought against us or our collaborators, we or they could be forced to stop or delay manufacturing, sales, research or development of the product or product candidate that is the subject of the suit.

Several issued and pending U.S. patents claiming methods and devices for the treatment of eye diseases, including through the use of steroids, implants and injections into the eye, purport to cover aspects of our products. For example, one of our potential competitors holds issued and pending U.S. patents and a pending European patent application with claims covering injecting an ocular implant into a patient's eye similar to our current products' applicator. There is also an issued U.S. patent with claims covering implanting a steroidal anti-inflammatory agent to treat an inflammation-mediated condition of the eye. If these or any other patents were held by a court of competent jurisdiction to be valid and to cover aspects of our current products, then the owners of such patents would be able to block our ability to commercialize our current products unless and until we obtain a license under such patents (which license might require us to pay royalties or grant a cross-license to one or more patents that we own), until those patents expire or unless we are able to redesign our products to avoid any such valid patents.

As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from a third-party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be forced to cease some aspect of our business operations, or be prevented from commercializing a product if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. This could harm our business significantly.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical and biotechnology industries. In addition to infringement claims against us, we may become a party to other patent litigation and other proceedings, including interference proceedings declared by the U.S. Patent and Trademark Office and opposition proceedings in the European Patent Office, regarding intellectual property rights with respect to our products and technology. The cost to us of any litigation or other proceeding, regardless of its merit, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings better than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. Intellectual property litigation and other proceedings may, regardless of their merit, also absorb significant management time and employee resources.

If our efforts to protect the proprietary nature of the intellectual property related to our products are inadequate, we may not be able to compete effectively in our markets.

The strength of our patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. In addition to the rights we have licensed from EyePoint relating to ILUVIEN and YUTIQ, we rely upon intellectual property we own, including patents, patent applications and trade secrets. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be too narrow to prevent third parties from developing or designing around these patents. Moreover, it is possible that a third-party could successfully challenge the scope (i.e., whether a patent is infringed), validity and enforceability of our licensed patents before patent expiration and obtain approval to market a competitive product.

Further, the patent applications that we license or have filed may fail to result in issued patents. Patent examiners have rejected some claims in pending patent applications that we have filed or licensed. We may need to amend these claims. Even after amendment, a patent may not be permitted to issue. Further, the existing or future patents to which we have rights based on our New Collaboration Agreement with EyePoint may be too narrow to prevent third parties from developing or designing around these patents. Additionally, we may lose our rights to the patents and patent applications we license in the event of a breach or termination of our license agreement with EyePoint. Manufacturers may also seek to obtain approval to sell generic versions of our products before the expiration of the relevant licensed patents. If the sufficiency of the breadth or strength of protection provided by the patents we license with respect to our products or the patents we pursue related to our products or any future product candidate is threatened, it could dissuade companies from collaborating with us to commercialize our products and develop any future product candidates. Further, if we encounter delays in our clinical trials for any future product candidate, the period during which we could market those product candidates under patent protection would be reduced.

We may become involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or our licensors is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not being issued.

Interference proceedings brought by the U.S. Patent and Trademark Office may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our collaborators or licensors. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

We rely on trade secret protection and confidentiality agreements to protect certain proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our development processes with respect to our current products that involve proprietary know-how, information and technology that is not covered by patent applications. Any involuntary disclosure or misappropriation by third parties of our confidential or proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

We seek to protect confidential or proprietary information in part by confidentiality agreements with our employees, consultants and third parties. While we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and abroad. If we are unable to protect or defend the intellectual property related to our technologies, we will not be able to establish or maintain a competitive advantage in our market.

Our success is largely dependent upon certain key employees, including members of our senior management team, the loss of whom could adversely affect our operations. Competition for talent is intense, especially in northern Minnesota, where the population is small. If we cannot attract and retain qualified personnel, the growth and success of our business could be adversely affected.

Our success is dependent upon the efforts of certain key employees, including members of our senior management team. We have employment arrangements in place with our executive and other officers, but none of these executive and other officers are bound legally to remain employed with ANI for any specific term. We do not have key person life insurance policies covering our executive and other officers or any of our other employees. If key individuals were to leave ANI, our business could be affected adversely if suitable replacement personnel are not recruited quickly. Competition for personnel is intense in certain localities in which we operate, specifically northern Minnesota, where two of our three current manufacturing facilities are located, is small, and as a result, there is a limited number of qualified personnel available in all functional areas, which could make it difficult to retain and attract the qualified personnel necessary for the development and growth of our business. If we were unable to attract and retain qualified personnel, our business, financial position, and operating results could be materially adversely affected.

We rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate the business effectively.

We rely significantly on our information technology and manufacturing infrastructure to effectively manage and maintain inventory and financial reports, manufacture and ship products, and invoice customers in a timely manner. While we have invested in the protection of data and information technology, any failure, accidents, inadequacy, or interruption of that infrastructure or security lapse of that technology, including cybersecurity incidents, could harm our ability to operate our business effectively. Our ability to manage and maintain inventory and financial reports, manufacture and ship products, and invoice customers timely depends significantly on our general ledger, our contracted electronic data interface system, and other information systems. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of confidential or otherwise protected information and corruption of data. Cybersecurity incidents resulting in the failure of our information systems to operate effectively or to integrate with other systems, or a breach in security or other unauthorized access of these systems, may affect our ability to manage and maintain inventory and financial reports, and result in delays in product fulfillment and reduced efficiency of operations. A breach in security, unauthorized access resulting in misappropriation, theft, or sabotage with respect to proprietary and confidential information, including research or clinical data, could require significant capital investments to remediate any such failure, problem or breach, all of which could adversely affect our business, financial position, and operating results. See “Cybersecurity – Risk management and strategy,” Item 1C of this Annual Report on Form 10-K for additional information.

We are currently involved in and may from time to time become involved in legal proceedings, some of which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources.

We are currently involved in, and in the future may become involved in, legal proceedings in the ordinary course of our business, as a party or non-party witness, with both private parties and certain government agencies. We may incur substantial time and expenses participating in these types of lawsuits and investigations, which could also divert management’s attention from ongoing business concerns and normal operations. In addition, these matters and any other substantial litigation may result in verdicts against us or government enforcement actions, which may include significant monetary awards, and preventing the manufacture, marketing and sale of our products. Any dispute resolved unfavorably, could have a material adverse effect on our business, financial position, and operating results. For a description of legal proceedings which are currently pending, see Note 17 “Commitments and Contingencies” in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums.

Like all pharmaceutical companies, we face the risk of loss resulting from, and the adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. We likely cannot avoid such claims. Unanticipated side effects or unfavorable publicity concerning any of our products or product candidates would likely have an adverse effect on our ability to achieve acceptance by prescribing physicians, managed care providers, pharmacies and other retailers, customers, patients and clinical trial participants. Even unsuccessful product liability claims could require us to spend money on litigation, divert management's time, damage our reputation and impair the marketability of our products. In addition, although we believe that we have adequate product liability insurance coverage, we cannot be certain that our insurance will, in fact, be sufficient to cover such claims or that we will be able to obtain or maintain adequate insurance coverage in the future at acceptable prices. A successful product liability claim that is excluded from coverage or exceeds our policy limits could require us to pay substantial sums. Additionally, insurance coverage for product liability may become prohibitively expensive in the future or may not be available at all, and as a result, we may not be able to maintain adequate product liability insurance coverage to mitigate the risk of large claims, or we may be required to maintain a larger self-insured retention that we would otherwise choose.

We may fail to realize the benefits expected from our acquisition of Alimera and the combined company may not perform as we or the market expects, which could have an adverse effect on the price of our common stock.

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

The combined company may not perform as we or the market expects. Risks associated with the combined company following the Merger include:

- integrating businesses is a difficult, expensive, and time-consuming process, and the failure to successfully integrate our businesses with the business of Alimera timely would adversely affect our financial condition and results of operation;
- there may be inconsistencies in standards, controls, procedures and policies that will need to be reconciled;
- the Merger has materially increased the size of our operations, and if we are not able to effectively manage our expanded operations, our common stock price may be adversely affected;
- it is possible that our key employees or key employees of Alimera might decide not to remain with us, and the loss of such personnel could have a material adverse effect on the financial condition, results of operations, and growth prospects of the combined company;
- the success of the combined company will also depend upon relationships with third parties and Alimera's or our pre-existing customers, which relationships may be affected by customer preferences or public attitudes about the Merger. Any adverse changes in these relationships could adversely affect the combined company's business, financial condition, and results of operations;
- unanticipated write-offs or charges. In connection with the Merger we recorded goodwill and intangible assets in the fair value amount of the acquisition. If we conclude that some portion of such goodwill or intangible assets are impaired, a non-cash charge for the amount of such impairment would be recorded against earnings;
- our expansion into international operations as a result of the Merger (as discussed below);
- incurrence of significant costs in connection with consummating the Merger and integrating the operations of Alimera into our business;
- the potential for securities class action lawsuits and derivative lawsuits that may be brought as a result of the Merger, including costs associated with defending such lawsuits; and
- our failure to identify or accurately assess the magnitude of certain liabilities we assumed in the Merger could result in unexpected litigation or regulatory exposure, unfavorable accounting charges, unexpected increases in taxes due, a loss of anticipated tax benefits or other known and unknown liabilities which could result in adverse effects on our business, operating results or financial condition.

The occurrence of any of these Merger-related events individually or in combination could materially and adversely affect our business, results of operations, financial condition and the market price of our common stock.

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

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

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

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the Merger, including costs that we may not currently expect. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses. We must pay substantially all of the costs and expenses whether or not the transaction is completed. Moreover, many of the expenses that will be incurred are, by their nature, difficult to estimate accurately. To the extent these acquisition and integration expenses are higher than anticipated, we may experience liquidity or cash flow issues.

In connection with the Merger, we recorded goodwill and intangible assets and if either goodwill or intangible assets become impaired, our earnings could be significantly impacted.

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

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

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

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

Our business is subject to political, economic, legal, and social risks, and if we fail to successfully manage our domestic and international operations, our business, operating results and financial condition could suffer.

There are significant regulatory, economic and legal barriers in markets in the U.S. and outside the U.S. that we must overcome. Changes in U.S. social, political, regulatory, and economic conditions or in laws and policies governing foreign trade, manufacturing, development, and investment, and any negative sentiments towards the U.S. as a result of such changes, could adversely affect our business and decrease our anticipated revenue growth and profitability.

Further, in connection with the merger we have acquired direct international operations outside of the U.S., and are marketing products outside the United States, that cover the United Kingdom and much of Europe and the Middle East. We have not historically conducted any operations or marketed any of our products outside the United States. As a result of the closing of the Merger, the percentage of our revenues generated outside of the United States increased materially, and our new international operations require significant management attention and financial resources.

There is a high level of regulation in all markets where the products we acquired from Alimera have been sold and great diversity in how those markets operate. Consequently, experience and expertise will be required in understanding the market dynamics of each country, the rules and regulations in place governing the sale of medicines, the codes of practice governing promotion of medicines, different currencies, the financial frameworks applying to taxation (both corporate and value-added tax) and the need to communicate in different languages. We also import inputs for certain products, including API, from international suppliers. As a result, our operations may be affected by challenges to the global supply chain, including increased costs of API and other inputs for our products. The U.S. government recently announced tariffs on products manufactured in several jurisdictions, including China, Mexico and Canada. and has made announcements regarding the potential imposition of tariffs on other jurisdictions. Some countries have, and other countries may in the future, implement trade restrictions and/or retaliatory measures as well. Any such trade restrictions or measures could affect our operations, our imports into the U.S. and other countries and our supply chains.

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

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

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

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

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

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

Following the consummation of the Merger, we now have certain additional requirements that we need to meet in order to engage in international operations. For example, in the European Economic Area (“EEA”) and the United Kingdom, each country has a different reviewing body that evaluates reimbursement dossiers submitted by marketing authorization holders of new drugs and then makes recommendations as to whether or not the drug should be reimbursed. Limitations on reimbursement could be imposed at the national, regional or local level or by fiscal intermediaries in each country, either through the initial authorization process or at some point in the future. In addition, due to price referencing within the EEA, the United Kingdom and certain other countries, existing pricing in our current markets could be negatively affected by a change in pricing in a country where Alimera historically has reimbursement or by a new price in a country where we obtain reimbursement approval in the future.

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

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

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

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

Alimera did not have in-house manufacturing capability and depended entirely on single source third-party manufacturers for the manufacture of its products; following the consummation of the Merger, we rely on these third-party manufacturers for the manufacture of the products we acquired from Alimera, including for supply of active pharmaceutical ingredients, the product applicator, the product implants, and the final assembly of the injectors with the implants. In addition, Alimera relied, and we now rely, on third parties for the quality release testing. If any of these third-party manufacturers breaches its agreement, is unable to meet its contractual or quality requirements or becomes unwilling to perform for any reason, we may be unable, in a timely manner or at all, to locate alternative acceptable manufacturers or testing facilities, as applicable, enter into favorable agreements with them and ensure that they are approved by the applicable regulatory authorities, such as the FDA. For example, Alimera relied, and we now rely, on (subject to certain exceptions) the YUTIQ Supply Agreement with EyePoint for the manufacturing and supply of YUTIQ, which has an initial term of two years through May 2025. On February 27, 2025, the Company received written notice of non-renewal from EyePoint of the YUTIQ Supply Agreement, effective May 31, 2025. The Company has submitted a PAS to the FDA seeking to add YUTIQ’s indication of chronic NIU-PS to the ILUVIEN label. The Company expects FDA approval of the PAS in the second quarter of 2025 and plans to market ILUVIEN for chronic NIU-PS in addition to its current indication of DME in the U.S. In order to support the transition to of NIU-PS to ILUVIEN, in July 2024, the Company extended its partnership with Siegfried, its long-term supplier for ILUVIEN, through 2029, and contracted with Siegfried to upgrade equipment on the existing manufacturing line and significantly expand capacity through the addition of a second manufacturing line. If the PAS approval is delayed, or not approved at all, or we are unable to timely transfer manufacturing to Siegfried or another replacement supplier or make other arrangements to supply product, we may not be able to fulfill demand for

YUTIQ and / or the NIU-PS indication in the U.S. market. In addition, on July 12, 2024, EyePoint received a warning letter from the FDA alleging violations of current good manufacturing practice (CGMP) requirements in connection with a February 2024 FDA inspection and associated February 2024 Form FDA-483 specifically related to the manufacturing of YUTIQ at the supplier's facility (the "Warning Letter"). The Warning Letter requires the supplier to implement certain corrective and preventive actions. Any failure by the supplier to remediate to the FDA's satisfaction these findings or any future findings the FDA may have, could result in the supply of YUTIQ being adversely effected or terminated, and our ability to fulfill demand for YUTIQ prior to the addition of NIU-PS to the ILUVIEN label could be materially impaired.

Additionally, we may experience lengthy delays if we need to change a third-party supplier or manufacturer, including for YUTIQ, which could have a material impact on business and results of operations. Further, suppliers and manufacturers for the products we acquired from Alimera rely on additional third parties for the manufacture of component parts. Any inability of these contract manufacturers to acquire sufficient quantities of the active pharmaceutical ingredients and other component parts in a timely manner from these third parties could delay commercial production of YUTIQ or ILUVIEN.

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

Future acquisitions and investments could disrupt our business and harm our financial position and operating results.

Our growth will depend, in part, on our continued ability to develop, commercialize, and expand our products, including in response to changing regulatory and competitive pressures. In some circumstances, we have and may continue to grow our business through the acquisition of complementary businesses and technologies rather than through internal development. The identification of suitable acquisition candidates or products can be difficult, time-consuming, and costly, and we may not be able to successfully complete or successfully execute strategies for identified acquisitions. The risks faced in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition and/or product integration challenges;
- coordination of research and development and sales and marketing functions;
- retention of key employees from the acquired company;
- integration of the acquired company's accounting information, management, human resources, and other administrative systems;
- the need to implement or improve controls, procedures, and policies at a business that prior to the acquisition may have lacked effective controls, procedures and policies;
- difficulties relating to integrating the acquired business;
- liability for activities of the acquired company and/or products before the acquisition, including patent infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities;
- unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company or product, including claims from product users, former stockholders, or other third parties.

In any acquisition that we may undertake, our failure to address these risks or other problems encountered in connection with any acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally.

Risks Related to our Industry

Public health outbreaks, epidemics, or pandemics (such as the COVID-19 pandemic) have adversely affected and may in the future adversely affect our business.

The COVID-19 pandemic previously adversely affected us in the years ended December 31, 2021 and 2020, and the COVID-19 pandemic or other actual or threatened public health outbreaks, epidemics, or pandemics may in the future adversely affect, among other things, the economic and financial markets and labor resources of the countries in which we operate; our manufacturing and supply chain operations, research and development efforts, commercial operations and sales force, administrative personnel, third-party service providers, and business partners and customers; and the demand for our products.

Such disruptions in our operations could materially adversely impact our business, prospects, operating results, and financial condition. To the extent a public health outbreak, epidemic, or pandemic adversely affects our business, prospects, operating results, or financial condition, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section.

The continuing trend toward consolidation of customer groups could result in declines in the sales volume and prices of our products, and increased fees charged by customers, each of which could have a material adverse effect on our business, financial position, and operating results.

Consolidation and the formation of strategic partnerships among and between wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies, each controlling a larger share of pharmaceutical distribution channels. For example, our net revenues are concentrated among four customers representing 25%, 16%, 12%, and 11% of net revenues, respectively, during the year ended December 31, 2024. As of December 31, 2024, accounts receivable from these four customers was approximately 70% of our accounts receivable, net. Drug wholesalers and retail pharmacy chains, which represent an essential part of the distribution chain for generic pharmaceutical products, have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in declines in our sales volumes if a customer is consolidated into another company that purchases products from a competitor. In addition, the consolidation of drug wholesalers and retail pharmacy chains could result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business and enabling those groups to charge us increased fees. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to extract price discounts on our products. The result of these developments or the loss of our relationship with one or more of these wholesalers, may have a material adverse effect on our business, financial position, and operating results.

Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions. Any determination that we have failed to comply with those obligations could subject us to penalties and sanctions, which could adversely affect our business, financial position, and operating results.

The regulations regarding reporting and payment obligations with respect to Medicaid rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. Our calculations and methodologies are subject to review and challenge by governmental agencies, and it is possible that such reviews could result in changes. Any determination by governmental agencies that we have failed to comply with our reporting and payment obligations could subject us to penalties and sanctions, which could have a material adverse effect on our business, financial position, and operating results.

Four products, which together comprised less than 10% of our total revenue in 2024, are marketed without approved NDAs or Abbreviated New Drug Applications (“ANDAs”) and we can offer no assurances that the U.S. Food and Drug Administration (“FDA”) will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected.

Four products, Esterified Estrogen with Methyltestosterone (“EEMT”), Opium Tincture, Thyroid Tablets, and Hyoscyamine are marketed without approved NDAs or ANDAs.

The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled “Marketed New Drugs without Approved NDAs or ANDAs.” Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness.

We continue to believe that, so long as we comply with applicable manufacturing standards, the FDA will continue to operate on a risk-based approach and will not take action against us. However, we can offer no assurance that the FDA will continue to follow this approach or that it will not take a contrary position with any individual product or group of products.

Additionally, our EEMT products are related to an outstanding Notice of Opportunity for Hearing on estrogen-androgen products. The hearing relates to the FDA's intent to reclassify certain estrogen-androgen combination drugs as lacking substantial evidence of their effectiveness for the treatment of moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone.

If the FDA were to move away from the risk-based approach to enforcement against marketing of unapproved products, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval.

Imported API are subject to inspection by the FDA and the FDA can refuse to permit the importation of API for use in products that are marketed without approved NDAs or ANDAs. We are dependent on imported API to make certain of our products. If the FDA detained or refused to allow the importation of such API or if tariffs or other governmental action make the import of such API costly, our revenues from certain of our products would be reduced or eliminated and our business, financial position, and operating results could be materially adversely affected.

We source some of the API for our products, including those that are marketed without approved NDAs or ANDAs, from international suppliers. From time to time, due to FDA inspections, we have experienced temporary disruptions in the supply of imported API. Any prolonged disruption in the supply of imported API or increased costs due to tariffs could materially affect our ability to manufacture and distribute our products, reduce or eliminate our revenues, and have a material adverse effect on our business, financial position, and operating results. In addition, as regulatory fees and compliance oversight of API manufacturers increase, this could result in certain companies discontinuing their supply of API to us, which would materially affect our ability to manufacture our products.

The FDA does not provide guidance on safety labeling for products that are marketed without approved NDAs or ANDAs. As a result, we are dependent on our internal post-approval drug safety surveillance program to identify necessary safety-related changes to the labels for EEMT, Opium Tincture, and Thyroid Tablets, and Hyoscyamine.

Pharmaceutical product labels contain important safety information including Black Box warnings, contraindications, dosing and administration, adverse reactions, drug interactions, use in specific populations such as pregnant women, pediatric, and geriatric patients, and other warnings and precautions. Pharmaceutical manufacturers may change product labels when post-approval drug safety surveillance programs identify previously unknown side-effects, drug interactions, and other risks. Manufacturers may also change product labels after conducting post-approval clinical studies and may receive or seek guidance from the FDA regarding updating safety labeling information. However, the FDA does not provide guidance on labeling for products that are marketed without approved NDAs or ANDAs. As a result, we are dependent on our internal post-approval drug safety surveillance program to identify necessary safety-related changes to the labels for EEMT, Opium Tincture, Thyroid Tablets, and Hyoscyamine. Additionally, because the FDA does not review and approve labeling for the products without approved NDAs or ANDAs, it would be difficult to make a claim for preemption due to the FDA's approval of the labeling and this could increase our potential liability with respect to failure-to-warn claims for these products. Such claims, even if successfully defended, could have an adverse impact on our business, financial position, and operating results.

We are entirely dependent on periodic approval by the DEA for the supply of the API needed to manufacture our controlled substances. An inability to obtain such approvals would reduce or eliminate our revenues for our controlled substances, and could have a material adverse effect on our business, financial position, and operating results. In addition, we are subject to strict regulation by the DEA and are subject to sanctions if we are unable to comply with related regulatory requirements.

The DEA regulates products containing controlled substances, such as opiates, pursuant to the U.S. Controlled Substances Act ("CSA"). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security, and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored, and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties.

In addition, each year, we must submit a request to the DEA for a procurement quota in order to purchase the amount of API needed to manufacture our Schedule II controlled substances. Without approved procurement quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are entirely dependent upon the DEA to approve, on an annual basis, a quota of API that is sufficiently large to support our plans for the continued manufacture of our controlled substances at commercial levels. In 2017, the DEA announced that the administration would decrease the total quotas approved for Schedule II opioid painkillers. In 2018, the DEA decreased quotas approved for Schedule II opioid painkillers. The DEA continues to closely monitor quotas of certain opioids and as a result there may be a reduction from what was requested; however, firms may file an application for a quota adjustment at any time during the calendar year. If the DEA does not approve our requested procurement quotas, we may be unable to obtain sufficient API to manufacture these products at levels required by our customers, which could have an adverse impact on our business, financial position, and operating results.

Our products are subject to regulatory and quality standards and guidelines set forth by FDA and other governmental agencies. Changes or developments in such standards and guidelines may affect the ability of our products to meet such standards, including with respect to already approved products. If our products are not able to meet these standards, we may be required to discontinue marketing and/or recall such products from the market.

Changes or developments in regulatory and quality standards and guidelines set forth by FDA, such as criteria for residual solvents, periodic guidance from the FDA regarding testing for impurities, such as nitrosamines, in our products, and updated U.S. Pharmacopeial Convention (“USP”) Reference Standards may impact our ability to sell certain drug products. The USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide.

Pharmaceutical products approved prior to the implementation of new or revised quality standards, including those produced or sold by us, may not meet these standards, which could require us to discontinue marketing and/or recall such products from the market, either of which could adversely affect our business, financial position, and operating results. In addition, results of periodic testing we conduct on our products may indicate the presence of substances at levels greater than those deemed acceptable under FDA or other standards, which could potentially require a recall of the product. For example, during the fourth quarter of 2019, testing of the API used in our ranitidine drug product, as well as testing of the drug product itself, indicated a level of a nitrosamine impurity called N-nitrosodimethylamine (“NDMA”) above acceptable thresholds. NDMA is classified as a probable human carcinogen. Appco Pharma, LLC, with whom we had partnered to develop and market the product, initiated a voluntary recall, and we elected to exit the market for Ranitidine in 2019. For a description of legal proceedings which are currently pending relating to ranitidine, see Note 15 “Commitments and Contingencies” in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

In December of 2021, the FDA issued an information request to all manufacturers of propranolol products, including Inderal LA (Propranolol ER) currently being marketed by ANI in the United States to evaluate their product for the presence and level of a nitrosamine impurity known as N-nitroso-propranolol (“NNP”), which is distinct from NDMA. We undertook a review and analysis of NNP, working with testing and toxicology experts, and communicated with the FDA on the scientific bases for establishing appropriate acceptable daily intake for NNP and the appropriate approach for propranolol products in the U.S. On August 4, 2023, the FDA issued final guidance on acceptable intake limits for nitrosamine drug substance-related impurities (NDSRIs), with recommended limits for propranolol products of 1500 mg/day. Based on this guidance, we were able to continue sales of the product to our customers.

We may become subject to federal and state false claims litigation brought by private individuals and the government.

We are subject to state and federal laws that govern the submission of claims for reimbursement. The Federal False Claims Act (“FFCA”), also known as qui tam, imposes civil liability and criminal fines on individuals or entities that knowingly submit, or cause to be submitted, false or fraudulent claims for payment to the government. Violations of the FFCA and other similar laws may result in criminal fines, imprisonment, and civil penalties for each false claim submitted and exclusion from federally funded health care programs, including Medicare and Medicaid. The FFCA also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the FFCA. These suits, also known as qui tam actions, may be brought, with only a few exceptions, by any private citizen who has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the FFCA allows an individual to share in any amounts paid to the federal government from a successful qui tam action. If our past or present operations are found to be in violation of any of such laws or other applicable governmental regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from federal health care programs, and/or the curtailment or restructuring of our operations, any of which could materially adversely affect our business, financial position, and operating results. Actions brought against ANI for violations of these laws, even if successfully defended, could also have a material adverse effect on our business, financial position, and operating results.

The use of legal, regulatory, and legislative strategies by competitors, both branded and generic, including “authorized generics,” citizen’s petitions, and legislative proposals, may increase the costs to develop and market our generic products, could delay or prevent new product introductions, and could significantly reduce our profit potential. These factors could have a material adverse effect on our business, financial position, and operating results.

Our competitors, both branded and generic, often pursue legal, regulatory, and/or legislative strategies to prevent or delay competition from generic alternatives to branded products. These strategies include, but are not limited to:

- entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time generic competition initially enters the market;
- launching a generic version of their own branded product at the same time generic competition initially enters the market;
- filing citizen petitions with the FDA or other regulatory bodies, including timing the filings so as to thwart generic competition by causing delays of generic product approvals;
- seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or meet other approval requirements;
- initiating legislative and regulatory efforts to limit the substitution of generic versions of branded pharmaceuticals;
- filing suits for patent infringement that may delay regulatory approval of generic products;
- introducing “next-generation” products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product;
- obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other potential methods;
- persuading regulatory bodies to withdraw the approval of branded name drugs for which the patents are about to expire, thus allowing the branded company to obtain new patented products serving as substitutes for the products withdrawn; and
- seeking to obtain new patents on drugs for which patent protection is about to expire.

If we cannot compete with such strategies, our business, financial position, and operating results could be adversely impacted.

If third-party payers deny coverage, substitute another company’s product for our product, or offer inadequate levels of reimbursement, we may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

Third-party payers are increasingly challenging the prices charged for medical products and services. For example, third-party payers may deny coverage, choose to provide coverage for a competitor’s bioequivalent product rather than our product, or offer limited reimbursement if they determine that a prescribed product has not received appropriate clearances from the FDA, is not used in accordance with cost-effective treatment methods as determined by the third-party payer, or is experimental, unnecessary, or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third-party payers deny coverage or limit reimbursement, we may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated.

We are subject to federal, state, and local laws and regulations, and complying with these may cause us to incur significant additional costs.

The pharmaceutical industry is subject to regulation by various federal authorities, including the FDA, the DEA, and state governmental authorities and their respective foreign equivalents. Federal and state statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale, and distribution of our products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunctions, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment, and criminal prosecution.

All U.S. facilities where prescription drugs are manufactured, tested, packaged, stored, or distributed must comply with FDA current good manufacturing practices (“cGMPs”). All of our products are manufactured, tested, packaged, stored, and distributed according to cGMP regulations. The FDA performs periodic audits to ensure that our facilities remain in compliance with all applicable regulations. If it finds violations of cGMP, the FDA could make its concerns public and could impose sanctions including, among others, fines, product recalls, total or partial suspension of production and/or distribution, suspension of the FDA’s review of product applications, injunctions, and civil or criminal prosecution. If imposed, enforcement actions could have a material adverse effect on our business, financial position, and operating results. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs in place that we believe are adequate, the FDA may conclude that these programs do not meet regulatory standards. If compliance is deemed deficient in any significant way, it could have a material adverse effect on our business.

The U.S. government has enacted the Federal Drug Supply Chain Security Act (“DSCSA”) that requires development of an electronic pedigree to track and trace each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period. All prescription pharmaceutical products distributed in the U.S. must be serialized with unique product identifiers. ANI started manufacturing serialization-compliant products in November 2018. The DSCSA establishes national traceability standards requiring drugs to be labeled and tracked at the bottle level, preempts state drug pedigree requirements, and requires all supply-chain stakeholders to participate in an electronic, interoperable prescription drug traceability system by November 2023. In August 2023, however, the FDA established a one-year stabilization period to allow trading partners to implement, troubleshoot and mature their electronic interoperable systems. The FDA expects trading partners to use this stabilization period, which expired on November 27, 2024, to build and validate interoperable systems and processes, manage products and data, and ensure continuity of the supply chain and product availability to patients. The Company continues to provide serialized commercial products as required to comply with the DSCSA. Compliance with DSCSA and future U.S. federal or state electronic pedigree requirements may increase the Company’s operational expenses and impose significant administrative burdens.

Our research, product development, and manufacturing activities involve the controlled use of hazardous materials, and we may incur significant costs in complying with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the DEA, and other regulatory statutes including the Occupational Safety and Health Act (“OSHA”), the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local, and foreign laws and regulations governing the use, manufacture, storage, handling, and disposal of our products, materials used to develop and manufacture such products, and resulting waste products.

We cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts, from these materials. In the event of an accident, we could be held liable for any damages that result, and any resulting liability could exceed our resources. We may also incur significant costs in complying with environmental laws and regulations in the future. We are also subject to laws generally applicable to businesses, including but not limited to, federal, state, and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination, and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, financial position, and operating results.

Any of our products that are distributed, tested or marketed outside the U.S. are also subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation.

Our operations in an international market subject us to additional regulatory oversight both in the international market and in the U.S., as well as, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results.

We are subject to certain risks associated with having assets and operations located in foreign jurisdictions. Our operations in foreign jurisdictions may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results.

Additionally, involvement in a war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in (i) delays or cancellations of customer orders, (ii) a general decrease in consumer spending on healthcare technology, (iii) our inability to effectively market and distribute our products internationally (iv) our inability to timely engage with and collect payment from our customers or (v) our inability to access capital markets, our business and results of operations could be materially and adversely affected. For example, in response to the continued conflict between Russia and Ukraine, the United States has imposed and may further impose, and other countries may additionally impose, broad sanctions or other restrictive actions against governmental and other entities in Russia. Additionally, further escalation of geopolitical tensions, such as the conflict in the middle east and the surrounding areas, and conflicts related to the attacks on cargo ships in the Red Sea, could have a broader impact that extends into other markets where we do business. We are unable to predict whether acts of international terrorism or the involvement in a war or other military actions by the United States and/or the countries in which we sell or distribute our products will result in any long-term commercial disruptions or if such involvement or responses will have any long-term material adverse effect on our business, results of operations, or financial condition.

Healthcare reform and changes in pharmaceutical pricing, reimbursement and coverage, by governmental authorities and third-party payors may materially affect our business, financial position and operating results.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of, and reimbursement for healthcare services in the U.S. generally and prescription drug coverage, reimbursement and pricing specifically, and it is likely that federal and state legislatures will continue to advocate change to the healthcare system generally and to prescription drug coverage, reimbursement and pricing specifically.

At the federal level, the American Rescue Plan Act eliminated the cap on Medicaid Drug Rebate Program rebates beginning January 1, 2024. As such, we could end up owing additional rebates to state Medicaid programs related to utilization of our drug products negatively impacting profitability. States continue to look for ways to save on Medicaid spend specifically related to prescription drugs. As such, states are increasingly expanding or change supplemental rebates programs to secure additional rebates from manufacturers in exchange for drug coverage and to limit coverage of certain drugs for certain Medicaid patients or to all Medicaid patients. To the extent the Centers for Medicare & Medicaid Services entertains waivers to federal requirements under the Medicaid program to allow states Medicaid programs such flexibility, coverage of and payment for our drugs utilized by Medicaid beneficiaries could be negatively impacted.

Passage of the Inflation Reduction Act (“IRA”) has brought sweeping change to Medicare coverage of and reimbursement for prescription drugs. Most notably, CMS is able to directly negotiate the reimbursement for certain prescription drugs reimbursed under Medicare Part D or B to be effective for the 2026 plan year. If a manufacturer’s drug is selected for negotiation, the manufacturer must negotiate a Maximum Fair Price with CMS or be liable for an excise tax of 65% to 95% of Medicare utilization based on the prior year. While no ANI drugs have currently been selected for negotiation, ANI continues to evaluate the implications of direct negotiation on its products in the future and potential repercussions of competitive products being selected for direct negotiation. In addition, as previously noted, there are numerous legal challenges to the direct negotiation provisions of the IRA. If any of those challenges are successful, this could change the current competitive landscape for manufacturers generally and may change the dynamics of the Medicare Part D marketplace potentially resulting in increased premiums, fewer Part D plans and sponsors and increased pressure on manufacturers to offer formulary placement rebates and additional price concessions. In addition, under the IRA the Part D benefit design will be altered and the coverage gap discount program replaced by a new manufacturer discount program pursuant to which manufacturers will provide a 10 percent discount off the negotiated price for applicable drugs (branded drugs and biologics manufactured by companies that have Part D discount agreements) after the deductible is satisfied through the catastrophic phase of the benefit. In the catastrophic phase, manufacturers will provide a 20 percent discount off negotiated price. Any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a “generic,” is subject to the manufacturer discount requirement. This could increase discounts due on Medicare Part D utilization of our drug products. Lastly, the IRA imposed additional rebates on manufacturers including ANI to the extent certain drug pricing metrics are rising faster than inflation. These new inflation rebates are similar to those imposed on manufacturers under Medicaid and could result in additional rebates due from us on Medicare utilization of our products.

Certain U.S. states have implemented statutes aimed at prescription drug price transparency and some of those laws would permit state run boards or agencies to cap reimbursement for certain prescription drugs in the states. Such laws could negatively impact our financial performance and could result in us terminating distribution of certain products in certain states or regions.

Inflation could have a material adverse effect on our business, financial position, and operating results.

Inflationary pressures are currently being experienced and may continue to exist in the U.S. and key worldwide markets. The rate of inflation may significantly increase input costs for our products and, given the competitive nature of the markets in which we compete, including branded, generic, and rare disease pharmaceutical, and may not be able to pass those costs on to our customers.

Risks Related to Accounting, Tax, and SEC Rules and Regulations

We have increased exposure to tax liabilities, including foreign tax liabilities.

We are subject to, or potentially subject to, income taxes as well as non-income based taxes in various U.S. jurisdictions, Canada, India, the United Kingdom, Ireland, Portugal, and Germany. Significant judgment is required in determining our international provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. In addition, we have potential tax exposures resulting from the varying application of statutes, regulations, and interpretations, which include exposures on intercompany terms of cross-border arrangements between our U.S. operations and our Indian subsidiary in relation to various aspects of our business, including research and development services, tech transfers, and contract manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions; such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and which could have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations.

Our operations in an international market subject us to additional regulatory oversight both in the international market and in the U.S., as well as, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results.

We are subject to certain risks associated with having assets and operations located in foreign jurisdictions. Our international operations may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results.

Additionally, involvement in a war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in (i) delays or cancellations of customer orders, (ii) a general decrease in consumer spending on healthcare technology, (iii) our inability to effectively market and distribute our products internationally (iv) our inability to timely engage with and collect payment from our customers or (v) our inability to access capital markets, our business and results of operations could be materially and adversely affected. For example, in response to the continued conflict between Russia and Ukraine, the United States has imposed and may further impose, and other countries may additionally impose, broad sanctions or other restrictive actions against governmental and other entities in Russia. Additionally, further escalation of geopolitical tensions, such as the conflict in the middle east and the surrounding areas, and conflicts related to the attacks on cargo ships in the Red Sea, could have a broader impact that extends into other markets where we do business. We are unable to predict whether acts of international terrorism or the involvement in a war or other military actions by the United States and/or the countries in which we sell or distribute our products will result in any long-term commercial disruptions or if such involvement or responses will have any long-term material adverse effect on our business, results of operations, or financial condition.

Our expanded international operations from the Alimera Merger increased our exposure to potential liability under anti-corruption, trade protection, tax, and other laws and regulations.

The Foreign Corrupt Practices Act and other anti-corruption laws and regulations (“Anti-Corruption Laws”) prohibit corrupt payments by our employees, vendors, or agents. From time to time, we receive inquiries from authorities in the U.S. and elsewhere about our business activities outside of the U.S. and our compliance with Anti-Corruption Laws. While we devote substantial resources to our compliance programs and have implemented policies, training, and internal controls designed to reduce the risk of corrupt payments, our employees, vendors or agents may violate our policies and with the acquisition of Alimera, our expanded international operations would significantly increase our exposure to potential liability. Our failure to comply with Anti-Corruption Laws could result in significant fines and penalties, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business, and damage to our reputation. Operations outside of the U.S. may be affected by changes in trade production laws, policies, and measures, and other regulatory requirements affecting trade and investment.

We are also subject to tax regulations in certain foreign locations. Such regulations may not be clear, not consistently applied and subject to sudden change, particularly with regard to international transfer pricing. Our earnings could be reduced by changes to such tax regulations or changing interpretation of such tax regulations.

The international nature of our operations (including the acquisition of Alimera) will subject us to political and economic risks that could adversely affect our business, results of operations, or financial condition.

The risks presented by international operations include:

- limitations on ownership or participation in local enterprises;
- price controls, exchange controls, and limitations on repatriation of earnings;
- transportation delays and interruptions;
- the application of additional legal, regulatory and taxation regimes to our operations;
- political, social, and economic instability and disruptions in applicable regions, including as a result of war, such as the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, and conflicts related to the attacks on cargo ships in the Red Sea;
- acts of terrorism;
- government embargoes or foreign trade restrictions;
- imposition of duties and tariffs and other trade barriers;
- import and export controls;
- labor unrest and current and changing regulatory environments;
- fluctuations in foreign current exchange and interest rates;
- difficulties in staffing and managing multi-national operations;
- limitations on our ability to enforce legal rights and remedies.

If we are unable to successfully manage these and other risks associated with managing the expansion of our business to the jurisdictions in which Novitium and Alimera operate, the risks could have a material adverse effect on our business, results of operations, or financial condition.

Failure to comply with applicable transfer pricing and similar regulations could have a material adverse effect on our financial position and operating results.

We are subject to complex transfer pricing and other tax regulations in the United States and other foreign locations designed to ensure that appropriate levels of income are reported as earned and are taxed in the appropriate taxing jurisdictions. Although we believe that we are in substantial compliance with all applicable regulations and restrictions, we are subject to the risk that governmental authorities could audit our transfer pricing and related practices and assert that additional taxes are owed. In the event that such audits or assessments are concluded adversely against us, we may or may not be able to offset or mitigate the consolidated effect of any such assessments.

Changes in estimates regarding the fair value of goodwill or intangible assets may result in an adverse impact to our business, financial position, and operating results.

We test goodwill for impairment annually, or more frequently if changes in circumstances indicate that the carrying amount of goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. We perform our annual assessment of goodwill based on our two reporting units. If we determine that the carrying value of our assets may not be recoverable, we assess, using judgment and estimates, the fair value of our assets and to determine the amount of any impairment loss, if any. Changes in judgments and estimates may result in the recognition of an impairment loss, which could have a material negative impact on our business, financial position, and operating results. While our testing in fiscal 2024 did not result in an impairment charge related to goodwill, there can be no assurances that our goodwill will not be impaired in the future.

Our material definite-lived intangible assets consist of ANDAs for previously marketed generic products, NDAs and product rights for our branded products, product rights related to certain generic products, and a non-compete agreement. These assets are being amortized over their useful lives of seven to twelve years. For these definite-lived intangible assets, we perform an impairment analysis when events or circumstances indicate that the carrying value of the assets may not be recoverable. An impairment loss is recognized if, based on our impairment analysis, the carrying amount of the asset is not recoverable and its carrying amount exceeds its fair value. Any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicate a reduction in carrying value may give rise to impairment in the period that the change becomes known. An impairment charge could have a material negative impact on our business, financial position, and operating results. We recorded impairment losses of \$7.6 million in the year ended December 31, 2024.

Our management is required to devote substantial time to comply with public company regulations. If we are unable to comply with these regulations, investors could lose confidence in us, which could have a material adverse effect on our stock price, business, financial position, and operating results.

As a public company, we are required to comply with significant legal, accounting, and other requirements, and as a result, we incur significant regulatory compliance-related expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and The Nasdaq Stock Market, impose various requirements on public companies, including those related to corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Some members of management do not have significant experience in addressing these requirements. Moreover, these rules and regulations have increased our legal and financial compliance costs relative to those of previous years and make some activities more time consuming and costly.

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) provides a framework for companies to assess and improve their internal control systems. Our compliance with these requirements has required that we incur substantial accounting and related expenses and expend significant management efforts. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, are unable to assert that our internal controls over financial reporting are effective, or identify deficiencies that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the SEC, or other regulatory authorities, which would require additional financial and management resources and could damage our reputation. Further, if we identify any material weaknesses or deficiencies that aggregate to a material weakness in our internal controls, we will have to implement appropriate changes to these controls, which may require specific compliance training for our directors, officers and employees, require the hiring of additional finance, accounting, legal and other personnel, entail substantial costs to modify our existing accounting systems and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Any of these events could have a material adverse effect on our business, financial position, and operating results.

Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods.

We, like other generic drug manufacturers, have agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates. Under many of these arrangements, we may match lower prices offered to customers by competitors. If we choose to lower our prices, we generally give the customer a credit on the products that the customer is holding in inventory, which could reduce sales revenue for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesalers with whom we have contracts for their sales to hospitals, group purchasing organizations, pharmacies, or other customers. A chargeback is the difference between the price at which we invoice the wholesaler and the price that the wholesaler’s end-customer pays for a product. Although we establish reserves based on prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances, and chargebacks will not exceed our estimates.

Risks Related to our Debt

Our indebtedness and liabilities could limit the cash flow available for our operations and expose us to risks that could adversely affect our business, financial condition and results of operation.

We have a substantial amount of indebtedness. As of December 31, 2024, we had approximately \$639.2 million of indebtedness and other liabilities on a consolidated basis. Subject to the limitations in the New Credit Agreement, we may also incur additional debt to meet future financing needs. Our level of indebtedness could have negative consequences for our security holders and our business, results of operation and financial condition by, among other things:

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of our 2.25% Convertible Senior Notes due 2029 (“Senior Notes”);
- placing us at a competitive disadvantage with competitors that are less leveraged than us or have better access to capital; and
- making it more difficult for us to satisfy our obligations with respect to our indebtedness, and any failure to comply with the obligations under any of our debt instruments, including restrictive covenants, could result in an event of default under the New Credit Agreement, the indenture governing our Senior Notes and the agreements governing our other indebtedness.

In connection with the completion of the Merger, we entered into the New Credit Agreement consisting of a \$325.0 million term loan and a \$75.0 million revolving credit facility. The New Credit Agreement, which is secured by all our assets and the assets of our subsidiaries, was used to finance the cash consideration of the Merger. In addition, in August 2024 the Company completed an offering of \$316.25 million aggregate principal amount of Senior Notes at an interest rate of 2.25% per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2025. In order to service the indebtedness we have incurred, and may in the future incur, under the New Credit Agreement, as well as the Senior Notes, we will require a significant amount of cash. Our ability to make scheduled payments of principal and interest depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control.

Our business may not continue to generate cash flow from operations in the future, and we may otherwise be unable to maintain cash reserves sufficient to service our indebtedness, including the Senior Notes and indebtedness incurred under the New Credit Agreement, and our cash needs may increase in the future. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring indebtedness, or obtaining additional indebtedness or equity financing on terms that may not be favorable to us or available to us at all. Our ability to refinance any such indebtedness will depend on the capital markets and our financial condition at that time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default under our current or future indebtedness. Our indebtedness could have significant negative consequences for our stockholders and our business and any event of default or inability to otherwise satisfy our obligations could have a material adverse effect on our future operating results and financial condition.

Our New Credit Agreement contains restrictive and financial covenants and if we are not in compliance with these covenants, our outstanding indebtedness under this facility could be accelerated and the lenders could terminate their commitments under the facility.

The New Credit Agreement contains customary covenants that require maintenance of a leverage ratio at or below specified thresholds and restricts our ability to make certain distributions with respect to our capital stock, prepay other debt, make certain investments, encumber our assets, incur additional indebtedness, make capital expenditures, engage in certain business combinations, transfer, lease or dispose of our assets, alter the character of our business in any material respect or undertake various other corporate activities. Therefore, as a practical matter, these covenants, and any other additional restrictive covenants that may be included in the terms of any future indebtedness, restrict our ability to engage in or benefit from such activities. In addition, we pledged our assets in order to secure our repayment obligations under the New Credit Agreement. This pledge may reduce our operating flexibility because it restricts our ability to dispose of our assets or engage in other transactions that may be beneficial to us.

If we are unable to comply with the covenants in the New Credit Agreement or any future indebtedness, we will be in default, which could result in the acceleration of our outstanding indebtedness and termination of funding commitments by the lenders. If such an acceleration occurs, we may not be able to repay our debt and we may not be able to borrow sufficient additional funds to refinance our debt, which would have a material adverse effect on our business, financial position, and operating results.

Our variable rate indebtedness subjects us to interest rate risk, which could cause our debt service obligations to increase and our net income and cash flows to correspondingly decrease.

Borrowings under our New Credit Agreement are at variable rates of interest and expose us to interest rate risk. If interest rates were to increase, our debt service obligations on the variable rate indebtedness referred to above would increase even if the principal amount borrowed remained the same, and our net income and cash flows will correspondingly decrease. Our New Credit Agreement references the Secured Overnight Financing Rate (“SOFR”) as the primary benchmark rate for our variable rate indebtedness.

We are also currently party to, and in the future, we may enter into additional, interest rate swaps that involve the exchange of floating for fixed rate interest payments, in order to reduce interest rate volatility. However, we may not maintain interest rate swaps with respect to all of our variable rate indebtedness, and any swaps we enter into may not fully mitigate our interest rate risk.

Additionally, SOFR is a relatively new reference rate and with a limited history, and changes in SOFR have, on occasion, been more volatile than changes in other benchmark or market rates. As a result, the amount of interest we may pay on our variable rate indebtedness is difficult to predict.

Shares of our common stock issuable upon conversion of the Senior Notes may dilute the ownership interest of our common stockholders or may adversely affect the market price of our common stock.

The conversion of the Senior Notes may dilute the ownership interests of our stockholders. Upon conversion of the Senior Notes, we will generally have the right to elect to settle our conversion obligation in excess of the principal amount of any converted Senior Notes by paying or delivering, as applicable, cash, shares of our common stock, or a combination of cash and shares of our common stock. If we elect to settle our conversion obligation in excess of the principal amount of any converted Senior Notes in shares of our common stock or a combination of cash and shares of our common stock, any sales in the public market of shares of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. Also, the existence of the Senior Notes may encourage short-selling by market participants because the conversion of the Senior Notes could be used to satisfy short positions, or anticipated conversion of the Senior Notes into, in part, shares of common stock could depress the price of our common stock.

We may be unable to raise the funds necessary to repurchase the Senior Notes for cash following a fundamental change or to pay the cash amounts due upon maturity or conversion of the Senior Notes, and our other indebtedness limits our ability to repurchase the Senior Notes or to pay the cash amounts due upon their maturity or conversion.

Holders of the Senior Notes may, subject to limited exceptions, require us to repurchase their Senior Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Senior Notes to be repurchased, plus accrued and unpaid interest, if any. Upon maturity of the Senior Notes, we must pay their principal amount and accrued and unpaid interest in cash, unless they have been previously repurchased, redeemed or converted. In addition, all conversions of Senior Notes will be settled partially or entirely in cash. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Senior Notes or pay the cash amounts due upon their maturity or conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the Senior Notes or to pay the cash amounts due upon their maturity or conversion. The New Credit Agreement contains restrictive covenants that limit our ability to repay other indebtedness. Our failure to repurchase Senior Notes or to pay the cash amounts due upon their maturity or conversion when required will constitute a default under the indenture governing the Senior Notes. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Senior Notes.

Provisions in the indenture governing the Senior Notes could delay or prevent an otherwise beneficial takeover of us.

Certain provisions in the Senior Notes and the indenture governing the Senior Notes could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then, subject to limited exceptions, holders of the Senior Notes will have the right to require us to repurchase their Senior Notes for cash. In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the Senior Notes and the indenture governing the Senior Notes could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of the Senior Notes or holders of our common stock may view as favorable.

The conversion of the Senior Notes could impair our financial position and liquidity.

Because we must settle at least a portion of our conversion obligation in cash, the conversion of the Senior Notes could materially and adversely affect our financial position and liquidity. Before June 1, 2029, holders of the Senior Notes will have the right to convert their Senior Notes only upon the occurrence of certain events. From and after June 1, 2029, holders of the Senior Notes may convert their Senior Notes at any time at their election until the close of business on the second scheduled trading day immediately before the maturity date. However, many of the conditions that permit the conversion of Senior Notes before June 1, 2029 are beyond our control. We could be required to expend a significant amount of cash to settle conversions, which could significantly harm our financial position and liquidity.

The accounting method for the Senior Notes could adversely affect our reported financial condition and results.

In accordance with applicable accounting standards, the Senior Notes are reflected as a liability on our balance sheets, with the carrying amount equal to the principal amount of the Senior Notes, net of issuance costs. The issuance costs are treated as a debt discount for accounting purposes, which will be amortized into interest expense over the term of the Senior Notes. As a result of this amortization, the interest expense that we recognize for the Senior Notes for accounting purposes is greater than the cash interest payments we pay on the Senior Notes, which results in lower reported income.

In addition, the shares underlying the Senior Notes are reflected in our diluted earnings per share using the “if converted” method. Under that method, if the conversion value of the Senior Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all of the Senior Notes were converted at the beginning of the reporting period and that we issued shares of our common stock to settle the excess. The after-tax interest expense associated with the Senior Notes will not be added back to the numerator of the diluted earnings per share calculation for these purposes. However, if reflecting the Senior Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the Senior Notes does not exceed their principal amount for a reporting period, then the shares underlying the Senior Notes will not be reflected in our diluted earnings per share. The application of the if-converted method may reduce our reported diluted earnings per share, and accounting standards may change in the future in a manner that may adversely affect our diluted earnings per share.

Furthermore, if any of the conditions to the convertibility of the Senior Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the Senior Notes as a current, rather than a long-term, liability. This reclassification could be required even if no holders of our Senior Notes convert their Senior Notes and could materially reduce our reported working capital.

The capped call transactions may affect the value of the Senior Notes and our common stock.

In connection with the pricing of the Senior Notes, we entered into privately negotiated capped call transactions with certain option counterparties. The capped call transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of the Senior Notes and/or offset any potential cash payments we are required to make in excess of the principal amount of converted Senior Notes, as the case may be, with such reduction and/or offset subject to a cap.

The option counterparties and/or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and/or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Senior Notes (and are likely to do so during any observation period related to a conversion of Senior Notes). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the Senior Notes.

We are subject to counterparty risk with respect to the capped call transactions, and the capped call may not operate as planned.

The option counterparties are, or are affiliates of, financial institutions, and we are subject to the risk that they might default under the capped call transactions. Our exposure to the credit risk of the option counterparties is not secured by any collateral. Global economic conditions have from time to time resulted in the actual or perceived failure or financial difficulties of many financial institutions, including the bankruptcy filing by Lehman Brothers Holdings Inc. and its various affiliates. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in those proceedings with a claim equal to our exposure at that time under our transactions with that option counterparty. Our exposure depends on many factors, but, generally, the increase in our exposure will be correlated with increases in the market price or the volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to the financial stability or viability of any option counterparty.

In addition, the capped call transactions are complex, and they may not operate as planned. For example, the terms of the capped call transactions may be subject to adjustment, modification or, in some cases, renegotiation if certain corporate or other transactions occur. Accordingly, these transactions may not operate as we intend if we are required to adjust their terms as a result of transactions in the future or upon unanticipated developments that may adversely affect the functioning of the capped call transactions.

Risks Related to our Common Stock

Our principal stockholders, directors, and executive officers own a significant percentage of our stock and will be able to exercise meaningful influence over our business.

Our current principal stockholders, directors, and executive officers beneficially own approximately 10% of our outstanding capital stock entitled to vote as of December 31, 2024. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions, or other extraordinary transactions. They may also have interests that differ from stockholders generally and may vote in a way with which other stockholders disagree and which may be adverse to their interests. This concentration of ownership may have the effect of delaying, preventing, or deterring a change of control of ANI, could deprive stockholders of an opportunity to receive a premium for their common stock as part of a sale of ANI, and might ultimately affect the market price of our common stock.

Raising additional funds by issuing additional equity securities may cause dilution to our current stockholders. Raising additional funds by entering into additional credit or other borrowing facilities or issuing debt may subject us to covenants and other requirements that may restrict our operations.

We may seek to raise additional funds through the issuance of equity or equity-linked securities. If we were to raise funds through the issuance of equity or equity-linked securities, the percentage ownership of our stockholders could be diluted, potentially significantly, and these newly issued securities may have rights, preferences, or privileges senior to those of our existing stockholders. In addition, the issuance of any equity securities could be at a discount to the then-prevailing market price of our common stock.

If we require new debt financing, there is no assurance that such a transaction will be available on terms acceptable to us, or at all. In addition, we could be subject to onerous repayment terms or covenants that restrict our ability to operate our business and make distributions to our stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock, or make investments. We can offer no assurance that any equity or debt financing transaction will be available on terms acceptable to us, or at all.

Provisions in our charter documents and Delaware law could discourage or prevent a takeover, even if such a transaction would be beneficial to our stockholders.

Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire ANI, even if doing so would be beneficial to our stockholders. These provisions include:

- authorizing the issuance of “blank check” preferred shares that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt;
- prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates;
- advance notice provisions and information submission requirements in connection with stockholder proposals and director nominations that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors; and
- as a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents certain stockholders holding more than 15% of our outstanding common stock from engaging in certain business combinations without approval of the holders of at least two-thirds of our outstanding common stock not held by such 15% or greater stockholder.

Any provision of our certificate of incorporation and bylaws or Delaware law that has the effect of delaying, preventing, or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

General Risk Factors

We use a variety of estimates, judgments, and assumptions in preparing our consolidated financial statements. Estimates, judgments, and assumptions are inherently subject to change, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses, and income. Any such changes could have a material adverse effect on our business, financial position, and operating results.

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“U.S. GAAP”) requires us to make estimates, judgments, 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 period. There are inherent uncertainties involved in estimates, judgments and assumptions, and any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position, and operating results.

In the consolidated financial statements included in the periodic reports filed with the SEC, estimates, judgments, and assumptions are used for, but not limited to, variable consideration determined based on accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, income tax provision or benefit, deferred taxes and valuation allowance, stock-based compensation, revenue recognition, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, including contingent consideration and contingent value rights in acquisitions, fair value of long-lived assets, determination of right-of-use assets and lease liabilities, allowance for credit losses, and the depreciable lives of long-lived assets. Actual results could differ from those estimates. Estimates, judgments, and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses, and income. Any such changes could have a material adverse effect on our business, financial position, and operating results.

The market price of our common stock has been volatile, and an investment in our common stock could decline in value.

The market price of our common stock has increased and decreased significantly and is likely to continue to fluctuate in the future. From time to time, the securities of small capitalization pharmaceutical companies, including ANI, experience significant market price fluctuations, often unrelated to these companies' operating performance. In particular, the market price of our common stock may fluctuate significantly due to a variety of factors, including, but not limited to, regulatory or legal developments with respect to our industry, variations in our financial results or those of companies that are perceived to be similar to us, and rumors or new announcements by third parties, many of which are beyond our control and that may not be related to our operating performance.

In addition, the occurrence of any of the risks described in this report or in subsequent reports we file with the SEC could have a material adverse impact on the market price of our common stock. Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. Securities litigation, whether with or without merit, could result in substantial costs and divert management's attention and resources, which could harm our business, financial position, and operating results, as well as the market price of our common stock.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

We rely on information technology systems and various software applications to operate our business. To address cybersecurity risks, we have implemented a comprehensive process for identifying, assessing, and managing material threats, and integrating these measures into our overall risk management framework. Our Security Operations Team and Security Audit/Advisory Team play a key role in this strategy.

Our senior leadership team, in collaboration with representatives from the Security Operations Team, as well as the legal, human resources, and finance departments, are responsible for developing and executing the company's overall risk management program, including cybersecurity policies. To enhance security, we have established an Information Security Program with a formal written security and incident response policy. This policy outlines methods for assessing, identifying, and mitigating risks. Our cybersecurity program incorporates multiple security layers, and we engage external security consultants to assess, audit, and monitor our security controls and events. Additionally, we require third-party service providers to implement and maintain appropriate security measures and promptly report any suspected breaches that may impact the Company. We also maintain a cybersecurity insurance policy.

We have invested in relevant tools and technologies to protect our data and business partners. Our Security Operations Team continuously monitors risks specific to our industry. We also leverage third-party assessors, consultants, and advisors to enhance our cybersecurity risk assessment and mitigation efforts. To foster a security-conscious culture, we have implemented a cybersecurity awareness program that educates employees on identifying and reporting threats. We conduct periodic phishing campaigns and training sessions to equip employees with the necessary skills to manage and defend against prevalent cybersecurity risks. Additionally, employees in specialized IT roles receive targeted training, including tabletop exercises, among other training.

We continuously update and improve our cybersecurity program through independent assessments, penetration testing, and system vulnerability scanning. Our security framework follows a hybrid approach, incorporating best practices from the Center for Internet Security framework and incorporating relevant standards from the National Institute of Standards and Technology Cybersecurity framework. We also undergo an annual third-party assessment to evaluate the maturity of our cybersecurity program. Additionally, we periodically engage external advisors to assess our program's effectiveness, strengthen policies, and identify potential vulnerabilities. Our Security Operations Team led by VP of Technology, collaborates regularly with IT network teams and other management stakeholders to review and address cybersecurity risks and opportunities. We have a global incident response plan with defined incident management protocols, escalation timelines, and responsibilities among other policies to manage data and its risks. As of the date of this Annual Report on Form 10-K, we are not aware of any previous cybersecurity incidents that have materially affected or are reasonably likely to materially affect the Company.

Governance

Our board of directors, with delegation to the audit committee, as appropriate, retains oversight of the Company's cybersecurity risks. The senior leadership team provides periodic reports to our board of directors, as well as the Chief Executive Officer and audit committee as necessary. In addition, we have contracted with certified security experts that act as an extension of the internal information technology team for all security related items. These communications include potential risks facing the Company, assessments and evaluations of our cybersecurity environment, results of internal controls testing, and reports on our on-going initiatives to strengthen our cybersecurity framework.

Item 2. Properties

Our corporate offices are located at 210 Main Street West, Baudette, Minnesota 56623. The facility, which we own, includes oral solid dose, powder and liquid manufacturing and packaging, warehouse facilities, analytical, stability, and microbiological laboratory space, and employee office and mechanical space. We own a manufacturing facility that includes oral solid dose manufacturing and packaging for pharmaceutical products that must be manufactured in a fully contained environment, warehouse facilities, and employee office and mechanical space, also located in Baudette, Minnesota. We own a cold storage facility located in Baudette, Minnesota. In addition, we own a facility in East Windsor, New Jersey, which includes manufacturing, warehousing, laboratory, product development, and employee office space, which was acquired as part of the acquisition of Novitium in November 2021.

We ceased operations at our subsidiary, ANI Pharmaceuticals Canada, Inc., a wholly owned subsidiary of the Company located in Oakville, Ontario, Canada as of March 31, 2023. This action is part of ongoing initiatives to capture operational synergies following our acquisition of Novitium. We have fully completed the transition of the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites. On November 6, 2023, ANI Pharmaceuticals Canada Inc., entered into an agreement for the sale of the Oakville, Ontario manufacturing facility. On December 22, 2023, the agreement was terminated by mutual agreement. In February 2024, the Company 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. On March 28, 2024 the Company completed the sale of the Property (see Note 4 "Restructuring Canada Operations" in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

We currently lease office space in Princeton, New Jersey, which is our commercial headquarters, which includes certain employees in our corporate, legal, human resources, business functions, and rare disease operations. The leases will expire between 2025 and 2028. We also entered into a new lease agreement for office space in Princeton, New Jersey, which is expected to have a commencement date during 2025. The Princeton, New Jersey lease will have a remaining term of approximately 10 years.

We lease spaces for warehouse and packaging activities in East Windsor, New Jersey, and for research and development activities in Chennai, India. During 2023, we have expanded our East Windsor, New Jersey facility to accommodate additional laboratory, product development, and employee office space.

In connection with the acquisition of Alimera, we also acquired office space in Alpharetta, Georgia. Our lease for this facility expires in December 2032 with an early termination option in December 2029 and an option to extend five years beyond December 2032.

Internationally, we lease office space in Dublin, Ireland, office space in Berlin, Germany, and office space in Hook, U.K. Our leases for the facilities in Ireland and Germany expire in August 2024 and June 2024, respectively. We entered into the Hook, UK lease in December 2024 and it expires in December 2034. We anticipate that following the expiration of these leases, we will be able to lease additional or alternative space at commercially reasonable terms. Additionally, we have an agreement to use approximately 400 square feet of office space in Lisbon, Portugal, which can be terminated with 90 days' notice.

We consider our leased and owned properties suitable and adequate for our current and foreseeable needs.

Item 3. Legal Proceedings

Our legal proceedings are discussed in Note 17. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock trades on the Nasdaq Global Market under the symbol “ANIP.”

Stockholder Information

As of February 21, 2025, there were approximately 358 shareholders of record of our common stock, which does not include stockholders that beneficially own shares held in a “nominee” or in “street” name, and six holders of record of Class C stock.

Dividends

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Our shares of Series A convertible preferred stock (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. To date, we have paid all preferred stock dividends in cash. We currently intend to retain all remaining available funds and any future earnings to fund the development and growth of our business.

Recent Sales of Unregistered Securities

None.

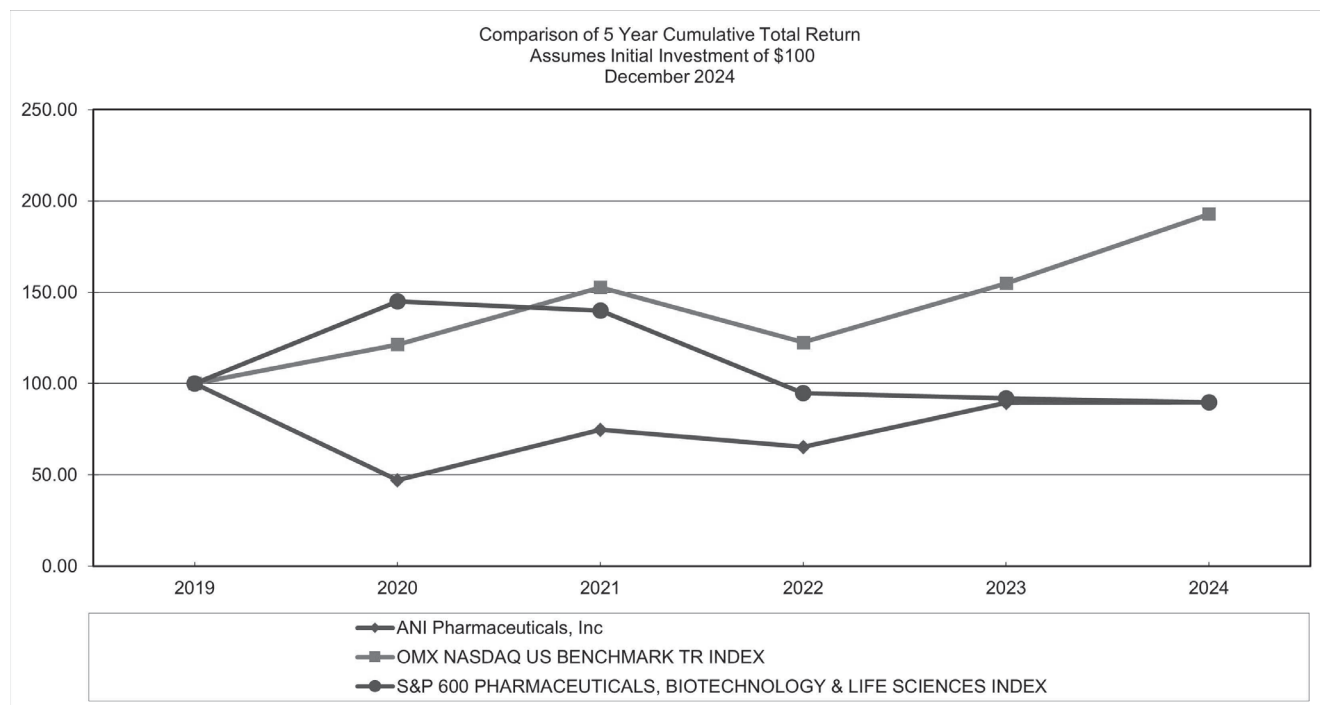
Issuer Purchases of Equity Securities

| Period | Total Number of Shares Purchased ⁽¹⁾ | Average Price Paid per Share | Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs | Maximum Number (or approximate dollar value) of Shares that may yet be Purchased Under the Plans or Programs |
|--------------------------------|---|------------------------------|--|--|
| October 1 - October 31, 2024 | — | \$ — | — | \$ — |
| November 1 - November 30, 2024 | 3,984 | \$ 56.58 | — | \$ — |
| December 1 - December 31, 2024 | 1,635 | \$ 56.59 | — | \$ — |
| Total | 5,619 | \$ 56.58 | — | |

⁽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.

Performance Graph

The graph below compares the five-year cumulative total stockholder return on our common stock, the Nasdaq Stock Market (US) Index, and the S&P 600 Pharmaceuticals, Biotechnology & Life Sciences Index, assuming the investment of \$100.00 on December 31, 2019, with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.



Item 6. Reserved

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Please read the following discussion in conjunction with Item 1A. ("Risk Factors") and our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. Some of the statements in the following discussion are forward-looking statements. See the discussion about forward-looking statements on page 1 of this Annual Report on Form 10-K.

This section of this Form 10-K generally discusses 2024 and 2023 items and year-to-year comparisons between 2024 and 2023. Discussions of 2022 items and year-to-year comparisons between 2023 and 2022 that are not included in this Form 10-K can be found in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Part II, Item 7 of the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 29, 2024.

Executive Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is a diversified bio-pharmaceutical company committed to its mission of "Serving Patients, Improving Lives" by developing, manufacturing, and commercializing innovative and high quality therapeutics.

On September 16, 2024, the Company completed its previously announced acquisition of Alimera Sciences, Inc., a Delaware corporation, pursuant to the terms of the Agreement and Plan of Merger, dated as of June 21, 2024 (the "Merger Agreement"), by and among the Company, Alimera and ANIP Merger Sub INC., a Delaware corporation and wholly-owned subsidiary of the Company ("Merger Sub"). Pursuant to the Merger Agreement, Merger Sub merged with and into Alimera, with Alimera surviving the merger as a wholly-owned subsidiary of the Company (the "Merger"). In connection with the Merger, the Company added a growing and durable franchise, ILUVIEN® (fluocinolone acetonide intravitreal implant) 0.19 mg, which has received marketing authorization and reimbursement in the United States ("U.S.") and 24 countries for the treatment of diabetic macular edema ("DME") and YUTIQ® (fluocinolone acetonide intravitreal implant) 0.18 mg, available in the U.S. for the treatment of non-infectious uveitis affecting the posterior segment of the eye ("NIU-PS"). In connection with the acquisition of Alimera, the Company has assessed its strategic goals and aligned its operational initiatives into two reportable segments, and the discussion of the historical results of operations below has been revised, as applicable, to be consistent with the presentation of the revised reportable segments (see Note 19 "Segment Reporting in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

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 4 "Restructuring Canada Operations" in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

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

On September 16, 2024, ANI drew the full \$325.0 million of New Credit Agreement principal, with proceeds used to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the acquisition. As of December 31, 2024, the revolving credit facility remains undrawn, and \$75.0 million is available for borrowing, subject to the satisfaction of certain conditions. The New Credit Agreement and the revolving credit facility mature on September 16, 2029.

On August 13, 2024, the Company completed an offering of \$316.25 million aggregate principal amount of the Company's Convertible Senior Notes due 2029 (the "Notes"). The Notes are due September 1, 2029, unless earlier repurchased, redeemed, or converted. After deducting the initial purchasers' discounts and commissions of approximately \$9.5 million, but before deducting the Company's offering expenses, the net proceeds to the Company from the offering of the Notes was approximately \$306.8 million. In connection with the offering of Notes, on August 7, 2024 and August 8, 2024, the Company entered into capped call transactions with certain financial institutions ("Capped Calls"). After payment of the cost of entering into the Capped Calls transactions, of approximately \$40.6 million, the Company used the remainder of the net proceeds from the Notes offering, together with cash on hand, to repay the Company's existing senior secured credit agreement with Truist Bank, dated as of November 19, 2021.

In May 2023, through a public offering, the Company 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.

Strategy

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

Our strategy is driven by the following key growth drivers:

Building a successful Rare Disease and Brands Segment

We have spent significant time, effort and resources in establishing and expanding our Rare Disease and Brands segment which consists of our Rare Disease and Brands portfolio of products. We plan to continue to expand our Rare Disease business, through a combination of organic growth and acquisition. While we 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. The Brands portion of the segment is comprised of various branded products.

The acquisition of Alimera is anticipated to strengthen our Rare Disease business and expand our footprint beyond the U.S. with the addition of Alimera's direct marketing operations located in Germany, the United Kingdom, Portugal, and Ireland, as well as its partnerships in Europe, Asia, and the Middle East. ILUVIEN and YUTIQ are a durable franchise with high barriers to genericization which the Company believes have a clear role for patients in need of alternative therapeutic options. ANI sees the potential to unlock significant additional growth for the ILUVIEN and YUTIQ franchise through commercial synergies and execution.

Purified Cortrophin® Gel

We acquired the NDAs for Purified Cortrophin® Gel (Repository Corticotropin Injection USP) ("Cortrophin Gel") and Cortrophin-ZincTM in January 2016 and executed long-term supply agreements with a supplier of our primary raw material for corticotrophin API, a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin Gel fill/finish contract manufacturer. On October 29, 2021, the FDA approved the Company's Supplemental New Drug Application ("sNDA") for Cortrophin Gel 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 adrenocorticotrophic hormone ("ACTH"), also known as purified corticotropin. On January 24, 2022, we announced the commercial launch of Cortrophin Gel in the U.S. as our foundational Rare Disease asset.

Throughout 2023 and 2024, we continued to build and invest in our infrastructure to support growth in new areas of opportunity, such as pulmonology, ophthalmology, and gout in the ACTH market. On October 2, 2023, we announced FDA approval and commercial availability of a 1-mL vial of Cortrophin Gel, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares.

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

ILUVIEN and YUTIQ

ILUVIEN (fluocinolone acetonide intravitreal implant) 0.19 mg, was developed in the U.S. and internationally for the treatment of diabetic macular edema (“DME”), a leading cause of severe vision loss and blindness, and certain international markets for chronic non-infectious uveitis affecting the posterior segment of the eye (“NIU-PS”). We acquired exclusive commercialization rights to YUTIQ (fluocinolone acetonide intravitreal implant) 0.18 mg, in May 2023 from EyePoint Pharmaceuticals, Inc. (“EyePoint”) for the treatment and prevention of NIU-PS worldwide except for Europe, the Middle East, Africa, (known as ILUVIEN in Europe, the Middle East and Africa) and certain Asian countries including China. ILUVIEN and YUTIQ are state-of-the-art sustained release intravitreal implants that respectively help patients maintain vision longer and reduce disease recurrence. ILUVIEN is being evaluated as baseline therapy in naïve or near naïve patients with early DME in combination with the current standard of care, anti-vascular endothelial growth factor (“VEGF”) therapy in the NEW DAY clinical trial. YUTIQ is being further studied in the SYNCHRONICITY Clinical Trial, a prospective, open-label clinical trial evaluating the safety and efficacy of YUTIQ for the treatment and prevention of chronic NIU-PS and related intraocular inflammation.

Both ILUVIEN and YUTIQ treat patients by delivering a continuous microdose of the corticosteroid fluocinolone acetonide (“FAC”) in the eye, for up to 36 months. ILUVIEN was developed internally and initially to treat DME, a disease of the retina that affects individuals with Type 1 or Type 2 diabetes and can lead to severe vision loss and blindness. ILUVIEN is sold to treat DME only in the U.S. YUTIQ is sold to treat NIU-PS only in the U.S. In certain European and Middle Eastern countries, ILUVIEN is approved and commercialized to treat DME and to prevent relapse in recurrent NIU-PS, an inflammatory disease of the uveal tract, which is comprised of the iris, ciliary body and choroid, that can lead to severe vision loss and blindness. We also have rights to commercialize ILUVIEN for NIU-PS in Africa.

ILUVIEN and YUTIQ are both intravitreal implants that are inserted into the back of the patient’s eye in non-surgical procedures employing devices with 25-gauge needles, which allow for a self-sealing wounds. “Intravitreal” refers to the space inside the eye behind the lens that contains the jelly-like substance called vitreous. The implants, which are non-bioerodible, provide consistent delivery as a result of their constant surface area, permitting elution of FAC to the vitreous. We call this CONTINUOUS MICRODOSING™. This delivery mechanism provides lower daily and aggregate exposure to corticosteroids than any other intraocular dosage forms currently available, which we believe mitigates the typical risks associated with corticosteroid therapy. CONTINUOUS MICRODOSING delivery makes ILUVIEN and YUTIQ the only approved drug therapies for DME and NIU-PS that are designed to deliver consistent daily therapeutic levels of corticosteroid and reduce the recurrence of DME and uveitis for up to three years. Other therapies that physicians currently use to treat DME, such as anti-VEGF treatments and other corticosteroids, are acute (short-acting) therapies that provide a higher initial daily dose but then rapidly decline, requiring frequent reinjection by the physician to maintain an effective dose or reestablish the therapeutic effect after the disease has recurred.

FAC is a non-proprietary corticosteroid and the active compound in ILUVIEN (0.19mg) and YUTIQ (0.18mg). We believe that corticosteroids provide the best option in the treatment of DME and NIU-PS because they reduce the inflammatory aspects of both diseases. ILUVIEN and YUTIQ deliver continuous daily sub-microgram levels of FAC in in vivo release kinetic studies for up to 36 months. ILUVIEN and YUTIQ are the only single injection therapies available to treat retinal diseases consistently every day for up to three years, which may allow patients to see better, longer, with fewer injections.

Brands

We have grown our brands portfolio of products through acquisition. We have acquired the NDAs for and market Atacand, Atacand HCT, Arimidex, Casodex, Lithobid, Vancocin, Inderal LA, Inderal XL, InnoPran XL, Oxistat, and Veregen. We are innovating in our go-to-market strategy through creative partnerships and a sales force for these products.

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

We have grown our generics business through a combination of market share gains on existing products and new product launches. We have also successfully acquired numerous ANDAs through business and asset acquisitions. Our most recent business acquisition in the Generics and Other segment was the acquisition of Novitium in 2021, which included its portfolio of commercial and pipeline generic products, manufacturing and development facilities and expert workforce. The Novitium acquisition significantly increased our generic pharmaceutical research and development and manufacturing capabilities. We have begun to increase our focus on niche lower competition opportunities such as injectables, Paragraph IV, and competitive generic therapy (“CGT”) designation filings.

Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses. During 2023, we acquired two ANDAs and one pipeline product from the Chapter 7 Trustee for the estates of Akorn Holding Company and certain of its affiliates, acquired an ANDA and registered patents and pending patent applications from Slayback Pharma Limited Liability Company, and acquired additional ANDAs and product rights for two products in the second half of 2023. During 2022, we completed an asset acquisition of four ANDAs from Oakrum Pharma, including two that were commercial at the time of acquisition.

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.

Fiscal 2024 Developments

Acquisition of Alimera Sciences, Inc.

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

Each CVR entitles the holder to receive milestone payments for 2026 and 2027. The milestone payments for each CVR equals the product (rounded to the nearest 1/100 of \$0.01) of \$0.25 multiplied by a fraction (which is no case will exceed one), and (i) for 2026, equals the amount, if any, by which the 2026 Net Revenue exceeds \$140.0 million, divided by \$10.0 million (subject to adjustment for the exercise price of eligible options), and (ii) for 2027, equals the amount, if any, by which the 2027 Net Revenue exceeds \$160.0 million, divided by \$15.0 million (subject to adjustment for the exercise price of applicable Alimera Options).

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

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

During the year ended December 31, 2024, the Company incurred approximately \$12.4 million in transaction costs related to the Merger Agreement, all of which were expensed. See Note 3 “Business Combination” to the notes to the consolidated financial statements for further information on the acquisition.

New Capital Structure

Refer to the Liquidity and Capital Resources below for further discussion of changes to our capital structure during 2024.

Restructuring

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

On March 28, 2024 the Company completed the sale of the Property. After payment of commissions, taxes, and other related costs of approximately \$0.7 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 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 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:

| (in thousands) | Year Ended December 31, | |
|---|----------------------------|------------------|
| | 2024 | 2023 |
| Net Revenues | \$ 614,376 | \$ 486,816 |
| Operating Expenses | | |
| Cost of sales (excluding depreciation and amortization) | 250,210 | 181,513 |
| Research and development | 44,581 | 34,286 |
| Selling, general, and administrative | 249,636 | 161,697 |
| Depreciation and amortization | 67,731 | 59,791 |
| Contingent consideration fair value adjustment | (619) | 1,426 |
| Gain on sale of building | (5,347) | — |
| Restructuring activities | — | 1,132 |
| Intangible asset impairment charge | 7,600 | — |
| Operating Income | 584 | 46,971 |
| Unrealized gain on investment in equity securities | 6,307 | — |
| Interest expense, net | (17,602) | (26,940) |
| Other expense, net | (4,033) | (159) |
| Loss on extinguishment of debt | (7,468) | — |
| (Loss) Income Before (Benefit) Expense for Income Taxes | (22,212) | 19,872 |
| Income tax (benefit) expense | (3,690) | 1,093 |
| Net (Loss) Income | <u>\$ (18,522)</u> | <u>\$ 18,779</u> |

The following table sets forth, for the periods indicated, items in our consolidated statements of operations as a percentage of net revenues.

| | Year Ended December 31, | |
|---|----------------------------|--------------|
| | 2024 | 2023 |
| Net Revenues | 100.0 % | 100.0 % |
| Operating Expenses | | |
| Cost of sales (excluding depreciation and amortization) | 40.7 % | 37.3 % |
| Research and development | 7.3 % | 7.0 % |
| Selling, general, and administrative | 40.6 % | 33.2 % |
| Depreciation and amortization | 11.0 % | 12.3 % |
| Contingent consideration fair value adjustment | (0.1)% | 0.3 % |
| Gain on sale of building | (0.9)% | — % |
| Restructuring activities | — % | 0.2 % |
| Intangible asset impairment charge | 1.2 % | — % |
| Operating Income | 0.2 % | 9.7 % |
| Unrealized gain on investment in equity securities | 1.0 % | — % |
| Interest expense, net | (2.9)% | (5.5)% |
| Other expense, net | (0.7)% | — % |
| Loss on extinguishment of debt | (1.2)% | — % |
| (Loss) Income Before (Benefit) Expense for Income Taxes | (3.6)% | 4.2 % |
| Income tax (benefit) expense | (0.6)% | 0.2 % |
| Net (Loss) Income | <u>(3.0)%</u> | <u>4.0 %</u> |

Results of Operations for the Years Ended December 31, 2024 and 2023

Net Revenue

| | Year Ended December 31, | | | |
|---|----------------------------|------------|------------|----------|
| (in thousands) | 2024 | 2023 | Change | % Change |
| Rare Disease and Brands | | | | |
| Cortrophin Gel | \$ 198,085 | \$ 112,117 | \$ 85,968 | 76.7 % |
| ILUVIEN and YUTIQ | 31,514 | — | 31,514 | 100.0 % |
| Rare Disease total net revenues | \$ 229,599 | \$ 112,117 | \$ 117,482 | 104.8 % |
| Brands | 64,743 | 85,384 | (20,641) | (24.2)% |
| Rare Disease and Brands total net revenues | \$ 294,342 | \$ 197,501 | \$ 96,841 | 49.0 % |
| Generics and Other | | | | |
| Generic pharmaceutical products | 301,004 | 269,449 | 31,555 | 11.7 % |
| Royalties and other pharmaceutical services | 19,030 | 19,866 | (836) | (4.2)% |
| Generics and Other total net revenues | \$ 320,034 | \$ 289,315 | \$ 30,719 | 10.6 % |
| Total net revenues | \$ 614,376 | \$ 486,816 | \$ 127,560 | 26.2 % |

We derive substantially all of our revenues from sales of rare disease, brands portfolio of pharmaceutical products, generics, and other sources of revenue such as royalties on net sales of certain products, and other pharmaceutical services. Essentially all of our generic products face competition from other generic products, as do many of our brands 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 brands 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 year ended December 31, 2024 were \$614.4 million compared to \$486.8 million for the same period in 2023, an increase of \$127.6 million, or 26.2%, primarily as a result of the following:

- Net revenues from Rare Disease and Brands, includes rare disease and brands portfolio of pharmaceutical products was \$294.3 million during the year ended December 31, 2024, an increase of \$96.8 million, compared to \$197.5 million, for the same period in 2023.
 - Net revenues for rare disease pharmaceutical products, include Cortrophin Gel and a full quarter contribution from ILUVIEN and YUTIQ, were \$229.6 million during the year ended December 31, 2024, an increase of \$117.5 million from \$112.1 million for the same period in 2023. This increase was driven by increased volume in this third year of launch of Cortrophin Gel (product was launched in late January 2022) from overall ACTH market growth and share growth, and a full quarter of sales from ILUVIEN and YUTIQ, as a result of the acquisition of Alimera on September 16, 2024.
 - Net revenues for brands portfolio of pharmaceutical products were \$64.7 million during the year ended December 31, 2024, a decrease of \$20.6 million compared to \$85.4 million for the same period in 2023, driven by a net decrease in volume. During portions of the prior year and the first quarter and portions of the fourth quarter of 2024, we were successful in supplying incremental volume in markets that were experiencing supply chain disruptions for competing products. This incremental volume was not a significant factor in the second and third quarter of 2024. Incremental volume achieved toward the end of 2024 continued into the first half of the first quarter of 2025. The timing, magnitude and persistence of such market share gains are inherently difficult to predict and they may not persist in future reporting periods.

- Net revenues for generic and other pharmaceutical products were \$320.0 million during the year ended December 31, 2024, an increase of 10.6% compared to \$289.3 million for the same period in 2023, primarily a result of the following:
 - Generic pharmaceutical products net revenues were \$301.0 million during the year ended December 31, 2024, an increase of \$31.6 million over the prior year. This increase was driven by increased volumes on the base business, increased volumes from the full year benefit of 2023 launches in 2024 and 2024 new product launches. The Company launched a total of 17 new products in 2024. From a product perspective, the increase was principally driven by revenues from year over year increases in products such as Baclofen OS, Candesartan, Colestipol, Estradiol, Ketoconazole, L-Glutamine, Pentoxifylline, Pirfenidone, Prednisone, Vancomycin, among others.
 - Net revenues from royalties and other pharmaceuticals was down modestly between December 31, 2024 and the prior year.

Cost of Sales (Excluding Depreciation and Amortization)

| (in thousands) | Year Ended December 31, | | Change | % Change |
|---|----------------------------|------------|-----------|----------|
| | 2024 | 2023 | | |
| Cost of sales (excluding depreciation and amortization) | \$ 250,210 | \$ 181,513 | \$ 68,697 | 37.8 % |

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

For the year ended December 31, 2024, cost of sales increased to \$250.2 million from \$181.5 million for the same period in 2023, an increase of \$68.7 million or 37.8%. The increase is primarily due to significant net growth in sales volumes of pharmaceutical products, significant growth of royalty bearing products, including Cortrophin Gel, and the amortization of the inventory step up related to the acquisition of Alimera of approximately \$13.6 million.

Cost of sales, as a percentage of net revenues, increased from 37.3% to 40.7% for the year ended December 31, 2024, compared to the same period in 2023, primarily due to a shift in product mix year over year, and increase in sales of products that bear a royalty payable.

During the year ended December 31, 2024, 12% of our raw material inventory purchases were from one domestic supplier. During the year ended December 31, 2023, no single vendor represented at least 10% of our raw material inventory purchases. During the year ended December 31, 2022 approximately 19%, of our raw material inventory purchases were from one domestic supplier.

Other Operating Expenses, net

| (in thousands) | Year Ended December 31, | | Change | % Change |
|--|----------------------------|------------|------------|----------|
| | 2024 | 2023 | | |
| Research and development | \$ 44,581 | \$ 34,286 | \$ 10,295 | 30.0 % |
| Selling, general, and administrative | 249,636 | 161,697 | 87,939 | 54.4 % |
| Depreciation and amortization | 67,731 | 59,791 | 7,940 | 13.3 % |
| Contingent consideration fair value adjustment | (619) | 1,426 | (2,045) | (143.4)% |
| Restructuring activities | — | 1,132 | (1,132) | (100.0)% |
| Gain on sale of building | (5,347) | — | (5,347) | (100.0)% |
| Intangible asset impairment charge | 7,600 | — | 7,600 | 100.0 % |
| Total other operating expenses | \$ 363,582 | \$ 258,332 | \$ 105,250 | 40.7 % |

For the year ended December 31, 2024, other operating expenses increased to \$363.6 million from \$258.3 million for the same period in 2023, an increase of \$105.3 million, or 40.7%, primarily as a result of the following factors:

- Research and development expenses increased from \$34.3 million to \$44.6 million, an increase of 30.0%, primarily due to a higher level of activity associated with ongoing and new projects, including expenses related to the New Day and Synchronicity clinical trials during the year ended December 31, 2024.
- Selling, general, and administrative expenses increased from \$161.7 million to \$249.6 million, an increase of 54.4%, due to increased employment related costs, including incentive based compensation tied to record 2024 financial performance, investment in Rare Disease sales and marketing infrastructure and activities, legal expenses, transaction and integration expenses related to the acquisition of Alimera of approximately \$18.2 million, severance expense of approximately \$5.3 million and the settlement of all outstanding equity awards held by Alimera employees of approximately \$9.2 million, and an overall increase in activities to support revenue growth in our Rare Disease and Brands segment.
- Depreciation and amortization expense was \$67.7 million for the year ended December 31, 2024, compared to \$59.8 million for the same period in 2023, an increase of approximately \$7.9 million, primarily related to the amortization expense of the acquired intangible assets of ILUVIEN and YUTIQ of approximately \$9.6 million. These assets were acquired on September 16, 2024 from Alimera.
- We recognized a gain of \$0.6 million and loss of \$1.4 million in the year ended December 31, 2024 and 2023, respectively, for the contingent consideration fair value adjustment. This financial statement line item consists of three components; the changes in fair value of (1) the Novitium contingent consideration; (2) the Alimera contingent value rights; and (3) the accrued Alimera licensor payments.
 - We recorded a gain of approximately \$0.6 million related to the decrease in the expected future payments related to Novitium contingent consideration, and a decrease in fair value of \$0.3 million related to the decrease in expected future payments of the accrued licensor payments. The gain was offset by a loss related to the increase in fair value of \$0.3 million related to the Alimera contingent value rights.
- We recognized restructuring activities expenses of \$1.1 million of expense in the year ended December 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. There were no restructuring expenses recognized in the year ended December 31, 2024.
- We recognized a gain related to the sale of the former Oakville, Ontario manufacturing site of approximately \$5.3 million during the year ended December 31, 2024. There was no comparable sale in the year ended December 31, 2023.

- We recognized an impairment charge related to a portfolio of definite-lived intangible assets of \$3.6 million and IPR&D of approximately \$4.0 million during the three months ended December 31, 2024. There was no comparable intangible asset impairment charge in the year ended December 31, 2023.

Other Expense, net

| (in thousands) | Year Ended December 31, | | Change | % Change |
|--|----------------------------|--------------------|-----------------|----------------|
| | 2024 | 2023 | | |
| Unrealized gain on investment in equity securities | \$ 6,307 | \$ — | \$ 6,307 | 100.0 % |
| Interest expense, net | (17,602) | (26,940) | 9,338 | (34.7)% |
| Other expense, net | (4,033) | (159) | (3,874) | 2436.5 % |
| Loss on extinguishment of debt | (7,468) | — | (7,468) | (100.0)% |
| Total other expense, net | <u>\$ (22,796)</u> | <u>\$ (27,099)</u> | <u>\$ 4,303</u> | <u>(15.9)%</u> |

For the year ended December 31, 2024, we recognized total other expense, net of \$22.8 million as compared to total other expense of \$27.1 million for the same period in 2023, a decrease of \$4.3 million.

- The unrealized gain on investment in equity securities of approximately \$6.3 million is due to the mark to market to fair value of the equity securities held in CG Oncology as of the balance sheet date. There was no comparable gain on investment in the year ended December 31, 2023.
- Interest expense, for the year ended December 31, 2024 consists primarily of coupon interest expense on borrowings under our outstanding debt and amortization of deferred financings costs on these debt instruments, interest income earned on our bank balances, and interest earned on our interest rate swap. During 2023 and for the first 8 months of 2024, only the Credit Facility with Truist was outstanding, however, in Q3 2024 we entered into a New Credit Facility and Convertible Senior Notes in an aggregate principal amount of approximately \$641.3 million. The decrease in interest expense, net, of \$9.3 million is primarily attributable to favorable interest rates on the New Credit Facility, Convertible Notes, and favorable bank interest rates during 2024.
 - Interest expense decreased approximately \$2.0 million compared to prior year primarily due to the favorable interest rates on the New Credit Facility. Interest expense related to our debt during 2024 was \$33.6 million, as compared to \$35.6 million in the prior year.
 - Interest income increased approximately \$7.3 million compared to prior year, primarily due to interest and dividends earned on our bank balances and interest rate swap which increased to \$16.0 million during 2024 from \$8.7 million during 2023.
- Other expense, net, increased to approximately \$4.0 million, primarily due to the fees paid to JPMorgan Chase Bank, N.A. and Blackstone Credit & Insurance of \$2.8 million pursuant to the terms of the debt commitment letter, dated June 21, 2024, entered into in connection with the acquisition of Alimera.
- We recorded a loss on debt extinguishment of approximately \$7.5 million, comprised of the write-off unamortized deferred financing fees related to the Credit Facility. On August 13, 2024, the Company entered into the 2.25% Convertible Senior Notes due 2029 (as described in Note 7 “2.25% Convertible Senior Notes” to the notes to consolidated financial statements). The proceeds of the Convertible Senior Notes were used to repay the Truist Credit Facility in its entirety, approximately \$294.0 million, comprised of \$292.5 million of unpaid principal, \$1.2 million in accrued and unpaid interest, and \$0.3 million of legal fees. There was no comparable transaction in the year ended December 31, 2023.

Income Tax (Benefit) Expense

| (in thousands) | Year Ended December 31, | | Change | % Change |
|------------------------------|----------------------------|----------|------------|----------|
| | 2024 | 2023 | | |
| Income tax (benefit) expense | \$ (3,690) | \$ 1,093 | \$ (4,783) | (437.6)% |

Income tax (benefit) expense consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance. See Note 16 "Income Taxes" in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K for further information.

For the year ended December 31, 2024, we recognized an income tax benefit of approximately \$3.7 million, an effective tax rate of 16.6% of pre-tax loss reported in the period, as well as the net effect of certain discrete items for the year ended December 31, 2024 which impact our income tax expense in the period in which they occur. Discrete items occurring in 2024 include the U.S. federal research and development credit, permanent differences, and stock based compensation.

For the year ended December 31, 2023, we recognized an income tax expense of \$1.1 million, an effective rate of 5.5% of pre-tax income reported in the period, as well as the net effects of certain discrete items occurring in 2023 which impact our income tax benefit in the period in which they occur. There were no material discrete items occurring during the year ended December 31, 2023.

Liquidity and Capital Resources

The following table highlights selected liquidity and working capital information from our consolidated balance sheets.

| (in thousands) | December 31, 2024 | December 31, 2023 |
|---|----------------------|----------------------|
| Cash and cash equivalents | \$ 144,861 | \$ 221,121 |
| Restricted cash | 33 | — |
| Accounts receivable, net | 221,726 | 162,079 |
| Inventories | 136,782 | 111,196 |
| Assets held for sale | — | 8,020 |
| Prepaid expenses and other current assets | 17,975 | 17,400 |
| Investment in equity securities | 6,307 | — |
| Total current assets | <u>\$ 527,684</u> | <u>\$ 519,816</u> |
| Current debt, net of deferred financing costs | \$ 9,172 | \$ 850 |
| Accounts payable | 45,656 | 36,683 |
| Accrued royalties | 22,626 | 16,276 |
| Accrued compensation and related expenses | 37,725 | 23,786 |
| Accrued government rebates | 18,714 | 12,168 |
| Income taxes payable | 6,749 | 8,164 |
| Returned goods reserve | 39,274 | 29,678 |
| Current contingent consideration | 29 | 12,266 |
| Accrued expenses and other | 13,735 | 5,606 |
| Total current liabilities | <u>\$ 193,680</u> | <u>\$ 145,477</u> |

As of December 31, 2024, we had \$144.9 million in unrestricted cash and cash equivalents. On December 31, 2023, we had \$221.1 million in unrestricted cash and cash equivalents.

We are focused on expanding our business and product pipeline through collaborations, and also through acquisitions of products and companies. We are continually evaluating potential asset acquisitions and business combinations. To finance such acquisitions, we might raise additional equity capital, incur additional debt, or both.

Our working capital ratio, defined as total current assets divided by total current liabilities, is 2.7 as of December 31, 2024. We believe that our financial resources, consisting of net current working capital of approximately \$334.0 million, anticipated future operating revenue and corresponding collections from customers, and our New Credit Agreement, under which \$75.0 million remains available for borrowing as of December 31, 2024, will be sufficient to enable us to meet our working capital requirements, debt obligations, and other liability obligations for at least the next 12 months from the date of filing of this report, and for the foreseeable future thereafter. If our assumptions underlying estimated revenue and expenses are wrong, or if our cash requirements change materially as a result of shifts in our business or strategy, we could require additional financing. If we are not able to continue to be profitable in future years or are not able to continue to generate cash from operations as anticipated and additional capital is needed to support operations, we may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations, or accept financing terms that are not as attractive as desired.

Consolidation among wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. Our net revenues were concentrated among four customers representing 25%, 16%, 12%, and 11% of net revenues during the year ended December 31, 2024. As of December 31, 2024 accounts receivable from these four customers totaled approximately 70% of accounts receivable, net. Our net revenues were concentrated among four customers representing 31%, 13%, 13%, and 12% of net revenues during the year ended December 31, 2023. As of December 31, 2023, accounts receivable from these four customers totaled approximately 81% of accounts receivable, net. As a result, negotiated payment terms with these customers have a material impact on our liquidity and working capital.

Our Cortrophin Gel product accounted for approximately 32% and 23% of our net revenues in 2024 and 2023, respectively. We pay to Merck Sharpe & Dohme B.V. ("Merck") quarterly contingent consideration in the form of a perpetual, tiered royalty expressed as a percentage of Cortrophin Gel net sales. During the initial two years of commercialization (2022 and 2023) this royalty approximated 10% of net sales. During 2024, the blended Merck royalty rate was in the upper teens, and we currently anticipate the blended royalty rate to be in the low 20 percent range in 2025.

Sources and Uses of Cash

Term Loan A

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

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

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

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

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

On September 16, 2024 (the “Closing Date”) the Company drew the full \$325.0 million of Term Loan A principal on September 16, 2024, with proceeds used to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the transaction. As of December 31, 2024, the TLA Revolver remains undrawn, and \$75.0 million is available for borrowing, subject to certain conditions. The TLA and the TLA Revolver mature on September 16, 2029. The New Credit Facility contains certain contingent acceleration clauses, none of which have been triggered as of December 31, 2024. The cash interest rate and effective rate under the Term Loan A was approximately 6.98% at December 31, 2024.

2.25% Convertible Senior Notes Due 2029

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

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

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

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

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

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

Capped Call Transactions

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

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

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

Debt Extinguishment

On November 19, 2021, the Company, as borrower, entered into a credit agreement (the “Credit Agreement”) with Truist Bank and other lenders, which provided for credit facilities consisting of (i) a senior secured term loan facility in an aggregate principal amount of \$300.0 million (the “Term Facility”) and (ii) a senior secured revolving credit facility in an aggregate commitment amount of \$40.0 million, which may be used for revolving credit loans, swingline loans and letters of credit (the “Revolving Facility,” and together with the Term Facility, the “Credit Facility”). The Credit Facility was secured by substantially all our assets and the assets of our domestic subsidiaries. On August 13, 2024, the Company entered into the 2.25% Convertible Senior Notes due 2029. The proceeds of the Convertible Senior Notes were used to repay the Credit Facility in its entirety, approximately \$294.0 million, comprised of \$292.5 million of unpaid principal, \$1.2 million in accrued and unpaid interest, and \$0.3 million of legal fees. In connection with the issuance of the Convertible Senior Notes, the Company recorded a loss on debt extinguishment in the consolidated statement of operations for the year ended December 31, 2024, amounting to approximately \$7.5 million, comprised of the write-off unamortized deferred financing fees related to the Credit Facility as of August 13, 2024.

Accrued Licensor Payments

On May 17, 2023, Alimera entered into the Product Rights Agreement with EyePoint which granted Alimera an exclusive and sublicensable right and license under EyePoint’s and its affiliates’ interest in certain of EyePoint’s and its affiliates’ intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa, where the Company already has such rights pursuant to the New Collaboration Agreement, and except for China, Hong Kong, Macau, Taiwan, Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, South Korea, Thailand and Vietnam, where Ocumension holds a license from EyePoint. Pursuant to the agreement, Alimera paid EyePoint an upfront payment of an upfront payment of \$75.0 million and has also made four quarterly guaranteed payments to EyePoint totaling \$7.5 million during the year ended December 31, 2024.

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

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 approximately \$80.6 million, which was used to acquire and 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.

Uses of Cash

Our primary cash requirements are to fund operations of the rare disease portion of our Rare Disease and Brands segment, research and development programs and collaborations, to support general and administrative activities, to purchase equipment and machinery to expand our manufacturing capabilities as our product lines grow, and to expand our business and product pipeline through acquisitions of products and companies. We are continually evaluating potential asset acquisitions and business combinations. Our future capital requirements will depend on many factors, including, but not limited to:

- product mix and pricing for product sales and contract manufacturing;
- pricing and payment terms with customers;
- costs of raw materials and payment terms with suppliers;
- capital expenditures and equipment purchases to support product launches; and
- business and product acquisitions.

Discussion of Cash Flows

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

| (in thousands) | Year Ended December 31, | |
|----------------------|-------------------------|-------------|
| | 2024 | 2023 |
| Operating Activities | \$ 64,017 | \$ 118,959 |
| Investing Activities | \$ (404,719) | \$ (18,511) |
| Financing Activities | \$ 264,945 | \$ 67,439 |

Net Cash Provided by Operations

Net cash provided by operating activities was \$64.0 million for the year ended December 31, 2024, compared to \$119.0 million used in operating activities during the same period in 2023, a decrease of \$54.9 million. The decrease in cash provided by operating activities primarily resulted from our net loss of \$18.5 million adjusted for non-cash items, and an increase in working capital driven by the growth of our business, resulting in incremental accounts receivable and inventory.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2024 was \$404.7 million, principally due to the acquisition of Alimera of approximately \$401.3 million and capital expenditures of approximately \$16.2 million. These cash outflows were offset by proceeds received from the sale of Oakville, Ontario manufacturing site in March 2024 of approximately \$13.5 million. Net cash used in investing activities for the year ended December 31, 2023 was \$18.5 million, principally due to \$8.9 million of capital expenditures and the consideration paid for asset acquisitions of ANDAs and other product rights totaling \$9.6 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was \$264.9 million for the year ended December 31, 2024, principally resulting from proceeds from the New Credit Facility of \$325.0 million, proceeds from the offering of the Convertible Senior Notes of \$316.3 million, tempered by the repayment of the Truist Credit Facility of \$292.5 million, purchase of the capped calls of \$40.6 million, payments of debt issuance costs related to the Convertible Senior Notes and New Credit Facility of \$17.4 million, \$12.5 million paid to the Company Members of Novitium, and \$11.0 million of treasury stock purchase, and other items. Net cash provided by financing activities for the year ended December 31, 2023 was \$67.4 million, principally due to the \$80.6 million in net proceeds from the May 2023 public offering and \$9.0 million from proceeds from stock option exercises and ESPP purchases. This was offset by cash used in financing activities related to \$12.5 million to Company Members of Novitium, \$3.0 million maturity payments on the Term Facility, \$5.0 million of treasury stock purchased in relation to restricted stock vests, and \$1.6 million convertible preferred stock dividends paid.

Contractual Obligations

We believe our available cash and cash equivalents along with our ability to generate operating cash flow and continued access to debt markets are sufficient to fund existing and planned cash requirements. Our contractual obligations and commitments as of December 31, 2024 are comprised of principal payments on debt, interest payments on debt, operating leases, purchase obligations, dividends, and contingent consideration.

New Credit Agreement

Our largest contractual obligation relates to our principal payments on our interest payments on our debt. As of December 31, 2024, the principal amount of our New Credit Agreement was approximately \$323.0 million. At the Company's option, loans under the New Credit Facility accrue interest at a per annum rate equal to (i) the alternate base rate or (ii) the adjusted term SOFR rate for an interest period of one, three or six months, plus a spread depending on the Company's first lien net leverage ratio, between 1.25% and 2.00% in the case of ABR loans and between 2.25% and 3.00% in the case of adjusted term SOFR rate loans. A commitment fee accrues on the unutilized commitments under the TLA Revolver and, from and after the date that is two months after the closing date of the New Credit Agreement, the TLA at a per annum rate equal between 0.25% and 0.40% depending on the Company's first lien net leverage ratio. The cash interest rate under the Term Loan A was approximately 6.98% at December 31, 2024. See Note 6 "New Credit Agreement" in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information and timing on our principal payments on debt.

An interest rate swap is used to manage changes in SOFR-based variable interest rates underlying a portion of the borrowing under the New Credit Agreement. Pursuant to the terms of the swap agreement, ANI pays the counterparty an effective fixed rate of 2.313%. As of December 31, 2024, the notional value of the interest rate swap was \$139.4 million. See Note 8 "Derivative Financial Instruments and Hedging Activity" in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information.

2.25% Convertible Senior Notes Due 2029

On August 13, 2024, the Company completed an offering of \$316.25 million aggregate principal amount of Notes. The Notes were issued pursuant to an indenture (the "Indenture") dated as of August 13, 2024 between the Company and U.S. Bank Trust Company, National Association ("Trustee"). The Notes are due September 1, 2029, unless earlier repurchased, redeemed, or converted. The Notes will accrue interest at a rate of 2.25% per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2025. See Note 7 "2.25% Convertible Senior Notes Due 2029" in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information and timing on our principal payments on debt.

Leases

Our operating leases are primarily for warehouse, office space, and office equipment. As leases expire, we do not anticipate difficulty in negotiating renewals or finding other satisfactory space if the premise becomes unavailable. See Note 17 "Commitments and Contingencies" in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional discussion and timing of payments related to these operating lease obligations.

PIPE Shares

Our convertible preferred stock ("PIPE Shares") accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind. Dividends are payable until the preferred stock is converted, either at the option of the PIPE investor, at any time, or the option of ANI, beginning two years after the November 19, 2021 issuance provided ANI's stock price reaches a certain level. See Note 13 "Mezzanine and Stockholders' Equity" in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional discussion of dividends.

Novitium Contingent Consideration

Consideration of the Novitium acquisition included \$46.5 million in contingent future earn-out payments. The contingent consideration is based on the achievement of certain milestones, including milestones on gross profit of Novitium portfolio products over a 24-month period, regulatory filings completed during this 24-month period, and a percentage of net profits on certain products that are launched in the future. Pursuant to the terms of the Novitium 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, of Novitium for the achievement of the "ANDA Filing Earn-Out," as defined in the Agreement. On February 22, 2024, the Company paid \$12.5 million to Novitium related to the achievement of the milestone. See Note 12 "Fair Value" in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on our contingent consideration.

Alimera Contingent Value Rights

In connection with the acquisition of Alimera, purchase consideration included \$8.7 million in contingent value rights which provided for future contingent payments, based on the achievement of Net Revenue milestones in 2026 and 2027. The fair value of the contingent value rights as of December 31, 2024 was approximately \$9.0 million. See Note 3 and Note 12 "Business Combination" and "Fair Value", respectively, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on the contingent consideration.

Accrued Licensor Payments

The Company will also pay royalties to EyePoint from 2025 to 2028 at a percentage of mid-to-low double digits of annual U.S. net sales of certain products (including YUTIQ and ILUVIEN) in excess of certain thresholds, beginning at \$70.0 million in 2025, increasing annually thereafter. Upon making the quarterly payments in the aggregate amount of \$7.5 million in 2024, the licenses and rights granted to the Company will automatically become perpetual and irrevocable. The present value of the remaining payments to EyePoint for years 2025 to 2028 will continue to be revalued at an appropriate discount rate for the Company at each reporting date until they are settled. The fair value of the remaining future payments as of December 31, 2024 was approximately \$21.0 million. See Note 12 "Fair Value" in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional information on the licensor payments.

We expect to continue to incur significant expenditures in support of our commercial launch of Cortrophin, including costs related to service contracts and increased headcount.

Critical Accounting Estimates

The preparation of financial statements and related disclosures in conformity with U.S. generally accepted accounting principles ("GAAP") and the Company's discussion and analysis of its financial condition and operating results require the Company's management to make judgments, assumptions and estimates that affect the amounts reported. Our significant accounting policies are discussed in Note 1, "Description of Business and Summary of Significant Accounting Policies" of the Notes to the consolidated financial statements in Part II, Item 8. of this Form 10-K describes the significant accounting policies and methods used in the preparation of the Company's consolidated financial statements. On an ongoing basis, we evaluate these estimates and assumptions, including those described below. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. These estimates and assumptions form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition, and operating results.

Revenue Recognition

Revenues are primarily derived from sales of generic, rare disease, and brands portfolio of pharmaceutical products, royalties, and other pharmaceutical services. Revenue is recognized when our obligations under the terms of our contracts with customers are satisfied, which generally occurs when control of the products we sell is transferred to the customer.

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.

The Company's gross product revenue is subject to a variety of deductions, which are estimated and recorded in the same period that the revenue is recognized, and primarily represent chargebacks, rebates, prompt payment (cash) discounts, Medicaid and other government pricing programs, price protection and shelf stock adjustments, sales returns, and other potential adjustments. Those deductions represent estimates of rebates and discounts related to gross sales for the reporting period and, as such, knowledge and judgment of market conditions and practice are required when estimating the impact of these revenue deductions on gross sales for a reporting period.

Historically, the Company's changes of estimates reflecting actual results or updated expectations have not been material to our overall business. If any of our ratios, factors, assessments, experiences or judgments are not indicative or accurate predictors of our future experience, our results could be materially affected. The sensitivity of our estimates can vary by program, type of customer and geographic location. However, estimates associated with governmental allowances, Medicaid and other performance-based contract rebates are most at risk for material adjustment because of the extensive time delay between the recording of the accrual and its ultimate settlement, an interval that can generally range up to one year. Because of this time lag, in any given quarter, our adjustments to actual can incorporate revisions of several prior quarters.

Chargebacks

If actual results were not consistent with our estimates, the Company could be exposed to losses or gains that could be material, as changes to chargeback estimates could cause an increase or decrease in revenue recognized during the year and increase or decrease accounts receivable. If there were a 1% change in the chargeback estimates throughout the year, our net revenues would be affected by \$5.8 million for the year ended December 31, 2024.

Government Rebates

If actual results were not consistent with our estimates as related to government rebates, the Company could be exposed to losses or gains that could be material, as changes to government rebate estimates could cause an increase or decrease in revenue recognized during the year and decrease or increase the government rebate reserve. If there were a 10% change in the government rebate estimates throughout the year, our net revenues would be affected by \$3.2 million for the year ended December 31, 2024.

Returns

If actual results were not consistent with our estimates, the Company could be exposed to losses or gains that could be material, as changes to returns estimates could cause an increase or decrease in revenue recognized during the year and decrease or increase the returned goods reserve. If there were a 10% change in the returns estimates throughout the year, our net revenues would be affected by \$3.9 million for the year ended December 31, 2024.

Administrative Fees and Other Rebates

If actual results were not consistent with our estimates, the Company could be exposed to losses or gains that could be material, as changes to these estimates could cause an increase or decrease in revenue recognized during the year and increase or decrease accounts receivable. If there were a 10% change in the administrative fees estimates throughout the year, our net revenues would be affected by \$6.6 million for the year ended December 31, 2024.

Prompt Payment Discounts

If customers do not take 100% of available discounts as we estimate, the Company could need to re-adjust our methodology for calculating the prompt payment discount reserve. If there were a 10% decrease in the prompt payment discounts estimates throughout the year, our net revenues would increase by \$2.6 million for the year ended December 31, 2024.

Impairment of Goodwill and Intangible Assets

Goodwill

The Company allocates goodwill to reporting units based on the reporting unit expected to benefit from the business combination. The Company evaluates its reporting units on an annual basis and, if necessary, reassign goodwill using a relative fair value allocation approach. Goodwill is tested for impairment at the reporting unit level (operating segment or one level below an operating segment) on an annual basis (October 31) and between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of a reporting unit below its carrying value. These events or circumstances could include a significant change in the business climate, legal factors, operating performance indicators, competition, or sale or disposition of a significant portion of a reporting unit.

Application of the goodwill impairment test requires judgment, including the identification of reporting units, assignment of assets and liabilities to reporting units, assignment of goodwill to reporting units, and determination of the fair value of each reporting unit. The estimates used to calculate the fair value of a reporting unit change from year to year based on operating results, market conditions, and other factors. Changes in these estimates and assumptions could materially affect the determination of fair value and goodwill impairment for each reporting unit.

The carrying value of goodwill at December 31, 2024 was approximately \$60.0 million. As part of the Novitium acquisition on November 19, 2021, we acquired goodwill of \$24.6 million in the Generics and Other reporting unit. As a result of the acquisition of Alimera, on September 16, 2024, the Company recorded goodwill of \$31.8 million in the Rare Disease reporting unit. The Company believes it is unlikely that there will be a material change in the future estimates or assumptions used to test for impairment losses on goodwill. However, if actual results are not consistent with our estimates or assumptions, we could be exposed to an impairment charge that could be material.

Impairments of Long-Lived Assets

The Company reviews its long-lived assets, including intangible assets with finite lives, for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. The Company evaluates assets for potential impairment by comparing estimated future undiscounted net cash flows to the carrying amount of the asset. If the carrying amount of the assets exceeds the estimated future undiscounted cash flows, impairment is measured based on the difference between the carrying amount of the assets and fair value which is generally an expected present value cash flow technique. The Company's policy in determining whether an impairment indicator exists comprises measurable operating performance criteria as well as other qualitative measures. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Factors that we consider in deciding when to perform an impairment review include significant under-performance of a product in relation to expectations, significant negative industry or economic trends, and significant changes or planned changes in our use of the assets. If the Company's assumptions are not correct, there could be an impairment loss in subsequent periods or, in the case of a change in the estimated useful life of the asset, a change in amortization expense.

Intangible assets with indefinite lives, including IPR&D, are tested for impairment if impairment indicators arise and, at a minimum, annually. However, an entity is permitted to first assess qualitative factors to determine if a quantitative impairment test is necessary. Further testing is only required if the entity determines, based on the qualitative assessment, that it is more likely than not that an indefinite-lived intangible asset's fair value is less than its carrying amount. Otherwise, no further impairment testing is required. The indefinite-lived intangible asset impairment test consists of a one-step analysis that compares the fair value of the intangible asset with its carrying amount. If the carrying amount of an intangible asset exceeds its fair value, an impairment loss is recognized in an amount equal to that excess. We consider many factors in evaluating whether the value of its intangible assets with indefinite lives may not be recoverable, including, but not limited to the discount rate, terminal growth rates, general economic conditions, our outlook and market performance of our industry and recent and forecasted financial performance. We recognized an impairment loss of \$4.0 million during the three months ended December 31, 2024 related to IPR&D which was acquired as part of the Novitium acquisition during 2021, and also recorded an impairment loss of \$3.6 million on a basket of definite-lived intangible assets.

Contingent Consideration

Accrued Licensor Payments

The terms of the Product Rights Agreement between the Company and EyePoint include the potential payment of future consideration that is contingent upon the achievement of annual U.S. net sales of certain products (including YUTIQ and ILUVIEN) in excess of certain thresholds, beginning at \$70.0 million in 2025, increasing annually thereafter. The fair value of the Accrued Licensor Payments was approximately \$21.0 million at December 31, 2024. Significant inputs used in the measurement of the fair value include discount rates and probabilities of achievement of net revenue. Changes in fair value, which incorporate changes in assumptions and the passage of time, are recognized as an operating expense in the consolidated statements of operations.

Novitium Contingent Consideration

The fair value of the Novitium contingent consideration was \$10.9 million and \$24.0 million at December 31, 2024 and 2023, respectively. The fair value of contingent consideration is remeasured to the estimated fair value each reporting period with the change recognized as an operating expense in our consolidated statements of operations. Changes in fair value can result from changes in assumptions such as discount rates, probabilities or estimates of revenue and profits, and probability of achieving regulatory milestones, as well as the passage of time. These changes resulted in a decrease of the fair value of the liability of approximately \$0.6 million and an increase of the fair value of the liability of \$1.4 million during the years ended December 31, 2024 and 2023, respectively.

Alimera Contingent Value Rights

The fair value of the Alimera Contingent Value Rights consideration was \$9.0 million at December 31, 2024. The fair value of Alimera Contingent Value Rights is remeasured to the estimated fair value each reporting period with the change recognized as an operating expense in our consolidated statements of operations. Changes in fair value can result from changes in assumptions such as discount rates, probabilities or estimates of future revenue and profits, as well as the passage of time. These changes resulted in charges of \$0.3 million during the year ended December 31, 2024.

Stock-Based Compensation

Stock-based compensation cost for stock options is determined at the grant date using an option pricing model and stock-based compensation cost for restricted stock is based on the closing market price of the stock at the grant date. The value of the award is recognized as expense on a straight-line basis over the employee's requisite service period. Awards may also be issued in the form of Performance Stock Units ("PSUs") to certain employees of the Company. 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 and market objectives during a specified performance period. 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.

Valuation of stock awards requires us to make assumptions and to apply judgment to determine the fair value of the awards. These assumptions and judgments include estimating the future volatility of our stock price and dividend yields. Changes in these assumptions can affect the fair value estimate.

The following table summarizes stock-based compensation and ESPP expense included in our consolidated statements of operations:

| (in thousands) | Years Ended December 31, | | |
|--------------------------------------|---------------------------------|------------------|------------------|
| | 2024 | 2023 | 2022 |
| Selling, general, and administrative | \$ 26,534 | \$ 19,036 | \$ 13,316 |
| Research and development | 1,533 | 910 | 751 |
| Cost of sales | 1,277 | 706 | 532 |
| | <u>\$ 29,344</u> | <u>\$ 20,652</u> | <u>\$ 14,599</u> |

Stock-based compensation cost for stock options is determined at the grant date using an option pricing model and stock-based compensation cost for restricted stock is based on the closing market price of the stock at the grant date. The value of the award is recognized as expense on a straight-line basis over the employee's requisite service period.

Valuation of stock awards requires us to make assumptions and to apply judgment to determine the fair value of the awards. These assumptions and judgments include estimating the future volatility of our stock price and dividend yields. Changes in these assumptions can affect the fair value estimate.

Changes in estimates could affect compensation expense within individual periods. If there were to be a 10% change in our stock-based compensation expense for the year, our (Loss) Income Before (Benefit) Expense for Income Taxes would be affected by \$2.9 million for the year ended December 31, 2024.

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 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 is subject to taxation in various U.S. jurisdictions, Canada, India, the United Kingdom, Ireland, Portugal, and Germany and all of its income tax returns remain subject to examination by tax authorities due to the availability of net operating loss carryforwards. To the extent the Company is required to pay amounts in excess of our established liability, our effective income tax rate in a given financial statement period could be materially affected. An unfavorable tax settlement generally would require use of our cash and may result in an increase in our effective income tax rate in the period of resolution.

The Company considers potential tax effects resulting from discontinued operations and gains and losses included in other comprehensive (loss) income and record intra-period tax allocations, when those effects are deemed material. Our effective income tax rate is also affected by changes in tax law, our level of earnings, and the results of tax audits.

Although the Company believes that the judgments and estimates discussed herein are reasonable, actual results could differ, and we may be exposed to losses or gains that could be material.

Legal and Other Contingencies

The outcomes of legal proceedings and claims brought against us are subject to significant uncertainty. An estimated loss from a loss contingency such as a legal proceeding or claim is accrued by a charge to income if it is probable that an asset has been impaired or a liability has been incurred and the amount of the loss can be reasonably estimated. In determining whether a loss should be accrued we evaluate, among other factors, the degree of probability of an unfavorable outcome and the ability to make a reasonable estimate of the amount of loss. Changes in these factors could materially impact our consolidated financial statements.

Recent Accounting Standards

For information on recent accounting standards, see Note 1 "Description of Business and Summary of Significant Accounting Policies" of the Notes to the consolidated financial statements in Part II, Item 8. of this Form 10-K.

Item 7A. 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.

Interest Rate Risk

On August 13, 2024, the Company entered into a New Credit Agreement, which is secured by substantially all of the personal property and certain material real property owned by ANI and our wholly-owned domestic subsidiaries, and obligations under the New Credit Agreement are guaranteed by certain of our wholly-owned domestic subsidiaries. The Term Loan A proceeds were used to finance the acquisition of Alimera, including fees, costs, and expenses incurred in connection with the acquisition. Proceeds from the TLA Revolver are expected to be used, subject to certain limitations, for working capital and other general corporate purposes.

As of December 31, 2024, the Company had approximately \$323.0 million of debt outstanding under our New Credit Agreement, bearing interest at variable rates, tied to the Secured Overnight Financing Rate. Accordingly, our earnings and cash flows will be affected by changes in interest rates to the extent the principal balance is unhedged. Assuming no change in the amount of debt outstanding, a 100 basis point increase in the average interest rate under these borrowings would have increased the interest expense related to our variable rate debt by approximately \$1.8 million based upon our unhedged portion of principal debt outstanding as of December 31, 2024. Actual results may vary due to changes in the amount of variable rate debt outstanding.

A commitment fee accrues on the unutilized commitments under the TLA Revolver and, from and after the date that is two months after the closing date of the New Credit Agreement, the TLA at a per annum rate equal between 0.25% and 0.40% depending on the Company's first lien net leverage ratio.

The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the year ended December 31, 2024 by approximately \$1.4 million.

Foreign Currency Risk

In connection with our recent acquisition of Alimera, we have increased our international operations, exposing us to increased risk of foreign currency exchange fluctuations as compared to prior periods. In particular, we are now exposed to foreign currency fluctuations in British Pounds and Euros in addition to the Indian rupee. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. We do not use foreign exchange contracts for speculative trading purposes, nor do we hedge our foreign currency exposure in a manner that entirely offsets the effects of changes in foreign exchange rates. We regularly review our hedging program and assess the need to utilize financial instruments to hedge currency exposures on an ongoing basis. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the year ended December 31, 2024.

Equity Investment Risk

Our equity investment is held in the marketable equity security of one publicly traded company (CG Oncology, Inc.). As of December 31, 2024, the carrying value of our marketable equity security was approximately \$6.3 million. This security is subject to a wide variety of market-related risks that could substantially reduce or increase the fair value of our holding. A decline in financial condition or operating results of this investment could result in a loss of all or a substantial part of our carrying value in this company.

Item 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
ANI Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of ANI Pharmaceuticals, Inc. and Subsidiaries (the “Company”) as of December 31, 2024 and 2023, and the related consolidated statements of operations, comprehensive income (loss), mezzanine equity and stockholders’ equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2024 and 2023, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the Company’s internal control over financial reporting as of December 31, 2024, based on criteria established in Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”), and our report dated February 28, 2025 expressed an unqualified opinion.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Evaluation of the Chargeback Accrual

As described in Note 2 to the consolidated financial statements, the Company records variable consideration estimated at the time of sale, for chargebacks. The amount accrued for chargebacks as of December 31, 2024, is approximately \$105.6 million. Management’s estimate of the chargeback accrual is based on inventory levels in the distribution channel of wholesalers, impacted by the actual average selling price for each product and the wholesaler acquisition cost, utilized to estimate the expected chargeback provision and accrual.

We identified the chargeback accrual as a critical audit matter as there is especially challenging auditor judgment required with respect to the calculation of the chargeback accrual given certain assumptions used including purchasing trends of distributors and historical product sales used to predict future sales.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included assessing the design and testing the effectiveness of controls relating to the chargeback accrual, including management's control over the assumptions used to estimate the accrual. We evaluated the inventory levels in the distribution channel of wholesalers and considered the underlying contracts for the actual average selling price. We also validated the wholesaler acquisition costs for a selection of products. We evaluated the accrual for chargebacks by comparing historically recorded accruals to the actual amount that was ultimately claimed by the wholesalers. We analyzed year over year trends in the accrual in comparison with revenue trends to further evaluate reasonableness of the estimate and consistency with expectations.

Acquisition of Alimera – Valuation of Intangible Assets

As described in Note 3 to the consolidated financial statements, the Company acquired Alimera Sciences, Inc. ("Alimera") on September 16, 2024 and the transaction was accounted for using the acquisition method of accounting for business combinations. The acquisition of Alimera was complex due to the significant estimates required by management to determine the fair value of identified intangible assets of \$400.0 million. The determination of the fair value of the intangible assets acquired required management, to utilize the assistance of a third-party valuation specialist and to make significant estimates and assumptions including the estimated net revenue growth rate, gross profit margin, economic life and discount rate.

We identified the valuation of intangible assets resulting from the Alimera acquisition as a critical audit matter given the especially challenging auditor judgment required in evaluating the inputs and assumptions used in determining fair value of the intangible assets. The key assumptions include discount rates, projected revenues and gross profit margins. Changes in these significant assumptions could have a significant impact on the fair value of the intangible assets.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included assessing the design and testing the effectiveness of controls relating to the third-party valuation report which included management's review of the third-party valuation report for the completeness and mathematical accuracy of the data, and evaluating the reasonableness of assumptions used in the calculation such as economic life and discount rate. We utilized a valuation specialist to assist in evaluating the appropriateness of the Company's valuation models developed for acquired intangible assets and evaluating the reasonableness of the significant assumptions used including the estimated net revenue growth rate, gross margin percentages, economic life and discount rate as compared to industry and market data. We also examined the completeness and accuracy of the underlying data supporting the significant assumptions and estimates used in the third-party valuation report, including historical and projected financial information.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2013.

EISNERAMPER LLP
West Palm Beach, Florida
February 28, 2025

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
ANI Pharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting

We have audited ANI Pharmaceuticals, Inc. and Subsidiaries (the “Company”) internal control over financial reporting as of December 31, 2024, based on criteria established in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024, based on criteria established in the Internal Control - Integrated Framework (2013) issued by COSO.

As described in Management’s Annual Report on Internal Control over Financial Reporting, management’s assessment of the effectiveness of internal control over financial reporting did not include the internal controls of Alimera Sciences, Inc. (“Alimera”), which was acquired on September 16, 2024, and whose financial statements represent approximately 5% of the Company’s consolidated revenues for the year ended December 31, 2024 and assets associated with Alimera’s operations represent approximately 1% of the Company’s consolidated assets as of December 31, 2024. Accordingly, our audit of internal control over financial reporting of the Company also excluded an evaluation of the internal control over financial reporting of Alimera.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (“PCAOB”), the consolidated balance sheets of ANI Pharmaceuticals, Inc. and Subsidiaries as of December 31, 2024 and 2023, and the related consolidated statements of operations, comprehensive income (loss), mezzanine equity and stockholders’ equity, and cash flows for each of the years in the three-year period ended December 31, 2024 and the related notes and our report dated February 28, 2025 expressed an unqualified opinion.

Basis for Opinion

The Company’s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management’s Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

An entity’s internal control over financial reporting is a process designed 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. An entity’s internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the entity; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and directors of the entity; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity’s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ EisnerAmper LLP

EISNERAMPER LLP
West Palm Beach, Florida
February 28, 2025

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

| | December 31, 2024 | December 31, 2023 |
|---|----------------------|----------------------|
| Assets | | |
| Current Assets | | |
| Cash and cash equivalents | \$ 144,861 | \$ 221,121 |
| Restricted cash | 33 | — |
| Accounts receivable, net of \$127,824 and \$97,262 of adjustments for chargebacks and other allowances at December 31, 2024 and 2023, respectively | 221,726 | 162,079 |
| Inventories | 136,782 | 111,196 |
| Assets held for sale | — | 8,020 |
| Prepaid expenses and other current assets | 17,975 | 17,400 |
| Investment in equity securities | 6,307 | — |
| Total Current Assets | 527,684 | 519,816 |
| Non-current Assets | | |
| Property and equipment, net | 56,863 | 44,593 |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | 85,106 | 90,711 |
| Intangible assets, net | 541,834 | 209,009 |
| Goodwill | 59,990 | 28,221 |
| Derivatives and other non-current assets | 12,220 | 12,072 |
| Total Assets | \$ 1,283,697 | \$ 904,422 |
| Liabilities, Mezzanine Equity, and Stockholders' Equity | | |
| Current Liabilities | | |
| Current debt, net of deferred financing costs | \$ 9,172 | \$ 850 |
| Accounts payable | 45,656 | 36,683 |
| Accrued royalties | 22,626 | 16,276 |
| Accrued compensation and related expenses | 37,725 | 23,786 |
| Accrued government rebates | 18,714 | 12,168 |
| Income taxes payable | 6,749 | 8,164 |
| Returned goods reserve | 39,274 | 29,678 |
| Current contingent consideration | 29 | 12,266 |
| Accrued expenses and other | 13,735 | 5,606 |
| Total Current Liabilities | 193,680 | 145,477 |
| Non-current Liabilities | | |
| Non-current debt, net of deferred financing costs and current component | 309,108 | 284,819 |
| Non-current convertible notes, net of deferred financing costs | 305,812 | — |
| Accrued licensor payments due | 20,961 | — |
| Non-current contingent consideration, net of current | 19,825 | 11,718 |
| Other non-current liabilities | 5,781 | 4,809 |
| Total Liabilities | \$ 855,167 | \$ 446,823 |
| Commitments and Contingencies (Note 17) | | |
| Mezzanine Equity | | |
| Convertible Preferred Stock, Series A, \$0.0001 par value, 1,666,667 shares authorized; 25,000 shares issued and outstanding at December 31, 2024 and 2023 | 24,850 | 24,850 |
| Stockholders' Equity | | |
| Common Stock, \$0.0001 par value, 33,333,334 shares authorized; 21,537,707 shares issued and 21,108,152 outstanding at December 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 December 31, 2024 and 2023 respectively | — | — |
| Preferred Stock, \$0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2024 and 2023, respectively | — | — |
| Treasury stock, 429,555 shares of common stock, at cost, at December 31, 2024 and 263,943 shares of common stock, at cost, at December 31, 2023 | (21,040) | (10,081) |
| Additional paid-in capital | 519,653 | 514,103 |
| Accumulated deficit | (100,279) | (80,132) |
| Accumulated other comprehensive income, net of tax | 5,344 | 8,857 |
| Total Stockholders' Equity | 403,680 | 432,749 |
| Total Liabilities, Mezzanine Equity, and Stockholders' Equity | \$ 1,283,697 | \$ 904,422 |

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES

Consolidated Statements of Operations

(in thousands, except per share amounts)

| | Years Ended December 31, | | |
|---|---------------------------------|-------------|-------------|
| | 2024 | 2023 | 2022 |
| Net Revenues | \$ 614,376 | \$ 486,816 | \$ 316,385 |
| Operating Expenses | | | |
| Cost of sales (excluding depreciation and amortization) | 250,210 | 181,513 | 138,785 |
| Research and development | 44,581 | 34,286 | 22,318 |
| Selling, general, and administrative | 249,636 | 161,697 | 124,044 |
| Depreciation and amortization | 67,731 | 59,791 | 56,972 |
| Contingent consideration fair value adjustment | (619) | 1,426 | 3,758 |
| Gain on sale of building | (5,347) | — | — |
| Restructuring activities | — | 1,132 | 5,679 |
| Intangible asset impairment charge | 7,600 | — | 112 |
| Total Operating Expenses, net | 613,792 | 439,845 | 351,668 |
| Operating Income (Loss) | 584 | 46,971 | (35,283) |
| Other Expense, net | | | |
| Unrealized gain on investment in equity securities | 6,307 | — | — |
| Interest expense, net | (17,602) | (26,940) | (28,052) |
| Other (expense) income, net | (4,033) | (159) | 670 |
| Loss on extinguishment of debt | (7,468) | — | — |
| (Loss) Income Before (Benefit) Expense for Income Taxes | (22,212) | 19,872 | (62,665) |
| Income tax (benefit) expense | (3,690) | 1,093 | (14,769) |
| Net (Loss) Income | \$ (18,522) | \$ 18,779 | \$ (47,896) |
| Dividends on Series A Convertible Preferred Stock | \$ (1,625) | \$ (1,625) | \$ (1,625) |
| Net (Loss) Income Available to Common Shareholders | \$ (20,147) | \$ 17,154 | \$ (49,521) |
| Basic and Diluted (Loss) Income Per Share: | | | |
| Basic (Loss) Income Per Share | \$ (1.04) | \$ 0.86 | \$ (3.05) |
| Diluted (Loss) Income Per Share | \$ (1.04) | \$ 0.85 | \$ (3.05) |
| Basic Weighted-Average Shares Outstanding | 19,318 | 18,001 | 16,260 |
| Diluted Weighted-Average Shares Outstanding | 19,318 | 18,194 | 16,260 |

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

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

| | Years Ended December 31, | | |
|---|---------------------------------|------------------|--------------------|
| | 2024 | 2023 | 2022 |
| Net (loss) income | \$ (18,522) | \$ 18,779 | \$ (47,896) |
| Other comprehensive (loss) income, net of tax: | | | |
| Foreign currency translation adjustment | (644) | 44 | (112) |
| (Loss) gain on interest rate swap | (2,869) | (3,355) | 15,335 |
| Total other comprehensive (loss) income, net of tax | (3,513) | (3,311) | 15,223 |
| Total comprehensive (loss) income, net of tax | <u>\$ (22,035)</u> | <u>\$ 15,468</u> | <u>\$ (32,673)</u> |

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

ANI PHARMACEUTICALS, INC. AND SUBSIDIARIES
Consolidated Statements of Changes in Mezzanine Equity and Stockholders' Equity
For the Years Ended December 31, 2024, 2023, and 2022
(in thousands)

| | Mezzanine Equity Series A Convertible Preferred Stock | Mezzanine Equity Series A Convertible Preferred Stock Shares | Common Stock Par Value | Common Stock Shares | Class C Special Stock | Additional Paid-in Capital | Treasury Stock Shares | Treasury Stock | Accumulated Other Comprehensive (Loss) Gain Net of Tax | Accumulated Deficit | Total Mezzanine Equity and Stockholders' Equity |
|--|--|--|------------------------------|---------------------------|-----------------------------|----------------------------------|-----------------------------|-------------------|--|------------------------|--|
| Balance, December 31, 2021 | \$ 24,850 | 25 | \$ 1 | 16,913 | \$ — | \$ 387,844 | 83 | \$ (3,135) | \$ (3,055) | \$ (47,765) | \$ 358,740 |
| Stock-based Compensation Expense | — | — | — | — | — | 14,599 | — | — | — | — | 14,599 |
| Treasury Stock Purchases for Restricted Stock Vests | — | — | — | — | — | — | 66 | (1,959) | — | — | (1,959) |
| Issuance of Common Shares upon Stock Option and ESPP Exercise | — | — | — | 52 | — | 1,458 | — | — | — | — | 1,458 |
| Issuance of Restricted Stock Awards | — | — | — | 748 | — | — | — | — | — | — | — |
| Restricted Stock Awards Forfeitures | — | — | — | (69) | — | — | — | — | — | — | — |
| Dividends on Convertible Preferred Stock | — | — | — | — | — | — | — | — | — | (1,625) | (1,625) |
| Other comprehensive income | — | — | — | — | — | — | — | — | 15,223 | — | 15,223 |
| Net Loss | — | — | — | — | — | — | — | — | — | (47,896) | (47,896) |
| Balance, December 31, 2022 | \$ 24,850 | 25 | \$ 1 | 17,644 | \$ — | \$ 403,901 | 149 | \$ (5,094) | \$ 12,168 | \$ (97,286) | \$ 338,540 |
| Stock-based Compensation Expense | — | — | — | — | — | 20,652 | — | — | — | — | 20,652 |
| Treasury Stock Purchases for Restricted Stock Vests | — | — | — | — | — | — | 115 | (4,987) | — | — | (4,987) |
| Issuance of Common Shares upon Stock Option and ESPP Exercise | — | — | — | 227 | — | 8,996 | — | — | — | — | 8,996 |
| Issuance of Restricted Stock Awards | — | — | — | 674 | — | — | — | — | — | — | — |
| Issuance of Performance Stock Units | — | — | — | 85 | — | — | — | — | — | — | — |
| Restricted Stock Awards and Performance Stock Unit Forfeitures | — | — | — | (83) | — | (1) | — | — | — | — | (1) |
| Issuance of Common Stock in Public Offering, net of offering costs | — | — | 1 | 2,184 | — | 80,555 | — | — | — | — | 80,556 |
| Dividends on Convertible Preferred Stock | — | — | — | — | — | — | — | — | — | (1,625) | (1,625) |
| Other comprehensive loss | — | — | — | — | — | — | — | — | (3,311) | — | (3,311) |
| Net Income | — | — | — | — | — | — | — | — | — | 18,779 | 18,779 |
| 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 | — | — | — | — | — | 29,344 | — | — | — | — | 29,344 |
| Capped Call Transaction, net of tax | — | — | — | — | — | (30,281) | — | — | — | — | (30,281) |
| Treasury Stock Purchases for Restricted Stock Vests | — | — | — | — | — | — | 166 | (10,959) | — | — | (10,959) |
| Issuance of Common Shares upon Stock Option and ESPP Exercise | — | — | — | 152 | — | 6,488 | — | — | — | — | 6,488 |
| Issuance of Restricted Stock Awards | — | — | — | 708 | — | — | — | — | — | — | — |
| Issuance of Performance Stock Units | — | — | — | 74 | — | — | — | — | — | — | — |

| | Mezzanine Equity Series A Convertible Preferred Stock | Mezzanine Equity Series A Convertible Preferred Shares | Common Stock Par Value | Common Stock Shares | Class C Special Stock | Additional Paid-in Capital | Treasury Stock Shares | Treasury Stock | Accumulated Other Comprehensive (Loss) Gain Net of Tax | Accumulated Deficit | Total Mezzanine Equity and Stockholders' Equity |
|--|--|---|------------------------------|---------------------------|-----------------------------|----------------------------------|-----------------------------|-------------------|--|------------------------|--|
| Restricted Stock Awards and Performance Stock Units Forfeitures | — | — | — | (127) | — | (1) | — | — | — | — | (1) |
| Dividends on Series A Convertible Preferred Stock | — | — | — | — | — | — | — | — | — | (1,625) | (1,625) |
| Other comprehensive loss | — | — | — | — | — | — | — | — | (3,513) | — | (3,513) |
| Net Loss | — | — | — | — | — | — | — | — | — | (18,522) | (18,522) |
| Balance, December 31, 2024 | \$ 24,850 | 2.5 | 2 | 21,538 | \$ — | \$ 519,653 | 430 | \$ (21,040) | \$ 5,344 | \$ (100,279) | \$ 428,530 |

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

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

| | Year Ended December 31, | | |
|---|-------------------------|-------------------|------------------|
| | 2024 | 2023 | 2022 |
| Cash Flows From Operating Activities | | | |
| Net (loss) income | \$ (18,522) | \$ 18,779 | \$ (47,896) |
| Adjustments to reconcile net (loss) income to net cash and cash equivalents provided by (used in) operating activities: | | | |
| Stock-based compensation | 29,344 | 20,652 | 14,599 |
| Deferred taxes | (21,913) | (11,740) | (15,253) |
| Depreciation and amortization | 67,731 | 59,791 | 59,653 |
| Unrealized gain on investment in equity securities | (6,307) | — | — |
| Acquired in-process research and development ("IPR&D") | — | — | 1,151 |
| Non-cash operating lease expense | 1,526 | 1,269 | — |
| Non-cash interest | 642 | 3,922 | 3,961 |
| Contingent consideration fair value adjustment | (619) | 1,426 | 4,058 |
| Gain on sale of building | (5,347) | — | — |
| Loss on extinguishment of debt | 7,468 | — | — |
| Amortization of inventory step up | 13,599 | — | — |
| Asset impairment charges | 7,600 | — | 574 |
| Gain on sale of ANDAs | — | — | (750) |
| Changes in operating assets and liabilities, net of acquisitions: | | | |
| Accounts receivable, net | (21,087) | 3,359 | (36,912) |
| Inventories | (21,287) | (5,841) | (23,626) |
| Prepaid expenses and other assets | 2,129 | (9,015) | (798) |
| Accounts payable | 479 | 7,552 | 5,038 |
| Accrued royalties | 6,350 | 6,969 | 3,082 |
| Income taxes | (1,415) | 11,991 | (160) |
| Accrued government rebates | 6,160 | 1,296 | 5,380 |
| Returned goods reserve | 9,102 | (3,722) | (2,399) |
| Accrued expenses, accrued compensation, and other | 8,384 | 12,271 | (905) |
| Net Cash and Cash Equivalents Provided by (Used in) Operating Activities | 64,017 | 118,959 | (31,203) |
| Cash Flows From Investing Activities | | | |
| Acquisition of Alimera, net of cash acquired | (401,280) | — | — |
| Acquisition of Novitium Pharma LLC, net of cash acquired | — | — | (33) |
| Acquisition of product rights, intangible assets, and other related assets | (717) | (9,643) | (7,579) |
| Acquisition of property and equipment, net | (16,236) | (8,868) | (8,876) |
| Proceeds from the sale of long-lived assets | — | — | 750 |
| Proceeds from the sale of building | 13,514 | — | — |
| Net Cash and Cash Equivalents Used in Investing Activities | (404,719) | (18,511) | (15,738) |
| Cash Flows From Financing Activities | | | |
| Proceeds from convertible notes | 316,250 | — | — |
| Proceeds from term loan | 325,000 | — | — |
| Purchase of capped call transaction | (40,575) | — | — |
| Proceeds from public offering | — | 80,555 | — |
| Payments on contingent consideration | (12,500) | (12,500) | — |
| Principal payments on borrowings under credit agreements | (3,531) | (3,000) | (3,000) |
| Debt issuance costs | (17,353) | — | — |
| Repayment on borrowings under credit agreement | (292,500) | — | — |
| Payment of accrued licensor payment | (3,750) | — | — |
| Series A convertible preferred stock dividends paid | (1,625) | (1,625) | (1,625) |
| Proceeds from stock option exercises and ESPP purchases | 6,488 | 8,996 | 1,458 |
| Treasury stock purchases for restricted stock vests | (10,959) | (4,987) | (1,959) |
| Net Cash and Cash Equivalents Provided by (Used in) Financing Activities | 264,945 | 67,439 | (5,126) |
| Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash | (470) | — | — |
| Net Change in Cash, Cash Equivalents, and Restricted Cash | (76,227) | 167,887 | (52,067) |
| Cash and cash equivalents, beginning of year | 221,121 | 53,234 | 105,301 |
| Cash, cash equivalents and restricted cash, end of year | \$ 144,894 | \$ 221,121 | \$ 53,234 |

| | Year Ended December 31, | | |
|--|-------------------------|------------|------------|
| | 2024 | 2023 | 2022 |
| Reconciliation of cash, cash equivalents, and restricted cash, beginning of year | | | |
| Cash and cash equivalents | \$ 221,121 | \$ 48,228 | \$ 100,300 |
| Restricted cash | — | 5,006 | 5,001 |
| Cash, cash equivalents, and restricted cash, beginning of year | \$ 221,121 | \$ 53,234 | \$ 105,301 |
| Reconciliation of cash, cash equivalents, and restricted cash, end of year | | | |
| Cash and cash equivalents | \$ 144,861 | \$ 221,121 | \$ 48,228 |
| Restricted cash | 33 | — | 5,006 |
| Cash, cash equivalents, and restricted cash, end of year | \$ 144,894 | \$ 221,121 | \$ 53,234 |
| Supplemental disclosure for cash flow information: | | | |
| Cash paid for interest, net of amounts capitalized | \$ 24,379 | \$ 31,431 | \$ 21,477 |
| Cash paid for income taxes | \$ 19,061 | \$ 1,228 | \$ 288 |
| Right-of-use assets obtained in exchange for lease obligations | \$ — | \$ 4,715 | \$ — |
| Supplemental non-cash investing and financing activities: | | | |
| Purchase consideration for Alimera Acquisition | \$ (8,322) | \$ — | \$ — |
| Acquisition of product rights included in accounts payable | \$ — | \$ — | \$ 1,000 |
| Property and equipment purchased and included in accounts payable | \$ 529 | \$ 328 | \$ 452 |

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

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1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Organization and Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, “ANI,” the “Company,” “we,” “us,” or “our”) is a diversified bio-pharmaceutical company. The Company's mission is “Serving Patients, Improving Lives” by developing, manufacturing, and commercializing high-quality therapeutics.

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

The Company owns and operates 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 the Oakville, Ontario, manufacturing facility as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following the acquisition of Novitium Pharma LLC (“Novitium”) in November 2021. The Company has fully completed the transition of the products manufactured or packaged at Oakville to one of the three U.S.-based manufacturing sites. In February 2024, the Company entered into an agreement for the sale of the Oakville site, for a price of \$19.2 million Canadian Dollars, or approximately \$14.2 million, based on the exchange rate at closing of such transaction. The sale closed on March 28, 2024 (Note 4).

Basis of Presentation

The consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification (“ASC”) and Accounting Standards Updates (“ASU”) of the Financial Accounting Standards Board (“FASB”).

Principles of Consolidation

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

Foreign Currency

The Company currently has subsidiaries located in India, Ireland, Germany, and the United Kingdom. The India-based subsidiary generally conducts its transactions in Indian Rupees, which is also its functional currency. The Ireland and Germany locations generally conduct their transactions in Euros, which is also their functional currency. The United Kingdom subsidiary conducts its transactions in Euros and British Pounds, and their functional currency is Euros. The Company has ceased operations at its subsidiary in Oakville, Ontario, Canada as of March 31, 2023. The Canada-based subsidiary conducted its transactions in U.S. dollars and Canadian dollars, but its functional currency was the U.S. dollar.

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The results of any non-U.S. dollar transactions and balances are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net (loss) income. The gain or loss on transactions denominated in foreign currencies and the translation impact of local currencies to U.S. dollars was immaterial for the years ended December 31, 2024, 2023, and 2022. Unless otherwise noted, all references to “\$” or “dollar” refer to the U.S. dollar. The Company’s asset and liability accounts are translated using the current exchange rate as of the balance sheet date, except for shareholders’ equity accounts, which are translated using historical rates. Net revenues and expense accounts are translated using an average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company’s foreign subsidiaries into U.S. dollars are accumulated as a separate component of shareholders’ equity within accumulated other comprehensive (loss) income, net of tax.

Use of Estimates

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

Business Combination and Goodwill

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

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

Investment in Equity Securities

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

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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 consolidated statements of operations.

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 the Company satisfies a performance obligation.

The Company derives its revenues primarily from sales of generic, rare disease, and brands portfolio 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 is transferred to the customer. Generally, the Company does not incur incremental costs to obtain contracts that would otherwise not have been incurred. The Company has not identified any agreements or arrangement that would qualify as a significant financing component.

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.

Revenue from Distribution Agreements

From time to time, the Company may enter into marketing and distribution agreements with third parties in which products are sold under Abbreviated New Drug Applications (“ANDAs”) or New Drug Applications (“NDAs”) owned or licensed by third parties. These products are sold under the ANI label. The Company controls the products sold under these marketing and distribution agreements and therefore are the principal for sales under each of these marketing and distribution agreements. As a result, revenue is recognized on a gross basis when control has passed to the customer and the performance obligation has been satisfied. Under these agreements, the Company pays third parties a specified percentage of the gross profit earned on sales of the products. These profit-sharing percentages are recognized in cost of sales in the consolidated statements of operations and are accrued in accrued royalties in the consolidated balance sheets until payment has occurred.

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Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consist of agreements in which pharmaceutical products are manufactured by the Company on behalf of a third party. The performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The products are sold at predetermined standalone selling prices and the performance obligation is considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves the shipping dock to be shipped to the customer, as contract manufactured pharmaceutical products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally fewer than two months. Typically, there are no material returns for contract manufactured products.

Royalties from Licensing Agreements

From time to time, the Company enters into licensing agreements, under which the Company licenses to the seller the right to sell the acquired products. Because these royalties are sales-based, the Company recognizes the revenue when the underlying sales occur, based on sales and gross profit information received from the sellers. The Company may enter into agreements which include profit-sharing percentages on gross profits. The profit-sharing percentages are recorded in cost of sales in the consolidated statements of operations when the associated revenue is recognized and are recorded in accrued royalties in the consolidated balance sheets when the associated revenue is recognized and until payment has occurred.

Cash, Cash Equivalents, and Restricted Cash

All highly liquid investments with original maturities of three months or less from the date of purchase are classified as cash equivalents. Cash and cash equivalents consist of cash deposited in checking accounts, time deposits with original maturities of less than three months, and money market accounts with original maturities of three months or less at the date of purchase. Cash and cash equivalents include cash on-hand and money market funds which invest exclusively in high-quality, short-term securities that are issued or guaranteed by the U.S. government. Due to the short-term maturity of the funds invested in the money market accounts, the carrying amounts are a reasonable estimate of fair value. The majority of the Company's cash balances are held in interest bearing and non-interest bearing accounts in U.S.-based financial institutions which are guaranteed by the Federal Deposit Insurance Corporation ("FDIC") up to \$250 thousand. The majority of the Company's cash balances are in excess of FDIC coverage, which the Company considers to be a normal business risk. In addition, the Company has cash and cash equivalents held in international bank accounts that are denominated in various foreign currencies, specifically in the UK, Germany, Ireland, Portugal, and India.

Accounts Receivable

The Company extends credit to customers on an unsecured basis. Expected credit losses are measured at amortized cost, including trade and unbilled receivables, on a collective basis, based on their similar risk characteristics. Expected credit losses are based on historical credit loss experience, review of the current aging or status of accounts receivable and current and forward-looking views from an economic and industry perspective. Receivables are written off when it is determined that amounts are uncollectible. The allowance for credit losses was immaterial as of December 31, 2024 and 2023.

Inventories

Inventories consist of raw materials, packaging materials, work-in-progress, and finished goods. Inventories are stated at the lower of standard cost or net realizable value. The Company periodically reviews and adjusts standard costs, which generally approximate weighted average cost.

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Property and Equipment

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are charged to expense as incurred. Depreciation is recorded on a straight-line basis over estimated useful lives as follows:

| Classification | Years |
|-------------------------------------|---|
| Buildings and improvements | 20 - 40 years |
| Leasehold improvements | Shorter of asset's useful life or remaining life of lease |
| Machinery, furniture, and equipment | 3 - 10 years |

Construction in progress consists of multiple projects, primarily related to new equipment and expansion of laboratory and manufacturing facilities to expand manufacturing capability as product lines grow. Construction in progress includes the cost of construction and other direct costs attributable to the construction, along with capitalized interest. Depreciation is not recorded on construction in progress until such time as the assets are placed in service.

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the estimated fair value of the assets. No impairment loss related to property and equipment was recognized during the years ended December 31, 2024, 2023, and 2022.

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. See Note 4 "Restructuring Canada Operations" in the notes to the consolidated financial statements for additional information.

Leases

Operating lease right-of-use ("ROU") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term. Leases with an initial term of twelve months or less are not recorded on the consolidated balance sheet, and the Company does not separate lease and non-lease components of contracts. There are no material residual guarantees associated with any of the Company's leases, and there are no significant restrictions or covenants included in the Company's lease agreements. Operating lease ROU assets are included in other non-current assets and operating lease liabilities are included in accrued expenses and other and other non-current liabilities in the consolidated balance sheets. As of December 31, 2024, the Company had finance leases that consist of leases for automobiles. Finance leases are included in property and equipment, net, accrued expenses and other current liabilities, and other liabilities on our consolidated balance sheets. Finance lease assets are amortized on a straight-line basis over the shorter of the estimated useful lives of the assets or the lease terms.

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Intangible Assets

Intangible assets with definite lives are amortized based on their pattern of economic benefit over their estimated useful lives, or the straight-line amortization method if not materially different, and reviewed periodically for impairment. The definite-lived ANDAs, NDAs and product rights, marketing and distribution rights, customer relationships, and non-compete agreement are stated at cost, net of amortization, and generally amortized over their remaining estimated useful lives, ranging from seven to twelve years, based on the straight-line amortization method. In the case of certain NDA and product rights, an accelerated amortization method is used to better match the anticipated economic benefits expected to be provided. Management reviews definite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable, in a manner similar to that for property and equipment. During the year ended December 31, 2024, \$3.6 million of impairment charges were recognized on intangible assets. During the year ended December 31, 2023, no impairment charges were recognized on intangible assets. During the year ended December 31, 2022, the Company recognized an impairment charge of \$0.1 million related to a definite-lived ANDA intangible asset.

Indefinite-lived intangible assets other than goodwill include in-process research and development (“IPR&D”) projects. IPR&D intangible assets represent the fair value of technology acquired in a business combination for which the technology projects are incomplete but have substance. When an IPR&D project is completed (generally upon receipt of regulatory approval), the asset is then accounted for as a definite-lived intangible asset. Indefinite-lived intangibles are tested for impairment at least annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying amount of the asset might not be recoverable. Judgment is used in determining when these events and circumstances arise. During the year ended December 31, 2024, \$4.0 million of impairment charges were recognized on indefinite-lived intangible assets, respectively. During the year ended December 31, 2023, no impairment charges were recognized on indefinite-lived intangible assets.

Goodwill

Goodwill, which represents the excess of purchase price over the fair value of net assets acquired, is carried at cost, using the purchase method of accounting, and is related to past business combinations with BioSante Pharmaceuticals, Inc., WellSpring, Novitium, and Alimera. The Company is organized in three reporting units, Generics and Other, Brands, and Rare Disease. Goodwill is not amortized, but is subject to periodic review for impairment. All of the Company's goodwill is recorded in the Generics and Other reporting unit, except for goodwill recorded as a result of the Alimera acquisition, which is recorded in the Rare Disease reporting unit.

The Company reviews goodwill for impairment on a reporting unit basis annually, on October 31, and whenever events or changes in circumstances indicate the carrying value of goodwill might not be recoverable. Under the authoritative guidance issued by the FASB, the Company has the option to first assess the qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform a quantitative goodwill impairment test. If the Company determines that it is more likely than not that the fair value of a reporting unit is less than its carrying amount, then the goodwill impairment test is performed. The goodwill impairment test requires the Company to estimate the fair value of the reporting unit and to compare the fair value of the reporting unit with its carrying amount. If the fair value exceeds the carrying amount, then no impairment is recognized. If the carrying amount recorded exceeds the fair value calculated, then an impairment charge is recognized for the difference. The judgments made in determining the projected cash flows used to estimate the fair value can materially impact the Company's financial condition and results of operations.

The Company assessed the assets qualitatively, and concluded it was more likely than not that the fair value of the reporting units are greater than their carrying value as of October 31, 2024 and 2023, and therefore no quantitative testing for impairment was required. No impairment loss related to goodwill was recognized in the years ended December 31, 2024, 2023, and 2022.

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Collaborative Arrangements

The Company may enter into collaborative arrangements with various commercial partners to further business opportunities. In collaborative arrangements revenues and costs generated by collaborative arrangements may be presented on a gross or net basis depending on the specific facts of the collaborative arrangement.

Research and Development Expenses

Research and development ("R&D") activities are expensed as incurred. R&D expenses primarily consist of direct and allocated expenses incurred with the process of formulation, clinical research, and validation associated with new product development.

Stock-Based Compensation

The Company issues stock options and restricted stock awards, which are awarded in exchange for employee and non-employee director services. From time to time, the Company may grant awards through an inducement grant outside of the incentive plan to induce prospective employees to accept employment with the Company. These grants are made pursuant to inducement grants outside of the shareholder approved equity plan as permitted under the Nasdaq Stock Market listing rules. Stock-based compensation cost for stock options is determined at the grant date using an option pricing model and stock-based compensation cost for restricted stock awards is based on the closing market price of the stock at the grant date. The value of the award is recognized as expense on a straight-line basis over the employee's requisite service period and classified where the underlying salaries are classified. Forfeitures are accounted for as they occur. Excess tax benefits or tax deficiencies are recognized as a component of the current period provision for income taxes.

Awards may also be issued in the form of Performance Stock Units ("PSUs") to certain employees of the Company. PSUs represent the right to receive a number of shares of Company common stock, contingent upon the achievement of specified performance objectives during a specified performance period. PSUs granted vest over a three-year performance period. Currently, the PSU's vesting is contingent upon the Company meeting certain total shareholder return ("TSR") levels as compared to a select peer group over the over three years, and contingent upon the Company meeting certain adjusted non-GAAP year-on-year earnings before interest, income taxes, depreciation, and amortization ("EBITDA") growth rates over the vesting term. 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 also administers an Employee Stock Purchase Plan ("ESPP"). The estimated fair value of stock-based compensation awards are recognized and classified in the expense where the underlying salaries are classified.

Valuation of stock awards requires us to make assumptions and to apply judgment to determine the fair value of the awards. These assumptions and judgments include estimating the future volatility of the Company's stock price and dividend yields. Changes in these assumptions can affect the fair value estimate.

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.

The Company is subject to taxation in various U.S. jurisdictions, Canada, Europe, and India, and all of our income tax returns remain subject to examination by tax authorities due to the availability of net operating loss carryforwards.

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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.

Derivative Instruments and Hedge Accounting

The Company uses interest rate swaps to hedge exposure to interest rate risk, as well as benefit from favorable conditions. The Company recognizes all derivative instruments as either assets or liabilities at fair value. For all of the Company's derivative positions that are designated and qualify as part of a cash flow hedging relationship, the effective portion of the gain or loss on the derivatives is reported as a component of other comprehensive (loss) income and reclassified into earnings in the same period or periods during which the hedged transactions affect earnings. Gains and losses on derivatives representing any ineffective component of the hedge are recognized in current earnings. All of the Company's cash flow hedges have been deemed effective as of December 31, 2024 and 2023 for both accounting and tax purposes. The Company has elected hedge accounting for both U.S. GAAP and tax purposes. The Company maintains formal documentation through a periodic memo and accounting analysis that cover what is being hedged, how it is being hedged, hedge effectiveness, the nature of the risk being hedged, among other required analyses. Company policy further includes a quarterly probability analysis covering hedge effectiveness.

Contingent Consideration

The terms of the acquisition agreement between ANI and Novitium Pharma LLC include the potential payment of future consideration that is contingent upon the achievement of certain regulatory and financial performance milestones. At the acquisition date, contingent consideration is recorded at fair value based on the additional consideration expected to be transferred, which is based on the estimate of probability-weighted future cash flows as discounted to present value. Significant inputs used in the measurement of the fair value include discount rates, probabilities of achievement of regulatory-based milestones and payments, and projected revenues and gross profits. The discount rates are derived using accepted valuation methodologies. The probability of achievement of regulatory milestones is based on historical and projected success rates. The projected revenues and gross profits are based on internal forecasts and long-term plans. The contingent consideration is remeasured each reporting period using Level 3 inputs. Changes in fair value, which incorporate changes in assumptions and the passage of time, are recognized as an operating expense in the consolidated statements of operations. As payments are not expected to be made shortly after the acquisition, any future payment of contingent consideration will be reported as a financing cash flow for amounts paid up to the acquisition-date fair value of the consideration, and as an operating cash outflow for any amounts in excess of the acquisition-date fair value in our consolidated statement of cash flows.

Accrued Licensor Payments

The terms of an agreement between the Company and EyePoint Pharmaceuticals, Inc. ("EyePoint") include the potential payment of future consideration that is contingent upon the achievement of annual U.S. net sales of certain products (including YUTIQ and ILUVIEN) in excess of certain thresholds, beginning at \$70.0 million in 2025, increasing annually thereafter. Significant inputs used in the measurement of the fair value include discount rates and probabilities of achievement of net revenue. The discount rates are derived using accepted valuation methodologies. The projected net sales are based on internal forecasts and long-term plans. The contingent payments are remeasured each reporting period using Level 3 inputs. Changes in fair value, which incorporate changes in assumptions and the passage of time, are recognized as an operating expense in the consolidated statements of operations.

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Contingent Value Rights

In connection with the acquisition of Alimera, the Company issued Contingent Value Rights ("CVRs"), which provided for the holders to receive future contingent milestone cash payments based on certain net revenue thresholds established for 2026 and 2027. See Note 12 "Fair Value" in the notes to the consolidated financial statements for more information relating to CVR obligations. The contingent value rights are remeasured each reporting period using Level 3 inputs. Changes in fair value, which incorporate changes in assumptions and the passage of time, are recognized as an operating expense in the consolidated statements of operations. There were no amounts due and payable during the year ended December 31, 2024.

Fair Value Measurements

Fair value is defined as 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 which prioritizes and ranks the level of observability of inputs used in measuring fair value. These tiers include:

- Level 1—Quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.
- Level 2—Observable market-based inputs other than quoted prices in active markets for identical assets or liabilities.
- Level 3—Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

The consolidated balance sheets include certain financial instruments (primarily cash and cash equivalents, prepaid expenses, accounts receivable, accounts payable, accrued expenses, and other current liabilities) that are carried at cost and that approximate fair values as of December 31, 2024, 2023 due to their short term nature. See Note 12 "Fair Value" in the notes to the consolidated financial statements.

Recent Accounting Pronouncements

Recently Issued Accounting Pronouncements Not Yet Adopted

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and are adopted by the Company as of the specified effective date. Unless otherwise discussed, 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 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 is currently evaluating the impact that the adoption of ASU 2023-09 will have on the consolidated financial statements and disclosures and will adopt in the 2025 annual report on Form 10-K.

In November 2024, the FASB issued ASU 2024-03, *Disaggregation of Income Statement Expenses (DISE)*, which specifies additional disclosure requirements. The new guidance requires additional disclosures, including the composition of certain income expense line items (such as purchases of inventory, employee compensation, and "other expenses") and a separate disclosure for selling expenses. This change is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027, however, early adoption is permitted. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on the consolidated financial statements and disclosures and anticipate adoption in the 2027 annual report on Form 10-K.

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Recently Adopted Accounting Pronouncements

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 Company has adopted the provisions of ASU 2023-07 for the year ended December 31, 2024, and has applied this guidance to the disclosures for the year ended December 31, 2024, and retroactively for all previous periods presented. See Note 19 “Segment Reporting” in the notes to the consolidated financial statements.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

Revenues are primarily derived from sales of generic, rare disease, and brands portfolio 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 is 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 consolidated statements of operations is considered to be revenue from contracts with customers. The following table depicts the disaggregation of revenue:

| Products and Services (in thousands) | Years Ended December 31, | | |
|---|---------------------------------|-------------------|-------------------|
| | 2024 | 2023 | 2022 |
| Rare Disease and Brands | | | |
| Cortrophin Gel | \$ 198,085 | \$ 112,117 | \$ 41,686 |
| ILUVIEN and YUTIQ | 31,514 | — | — |
| Rare Disease total net revenues | \$ 229,599 | \$ 112,117 | \$ 41,686 |
| Brands | 64,743 | 85,384 | 39,462 |
| Rare Disease and Brands total net revenues | \$ 294,342 | \$ 197,501 | \$ 81,148 |
| Generics and Other | | | |
| Generic pharmaceutical products | \$ 301,004 | \$ 269,449 | \$ 210,120 |
| Royalties and other pharmaceutical services | 19,030 | 19,866 | 25,117 |
| Generics and Other total net revenues | \$ 320,034 | \$ 289,315 | \$ 235,237 |
| Total net revenue | \$ 614,376 | \$ 486,816 | \$ 316,385 |

| Timing of Revenue Recognition (in thousands) | Years Ended December 31, | | |
|--|---------------------------------|-------------------|-------------------|
| | 2024 | 2023 | 2022 |
| Performance obligations transferred at a point in time | \$ 614,376 | \$ 486,441 | \$ 313,436 |
| Performance obligations transferred over time | — | 375 | 2,949 |
| Total | \$ 614,376 | \$ 486,816 | \$ 316,385 |

In the years ended December 31, 2024 or 2023, the Company did not incur, and therefore did not defer, any material incremental costs to obtain or fulfill contracts. As of December 31, 2024, there were no contract assets recorded which were related to revenue recognized based on percentage of completion but not yet billed.

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The Company recognized a decrease of \$3.0 million of net revenue from performance obligations satisfied in prior periods during the year ended December 31, 2024, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales.

As of December 31, 2024, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was \$0.7 million, which consists of firm orders for contract manufactured products. ANI will recognize 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.

Chargebacks

Chargebacks, primarily from wholesalers, result from arrangements with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, the Company may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, the Company provides a chargeback credit to the wholesaler for any difference between the contracted price with the indirect customer and the wholesaler's invoice price, typically Wholesale Acquisition Cost ("WAC").

Prior period chargebacks claimed by wholesalers are analyzed to determine the actual average selling price ("ASP") for each product. This calculation is performed by product by wholesaler. ASPs can be affected by several factors such as:

- A change in customer mix
- A change in negotiated terms with customers
- A change in the volume of off-contract purchases
- Changes in WAC

As necessary, ASPs are adjusted based on anticipated changes in the factors above.

The difference between ASP and WAC is recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets, at the time revenue is recognized from the product sale. The Company continually monitors chargeback activity and adjusts ASPs when the Company believes that actual selling prices will differ from current ASPs.

Government Rebates

Government rebates reserve consists of estimated payments due to governmental agencies for utilization of our products by beneficiaries under such governmental programs. The two largest government programs are Medicaid and Medicare.

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The Company participates in the Medicaid Drug Rebate Program and pays rebates to the states related on Medicaid beneficiary utilization of the Company's products. Medicaid rebates are billed within 60-90 days of the end of the quarter in which the product was dispensed to a Medicaid beneficiary. Medicaid rebate amounts per product unit are established by law, based on the Average Manufacturer Price ("AMP"), which is reported on a monthly and quarterly basis, and, in the case of branded products, best price, which is reported on a quarterly basis. Medicaid reserves are based on expected claims from state Medicaid programs. Estimates for expected claims are driven by patient usage, sales mix, calculated AMP or best price, as well as inventory in the distribution channel that will be subject to a Medicaid rebate. As a result of the delay between selling the products, dispensing the products and rebate billing, the Medicaid rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to plan participants.

Many of the products are also covered under Medicare. ANI participates in the Coverage Gap Discount Program in order for its branded drugs to be covered by Medicare Part D and must provide a rebate for any products sold under NDAs dispensed to Medicare Part D beneficiaries while the beneficiaries are in the Coverage Gap phase of the benefit. This applies to all products sold under NDAs, regardless of whether the products are marketed as branded or generic. Estimates for these discounts are based on historical experience with Medicare rebates for products. Medicare rebates are billed quarterly for drugs dispensed to Medicare beneficiaries in the prior quarter, which is typically 120 days after the product is shipped. As a result of the delay between selling the products, dispensing the products and rebate billing, Medicare rebate reserve includes both an estimate of outstanding claims for end-customer sales that have occurred but for which the related claim has not been billed, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to Medicare Part D participants.

To evaluate the adequacy of the government rebate reserves, reserves are reviewed on a quarterly basis against actual claims data to ensure the liability is fairly stated. The Company continually monitors the government rebate reserve and adjusts estimates if it is expected that actual government rebates may differ from established accruals. Accruals for government rebates are recorded as a reduction to gross revenues in the consolidated statements of operations and as an increase to accrued government rebates in the consolidated balance sheets.

Returns

A returns policy is in place that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. Product returns are settled through the issuance of a credit to the customer. The estimate for returns is based upon historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. The Company continually monitors estimates for returns and make adjustments when it is expected that actual product returns may differ from the established accruals. Accruals for returns are recorded as a reduction to gross revenues in the consolidated statements of operations and as an increase to the return goods reserve in the consolidated balance sheets. Generally, the Company does not accept product returns in international markets, however, there is a limited history of returns in such areas.

Administrative Fees and Other Rebates

Administrative fees or rebates are offered to wholesalers, group purchasing organizations, and indirect customers. Fees and rebates are accrued, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of the administrative fee accruals, on-hand inventory counts are obtained from the wholesalers. The Company continually monitors administrative fee activity and adjust accruals when it is expected that actual administrative fees may differ from the accruals. Accruals for administrative fees and other rebates are recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable or accrued expenses in the consolidated balance sheets.

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Prompt Payment Discounts

Sales discounts may be granted to customers for prompt payment. The reserve for prompt payment discounts is based on invoices outstanding. Based on past experience, it is assumed that all available discounts will be taken. Accruals for prompt payment discounts are recorded as a reduction in both gross revenues in the consolidated statements of operations and accounts receivable in the consolidated balance sheets.

The following table summarizes activity in the consolidated balance sheets for accruals and allowances for the years ended December 31, 2024, 2023, and 2022:

| (in thousands) | Accruals for Chargebacks, Returns, and Other Allowances | | | | |
|----------------------------------|---|--------------------|-----------|---------------------------------------|--------------------------|
| | Chargebacks | Government Rebates | Returns | Administrative Fees and Other Rebates | Prompt Payment Discounts |
| Balance at December 31, 2022 (1) | \$ 148,562 | \$ 10,872 | \$ 33,399 | \$ 9,442 | \$ 6,488 |
| Accruals/Adjustments | 586,511 | 23,915 | 18,360 | 55,798 | 22,932 |
| Credits Taken Against Reserve | (650,865) | (22,619) | (22,081) | (53,828) | (24,555) |
| Balance at December 31, 2023 (1) | \$ 84,208 | \$ 12,168 | \$ 29,678 | \$ 11,412 | \$ 4,865 |
| Accruals/Adjustments | 576,461 | 32,008 | 38,587 | 65,661 | 25,760 |
| Credits Taken Against Reserve | (555,039) | (25,462) | (28,991) | (57,485) | (24,367) |
| Balance at December 31, 2024 (1) | \$ 105,630 | \$ 18,714 | \$ 39,274 | \$ 19,588 | \$ 6,258 |

(1) Chargebacks are included as an offset to accounts receivable, net of chargebacks and other allowances in the consolidated balance sheets. Administrative Fees and Other Rebates and Prompt Payment Discounts are included as a reduction to accounts receivable, net of chargebacks and other allowances or accrued expenses and other in the consolidated balance sheets. Returns are included in returned goods reserve in the consolidated balance sheets. Government Rebates are included in accrued government rebates in the consolidated balance sheets.

Credit Concentration

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

During the years ended December 31, 2024 and 2023 four customers accounted for 10% or more of net revenues. During the year ended December 31, 2022, three customers accounted for 10% or more of net revenues. As of December 31, 2024, accounts receivable from these customers totaled 70% of accounts receivable, net.

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

| | Years Ended December 31, | | |
|-------------------|--------------------------|------|------|
| | 2024 | 2023 | 2022 |
| Customer 1 | 25 % | 31 % | 26 % |
| Customer 2 | 11 % | 13 % | 18 % |
| Customer 3 | 12 % | 13 % | 15 % |
| Customer 4 | 16 % | 12 % | 6 % |

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3. BUSINESS COMBINATION

Summary

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

At the effective time of the Merger, each share of common stock, par value \$0.01 per share, of Alimera (the “Alimera Common Stock”) outstanding, including each Alimera RSA (as defined below), but excluding any treasury shares or shares owned by the Company, Merger Subs or any other subsidiary of the Company or Alimera, was canceled and ceased to exist and was converted into the right to receive (i) \$5.50 in cash (“Closing Cash Consideration”), and (ii) one contingent value right (a “CVR”), which represents the right to receive the milestone payments (as defined below) subject to the terms and conditions set forth in the CVR Agreement entered into on September 16, 2024 (collectively, the “Merger Consideration”). The CVRs have been remeasured to fair value as of December 31, 2024, see Note 12 “Fair Value” in the notes to the consolidated financial statements.

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

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

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

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

The cash payment was funded through the New Credit Facility, see Note 6 “New Credit Agreement” in the notes to the consolidated financial statements, and also cash on-hand from the Company's balance sheet.

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

In accordance with the terms of the Merger Agreement, the Company settled all outstanding equity awards held by Alimera employees, for a total cash amount of \$19.3 million, of which, \$1.3 million was paid in cash at the close of the Merger. Of the \$19.3 million, \$9.5 million was determined to be related to the pre-Merger services provided and as a result was allocated to the purchase consideration transferred. The remaining amounts were attributed to the post-Merger period and deemed to be for the benefit of the Company. As a result, \$8.8 million was recognized as selling, general, and administrative and \$1.0 million as research and development expense, respectively, for the year ended December 31, 2024.

The CVRs represent a form of contingent consideration and are included as part of the purchase consideration transferred. The CVRs represent the right to future cash payments for the former Alimera shareholders based on certain 2026 and 2027 revenue targets. Management determined the contingent consideration to be liability classified and will measure the liability at fair value each reporting period. The fair value of the CVRs have been estimated using a monte carlo simulation under an option pricing framework, \$8.3 million of the total \$8.7 million was related to the pre-combination period and recognized as consideration transferred. The remaining \$0.4 million of the fair value of the CVR was allocated to post-merger period and recognized as selling, general, and administrative for the year ended December 31, 2024. The CVRs have been remeasured to fair value as of December 31, 2024, see Note 12 “Fair Value” in the notes to the consolidated financial statements.

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

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| (in thousands) | Preliminary Purchase Price Allocation | Measurement Period Adjustment | Purchase Price Allocation |
|---|---|-------------------------------------|------------------------------|
| Cash and cash equivalents | \$ 9,247 | \$ — | \$ 9,247 |
| Accounts receivable | 38,605 | (43) | 38,562 |
| Prepaid expenses and other assets | 2,618 | — | 2,618 |
| Inventories | 19,457 | (1,559) | 17,898 |
| Property and equipment | 3,086 | — | 3,086 |
| Intangible assets | 400,000 | — | 400,000 |
| Deferred tax asset, net of deferred tax liabilities and valuation allowance | 198 | (80) | 118 |
| Derivative and other non-current assets | 1,224 | — | 1,224 |
| Total assets | \$ 474,435 | \$ (1,682) | \$ 472,753 |
| Accounts payable | \$ 8,001 | \$ — | \$ 8,001 |
| Accrued expenses and other | 11,396 | 96 | 11,492 |
| Accrued government rebates | — | 385 | 385 |
| Returned goods reserve | 3,095 | (2,600) | 495 |
| Current accrued licensor payment | 3,684 | — | 3,684 |
| Deferred tax liability | 37,932 | — | 37,932 |
| Accrued licensor payment, net of current | 21,316 | — | 21,316 |
| Other non-current liabilities | 2,364 | — | 2,364 |
| Total liabilities | \$ 87,788 | \$ (2,119) | \$ 85,669 |
| Total fair value of consideration transferred | \$ 418,849 | \$ — | \$ 418,849 |
| Less: fair value of net acquired identifiable assets and liabilities | 386,647 | 437 | 387,084 |
| Goodwill | \$ 32,202 | \$ (437) | \$ 31,765 |

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

During the fourth quarter of 2024, the Company updated its inventories fair value, accounts receivable, returned goods reserve, accrued government rebates, and accrued expenses and other based upon new information that was not available to the Company at the acquisition date. The Company determined that the adjustments would be considered measurement period adjustments under the accounting guidance. The Company recorded a net decrease to goodwill of approximately \$0.4 million, as a result of the adjustments identified in the table above.

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

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

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

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| | Fair Value (in thousands) | Amortization Period |
|---------|----------------------------------|--------------------------------|
| ILUVIEN | \$ 230,000 | 12 |
| YUTIQ | \$ 170,000 | 12 |

The estimated deferred tax liability, recognized based on the estimated tax impact of the differences between the financial reporting and tax bases of the assets and liabilities acquired, is included in Deferred tax assets, net of deferred tax liabilities and valuation allowance in the consolidated balance sheet as of December 31, 2024.

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

Alimera operations generated approximately \$31.5 million of net revenue and recorded a net loss of approximately \$14.4 million from the date of acquisition through December 31, 2024.

Transaction Costs

In conjunction with the acquisition, the Company incurred approximately \$12.4 million in transaction costs during the year ended December 31, 2024, all of which were recognized as selling, general, and administrative expense in the consolidated statement of operations.

Pro Forma Consolidated Financial Information (unaudited)

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

| (in thousands) | Year Ended December 31, | |
|-----------------------|--------------------------------|-------------|
| | 2024 | 2023 |
| Net revenues | \$ 680,911 | \$ 567,570 |
| Net loss | \$ (24,338) | \$ (71,552) |

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

4. RESTRUCTURING CANADA OPERATIONS

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

For the year ended December 31, 2024, there were no restructuring activities recorded in the consolidated statements of operations or the consolidated balance sheets.

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For the year ended December 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 asset-related impairment and accelerated depreciation costs, and \$0.2 million for other miscellaneous other costs.

For the year ended December 31, 2022, restructuring activities resulted in expenses of \$5.7 million. This included \$2.1 million of severance and other employee benefit costs and \$3.1 million of asset-related impairment and accelerated depreciation costs, and \$0.4 million for other miscellaneous other costs.

These costs were recorded as restructuring activities, an operating item, in the accompanying consolidated statements of operations. Certain of the severance and other employee benefit costs contain a service requirement, and as such, were accrued over time as they were earned.

In conjunction with the exit of the Canadian facility, the Company determined that the land and building at the Oakville, Ontario, Canada plant (the "Property") will be sold together and met the criteria to be classified as held for sale as of December 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 consolidated balance sheets as of December 31, 2023. These assets were part of the Generics and Other segment. As of December 31, 2024 these assets were sold.

On February 15, 2024, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement with 1540700 Ontario Limited for the sale of the Property for a total purchase price of \$19.2 million Canadian Dollars, or approximately \$14.2 million, based on the exchange rate at closing. On March 28, 2024 the Company completed the sale of the Property. After payment of commissions, real estate taxes, and other related costs of approximately \$0.7 million, the Company received a net proceeds of approximately \$13.5 million at closing. The gain on the sale of the Property was approximately \$5.3 million, recorded in the consolidated statements of operations for the year ended December 31, 2024.

5. TRUIST CREDIT FACILITY

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

The Company incurred \$14.0 million in deferred debt issuance costs associated with the Credit Facility. Costs allocated to the Term Facility 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 on any unused portion of the Revolving Facility.

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The carrying value of the current and non-current components of the Term Facility as of the years ended December 31:

| (in thousands) | Current | |
|---|-------------|---------------|
| | 2024 | 2023 |
| Current borrowing on debt | \$ — | \$ 3,000 |
| Deferred financing costs | — | (2,150) |
| Current debt, net of deferred financing costs | <u>\$ —</u> | <u>\$ 850</u> |

| (in thousands) | Non-Current | |
|---|-------------|-------------------|
| | 2024 | 2023 |
| Non-current borrowing on debt | \$ — | \$ 291,000 |
| Deferred financing costs | — | (6,181) |
| Non-current debt, net of deferred financing costs and current component | <u>\$ —</u> | <u>\$ 284,819</u> |

The following table sets forth the components of total interest expense related to the Term Facility recognized in the accompanying consolidated statements of operations for the years ended December 31:

| (in thousands) | 2024 | 2023 | 2022 |
|--|------------------|------------------|------------------|
| Contractual coupon | \$ 16,644 | \$ 30,692 | \$ 26,150 |
| Amortization of deferred financing costs | 1,477 | 2,364 | 2,363 |
| | <u>\$ 18,121</u> | <u>\$ 33,056</u> | <u>\$ 28,513</u> |

Extinguishment of the Credit Facility

On August 13, 2024, the Company entered into an indenture with U.S. Bank Trust Company, National Association, as trustee, for the issuance of the 2.25% Convertible Senior Notes due 2029 (as described in Note 7 “2.25% Convertible Senior Notes” to the notes to consolidated financial statements). The proceeds of the Convertible Senior Notes and cash on-hand were used to repay the Credit Facility in its entirety, approximately \$294.0 million, comprised of \$292.5 million of unpaid principal, \$1.2 million in accrued and unpaid interest, and \$0.3 million of legal fees. In connection with the issuance of the Convertible Senior Notes, the Company recorded a loss on debt extinguishment in the consolidated statement of operations for the year ended December 31, 2024, amounting to approximately \$7.5 million, comprised of the write-off unamortized deferred financing fees related to the Credit Facility as of August 13, 2024.

6. NEW CREDIT AGREEMENT

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

On September 16, 2024 (the “Closing Date”), ANIP drew the full \$325.0 million of Term Loan A principal, with proceeds used to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the acquisition. As of December 31, 2024, the TLA Revolver remains undrawn, and \$75.0 million is available for borrowing. The TLA and the TLA Revolver mature on September 16, 2029. The New Credit Facility contains certain contingent acceleration clauses that could result in an earlier maturity date, none of which have been triggered as of December 31, 2024.

The cash interest rate and effective rate under the Term Loan A was approximately 6.98% and 7.34% per annum at December 31, 2024, respectively.

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

The Company is required to make quarterly principal payments, beginning on December 31, 2024, in the amount of (i) 0.625% of the original principal amount of the Term Loan A on each quarterly payment date on or prior to the one year anniversary of the Closing Date, (ii) 1.25% of the original principal amount of the Term Loan A on each quarterly payment date following the one year anniversary of the Closing Date and 1.875% of the original principal amount of the Term Loan A on each quarterly payment date following the three year anniversary of the Closing Date and with the remaining unpaid principal amount due on the maturity date of the Term Loan A. A commitment fee accrues on the unutilized commitments under the TLA Revolver and, from and after the date that is two months after the closing date of the New Credit Agreement, the TLA at a per annum rate equal between 0.25% and 0.40% depending on the Company's first lien net leverage ratio.

The Company incurred \$5.0 million in deferred debt issuance costs associated with the TLA, which costs are classified as a direct reduction to the current and non-current portion of debt. The Company incurred \$1.1 million in deferred debt issuance costs associated with the TLA Revolver. Of the \$1.1 million of unamortized deferred debt issuance costs allocated to the TLA Revolver, \$0.9 million is included in other non-current assets in the consolidated balance sheets, and \$0.2 million is included in prepaid expenses and other current assets in the consolidated balance sheets.

The carrying value of the current and non-current components of the Term Loan A as of the years ended December 31:

| (in thousands) | Current | |
|---|--------------------|-------------|
| | 2024 | 2023 |
| Current borrowing on debt | \$ 10,156 | \$ — |
| Deferred financing costs | (984) | — |
| Current debt, net of deferred financing costs | <u>\$ 9,172</u> | <u>\$ —</u> |
| | | |
| (in thousands) | Non-Current | |
| | 2024 | 2023 |
| Non-current borrowing on debt | \$ 312,813 | \$ — |
| Deferred financing costs | (3,705) | — |
| Non-current debt, net of deferred financing costs and current component | <u>\$ 309,108</u> | <u>\$ —</u> |

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

| (in thousands) | New Term Facility |
|----------------|--------------------------|
| 2025 | \$ 10,156 |
| 2026 | 18,281 |
| 2027 | 24,375 |
| 2028 | 24,375 |
| 2029 | 245,782 |
| Total | <u>\$ 322,969</u> |

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The following table sets forth the components of total interest expense, net recognized in the accompanying consolidated statements of operations for the years ended December 31:

| (in thousands) | 2024 | 2023 | 2022 |
|--|------------------|------------------|------------------|
| Contractual coupon interest expense, Truist | \$ 20,993 | \$ 33,270 | \$ 23,870 |
| Contractual coupon interest expense, Term Loan A | 7,264 | — | — |
| Contractual coupon interest expense, Convertible Notes | 2,747 | — | — |
| Amortization of deferred financing costs | 2,624 | 2,364 | 2,363 |
| Interest expense on interest rate swap | — | — | 2,280 |
| Interest expense | 33,628 | 35,634 | 28,513 |
| Capitalized interest related to Construction in Progress | (492) | (588) | (95) |
| Interest and dividend income on bank balances | (9,268) | (5,528) | (366) |
| Interest income on interest rate swap | (6,266) | (2,578) | — |
| Interest income | (16,026) | (8,694) | (461) |
| Interest expense, net | \$ 17,602 | \$ 26,940 | \$ 28,052 |

7. 2.25% CONVERTIBLE SENIOR NOTES

Offering of Convertible Senior Notes

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

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

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

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Conversion Options

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

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

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

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

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

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Events of Default

The Notes include customary provisions relating to the occurrence of “Events of Default” (as defined in the Indenture), including breaches of covenants, breaches of warranty, change of control, nonpayment, bankruptcy, assignment, foreclosure, cessation of business, and defaults under ancillary documents. Certain of the Events of Default are subject to notice and cure periods. As of December 31, 2024, the Company was in compliance with all covenants associated with the Notes.

Debt issuance costs related to the Notes totaled \$11.2 million at inception and were comprised of discounts and commissions payable to the initial purchasers and third-party offering costs and will be amortized to interest expense using the effective interest method over the contractual term. As of December 31, 2024, the unamortized debt discount and debt issuance cost of the Notes was approximately \$10.4 million on the consolidated balance sheets. The effective interest rate during the year ended December 31, 2024 was 3.01%.

During the year ended December 31, 2024, the Notes did not meet any of the circumstances that would allow for a conversion. The Notes were therefore not convertible as of December 31, 2024, and were classified as long-term debt on the Company’s consolidated balance sheet as of December 31, 2024.

As of December 31, 2024, the total estimated fair value (which represents a Level 2 valuation) of the Notes is approximately \$317.6 million.

The Company recognized \$2.7 million of contractual coupon interest expense and \$0.8 million of interest expense related to the amortization of deferred financing costs for the year ended December 31, 2024.

Capped Call Transactions

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

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

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

8. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

In April 2020, the Company entered into an interest rate swap with Citizens Bank, N.A. to manage its exposure to changes in the London Interbank Offered Rate (“LIBOR”) LIBOR-based interest rates underlying total borrowings under term facilities related to the prior credit agreement, and the interest rate swap matures in December 2026. The Company amended its Credit Agreement to transition from LIBOR to the Secured Overnight Financing Rate (“SOFR”) due to the cessation of LIBOR in the third quarter of 2023, and accordingly, the interest rate swap transitioned from LIBOR to SOFR. The interest rate swap is used to manage changes in SOFR-based interest rates underlying a portion of the borrowing under the Term Facility. Concurrent with the termination of the prior credit agreement and entry into the Credit Agreement with Truist Bank, the interest rate swap with a notional value of \$168.6 million at origin on November 21, 2021 was novated and Truist Bank became the new counterparty.

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On August 30, 2024, in connection with the New Credit Facility, the interest rate swap with a notional value of \$139.4 million was transferred from Truist Bank to JPMorgan Chase Bank, N.A., as the new counterparty. The interest rate swap is used to manage changes in SOFR-based interest rates underlying a portion of the borrowing under the New Term Facility. The interest rate swap provides an effective fixed interest rate of 2.313% and is designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As of December 31, 2024, the notional amount of the interest rate swap was \$139.4 million, and will remain static until maturity in December 2026. As of December 31, 2024, the fair value of the interest rate swap asset recorded in other non-current assets in the consolidated balance sheets is \$4.9 million. As of December 31, 2024, \$6.1 million was recorded in accumulated other comprehensive (loss) income, net of tax in the consolidated balance sheets.

During the year ended December 31, 2024, the loss on fair value of the interest rate swaps, net of tax recorded in accumulated other comprehensive (loss) income in the consolidated statements of comprehensive income was approximately \$2.9 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 years ended December 31, 2024 and 2023, the Company recorded a reduction in interest expense of \$6.3 million and \$2.6 million in relation to the interest rate swaps, respectively. Included in these amounts for the years ended December 31, 2024 and 2023 are reclassifications out of accumulated other comprehensive (loss) income of \$0.8 million of interest income and \$2.8 million of interest expense, respectively, related to terminated and de-designated cash flow hedges.

9. INVENTORIES

The following table shows the Company's inventory by asset class as of the years ended December 31:

| (in thousands) | 2024 | 2023 |
|---------------------|-------------------|-------------------|
| Raw materials | \$ 67,174 | \$ 62,237 |
| Packaging materials | 9,977 | 9,617 |
| Work-in-progress | 1,665 | 3,144 |
| Finished goods | 57,966 | 36,198 |
| Inventories | <u>\$ 136,782</u> | <u>\$ 111,196</u> |

Note, Finished Goods as of December 31, 2024 does not include the inventory step-up from the acquisition of Alimera, as the step-up was fully amortized during 2024.

Vendor Concentration

Raw materials are sourced for products, including API, from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. As a result, the Company is dependent upon current vendors to reliably supply the API required for on-going product manufacturing. During the year ended December 31, 2024, approximately 12%, of our raw material inventory purchases were from one domestic supplier. During the year ended December 31, 2023, no single vendor represented more than 10% of our raw material inventory purchases. During the year ended December 31, 2022 approximately 19%, of our raw material inventory purchases were from one domestic supplier.

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10. PROPERTY AND EQUIPMENT, NET

The following tables show the Company's gross property and equipment by major asset class and accumulated depreciation as of the years ended December 31:

| (in thousands) | 2024 | 2023 |
|-------------------------------------|------------------|------------------|
| Land | \$ 1,582 | \$ 1,549 |
| Buildings | 24,438 | 17,875 |
| Machinery, furniture, and equipment | 68,697 | 50,412 |
| Leasehold improvements | 1,297 | — |
| Finance leases | 1,161 | — |
| Construction in progress | 4,568 | 7,692 |
| | 101,743 | 77,528 |
| Less: accumulated depreciation | (44,880) | (32,935) |
| Property and equipment, net | <u>\$ 56,863</u> | <u>\$ 44,593</u> |

Depreciation expense for the years ended December 31, 2024, 2023, and 2022 totaled \$7.4 million, \$7.5 million, and \$7.4 million, respectively. During the years ended December 31, 2024, 2023, and 2022 there was \$0.5 million, \$0.6 million, and \$0.1 million, respectively, of interest capitalized into construction in progress, respectively.

11. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As of December 31, 2024, the Company has assigned its goodwill in three reporting units, Generics and Other, Brands, and Rare Disease reporting units. As a result of the 2013 merger with BioSante Pharmaceuticals, Inc., the Company recorded goodwill of \$1.8 million. As a result of the acquisition of WellSpring Pharma Services Inc. in 2018, the Company recorded goodwill of \$1.7 million. From the acquisition of Novitium in 2021, the Company recorded goodwill of \$24.6 million. The goodwill from the transactions with BioSante Pharmaceuticals, Inc., WellSpring Pharma Services Inc., and Novitium is recorded in the Generics and Other reporting unit. As a result of the acquisition of Alimera, on September 16, 2024, the Company recorded goodwill of \$31.8 million in the Rare Disease reporting unit. Refer to Note 3 "Business Combination" to the notes to the consolidated financial statements for further information related to the acquisition.

There have been no events or changes in circumstances that would have reduced the fair value of the reporting units below their carrying value during the year ended December 31, 2024 and 2023, and as a result, no impairment charges have been recognized. In addition to the qualitative impairment analysis performed at October 31, 2024, there were no events or changes in circumstances that would have reduced the fair value of the reporting unit below its carrying value from October 31, 2024 to December 31, 2024. No impairment loss was recognized during the years ended December 31, 2024, 2023, and 2022.

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Intangible Assets

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

| (in thousands) | December 31, 2024 | | | December 31, 2023 | | | Remaining Weighted Average Amortization Period(1) |
|--|-----------------------------|-----------------------------|------------------------|-----------------------------|-----------------------------|------------------------|---|
| | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount | |
| Definite-Lived Intangible Assets: | | | | | | | |
| Acquired ANDA intangible assets | \$ 210,497 | \$ (124,874) | \$ 85,623 | \$ 209,780 | \$ (100,660) | \$ 109,120 | 4.4 years |
| NDA's and product rights | 641,271 | (216,420) | 424,851 | 244,871 | (184,861) | 60,010 | 10.9 years |
| Marketing and distribution rights | 17,157 | (15,233) | 1,924 | 17,157 | (14,271) | 2,886 | 2.0 years |
| Customer relationships | 24,900 | (11,264) | 13,636 | 24,900 | (7,707) | 17,193 | 3.8 years |
| Total Definite-Lived Intangible Assets | 893,825 | (367,791) | 526,034 | 496,708 | (307,499) | 189,209 | 9.7 years |
| Indefinite-Lived Intangible Assets: | | | | | | | |
| In process research and development | 15,800 | — | 15,800 | 19,800 | — | 19,800 | Indefinite |
| Total Intangible Assets, net | \$ 909,625 | \$ (367,791) | \$ 541,834 | \$ 516,508 | \$ (307,499) | \$ 209,009 | |

(1) Weighted average amortization period as of December 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 tested for impairment when events or changes in circumstances indicate that these asset might be impaired.

During the year ended December 31, 2024, the Company acquired Alimera, and as a result, acquired two intangible assets for ILUVIEN and YUTIQ, in the amount of \$170.0 million and \$230.0 million, respectively, which will be amortized over twelve years.

The Company recorded approximately \$3.6 million of impairment losses during the three months ended December 31, 2024 related to definite-lived intangibles. There were no impairment losses recorded during the year ended December 31, 2023. During the year ended December 31, 2022, impairment losses of approximately \$0.1 million, were recognized in relation to ANDA assets.

Amortization expense for definite-lived intangible assets was \$60.3 million, \$52.3 million, and \$49.5 million for the years ended December 31, 2024, 2023, and 2022, respectively. See Note 12 "Fair Value" in the notes to the consolidated financial statements for more details on acquired definite-lived and indefinite-lived intangible assets.

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

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Indefinite-lived intangible assets are not amortized, and the Company tests for impairment of indefinite-lived intangible assets annually as of October 31, 2024, as well as with definite-lived intangibles when events or circumstances indicate that the carrying value of the assets may not be recoverable. The Company performed qualitative assessments to determine whether it was more likely than not that the assets were impaired in order to determine the necessity of performing a quantitative impairment test, under which management would calculate the asset's fair value. When performing the qualitative assessments, the Company evaluated events and circumstances that would affect the significant inputs used to determine the fair value of the assets.

The Company recorded \$4.0 million of impairment losses on indefinite-lived intangible assets, more specifically, IPR&D during the three months ended December 31, 2024. No impairment charges were recorded during the years ended December 31, 2023 and 2022.

During 2023, definite-lived intangibles increased approximately \$16.4 million, which includes \$6.8 million which was reclassified from indefinite-lived IPR&D to acquired ANDA intangible assets upon completion of projects and launch of related products, and the Company added approximately \$9.6 million of intangible assets, comprised of \$7.1 million of ANDA intangible assets related to asset acquisitions with Slayback Pharma Limited Liability Company and Akorn Holding Company, \$2.0 million in product rights related to the transaction with Alvogen, Inc., and other asset acquisitions. No amounts were reclassified from indefinite-lived IPR&D to intangible assets during the year ended December 31, 2024.

Expected future amortization expense is as follows for the years ending December 31:

| (in thousands) | | |
|-----------------------|----|---------|
| 2025 | \$ | 79,974 |
| 2026 | | 66,489 |
| 2027 | | 57,522 |
| 2028 | | 51,532 |
| 2029 | | 45,263 |
| 2030 and thereafter | | 225,254 |
| Total | \$ | 526,034 |

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

12. FAIR VALUE

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

The inputs used in measuring the fair value of cash and cash equivalents are considered to be Level 1 in accordance with the three-tier fair value hierarchy. The fair market values are based on period-end statements supplied by the various banks and brokers that held the majority of our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Facility, which was extinguished on August 13, 2024, and the New Credit Facility bear interest rates that fluctuates with the changes in SOFR and because the variable interest rates approximate market borrowing rates available to us, the Company believes the carrying values of these borrowings approximated their fair values at December 31, 2024 and 2023.

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

Alimera Contingent Value Rights Agreement

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

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

The fair value of the CVR liability is based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The Company utilized a Monte Carlo simulation model to estimate the fair value of the CVR liability. For each simulated path of future revenue, the payments to the CVR holders were calculated based on the contractual terms of the rights. The average payments from all simulated paths were then discounted to present value at an estimated cost of debt. The CVR liability had an estimated fair value of approximately \$9.0 million as of December 31, 2024, and is classified as non-current contingent consideration in the Company's consolidated balance sheet.

| (in thousands) | Year Ended December 31, 2024 |
|-----------------------|---|
| Beginning balance | \$ — |
| CVR Agreement | 8,700 |
| Change in fair value | 300 |
| Ending balance | <u>\$ 9,000</u> |

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 December 31, 2024 was approximately \$84.3 million.

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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. The fair value of the interest rate swap is estimated based on the present value of projected future cash flows using the SOFR forward rate curve (see Note 6 "New Credit Agreement" in the notes to the consolidated financial statements). The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in further detail in Note 8 "Derivative Financial Instrument and Hedging Activity" to the notes to consolidated financial statements. As described in detail in Note 8, the fair value of the interest rate swap was a \$4.9 million and \$6.2 million at December 31, 2024 and 2023, respectively, and was classified as a non-current assets in the consolidated balance sheets.

CG Oncology Equity Securities

The Company currently holds 219,925 shares of common stock in CG Oncology (Nasdaq: CGON). The Company accounts for its investment in CG Oncology equity securities as an equity investment with a readily determinable fair value, as the securities are publicly traded on the Nasdaq Global Select Market. The fair value of the equity securities is based on its closing price on the Nasdaq and is classified within Level 1 of the fair value hierarchy because the equity securities are valued using quoted market prices. The Company does not adjust the quoted market price for such financial instruments. The fair value of the CG Oncology equity securities as of December 31, 2024 was approximately \$6.3 million based on a closing market price of \$28.68 on December 31, 2024. This amount is classified on the consolidated statements of operations as Unrealized gain on investment in equity securities for the year ended December 31, 2024. Between 2013 and 2023, CG Oncology securities held by the Company were valued at zero under U.S. GAAP.

Novitium Contingent Consideration

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

The discounted cash flow method used to value this contingent consideration includes inputs of not readily observable market data, which are Level 3 inputs. As of the November 19, 2021 acquisition date, the contingent consideration had a fair value of \$30.8 million.

Pursuant to the terms of the Agreement and Plan of Merger, 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 (see Note 18 "Related Party Transactions" in the notes to the consolidated financial statements). Furthermore, on February 22, 2024, the Company paid \$12.5 million to Company Members of Novitium upon the achievement of the "Gross Profit Earn-Out," as defined in the Agreement.

The fair value of the contingent consideration was approximately \$10.9 million and \$24.0 million as of December 31, 2024 and 2023, respectively, and is reflected as a current and non-current accrued contingent consideration liability in the consolidated balance sheets.

The recurring Level 3 fair value measurements of contingent consideration for which a liability is recorded include the following significant unobservable inputs as of December 31, 2024:

| Payment Type | Valuation Technique | Unobservable Input | Assumptions |
|---------------------------------|---|----------------------------------|--------------------|
| Profit-based milestone payments | Probability-weighted discounted cash flow | Discount rate | 12.0% |
| | | Projected fiscal year of payment | 2025-2035 |

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

| (in thousands) | Year Ended December 31, | |
|--|-------------------------|------------------|
| | 2024 | 2023 |
| Beginning balance | \$ 23,984 | \$ 35,058 |
| Payment of Gross-Profit and ANDA Filing earn-out | (12,500) | (12,500) |
| Change in fair value | (630) | 1,426 |
| Ending balance | <u>\$ 10,854</u> | <u>\$ 23,984</u> |

Accrued Licensor Payments

On May 17, 2023, Alimera entered into the Product Rights Agreement with EyePoint which granted Alimera an exclusive and sublicensable right and license under EyePoint's and its affiliates' interest in certain of EyePoint's and its affiliates' intellectual property to develop, manufacture, sell, commercialize and otherwise exploit certain products, including YUTIQ, for the treatment and prevention of uveitis in the entire world, except Europe, the Middle East and Africa, where the Company already has such rights pursuant to the New Collaboration Agreement, and except for China, Hong Kong, Macau, Taiwan, Brunei, Burma (Myanmar), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, South Korea, Thailand and Vietnam, where Ocumension holds a license from EyePoint. Pursuant to the agreement, Alimera paid EyePoint an upfront payment of \$75.0 million and has also made four quarterly guaranteed payments to EyePoint totaling \$7.5 million during the year ended December 31, 2024.

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

During the quarter ended December 31, 2024, the Company paid the final quarterly payment of \$1.9 million. The present value of the remaining payments to EyePoint for years 2025 to 2028 will continue to be revalued at an appropriate discount rate for the Company at each reporting date until they are settled. The fair value of the remaining future payments as of December 31, 2024 was approximately \$21.0 million.

The recurring Level 3 fair value measurements of the EyePoint royalty for which a liability is recorded include the following significant unobservable inputs as of December 31, 2024:

| Payment Type | Valuation Technique | Unobservable Input | Assumptions |
|---|---|----------------------------------|-------------|
| Annual royalty payments for US net revenues of sales of YUTIQ and ILUVIEN | Probability-weighted discounted cash flow | Discount rate | 12.0% |
| | | Projected fiscal year of payment | 2025-2029 |

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The following table presents the changes in accrued licensor payments classified as Level 3 balances for the year ended December 31, 2024:

| (in thousands) | Year Ended December 31, 2024 |
|---------------------------|------------------------------------|
| Beginning balance | \$ — |
| Accrued licensor payments | 25,000 |
| Payments during 2024 | (3,750) |
| Change in fair value | (289) |
| Ending balance | <u>\$ 20,961</u> |

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

| (in thousands) Description | Fair Value at December 31, 2024 | Level 1 | Level 2 | Level 3 |
|---|------------------------------------|-----------|----------|-----------|
| Assets | | | | |
| Money Market Fund | \$ 84,277 | \$ 84,277 | \$ — | \$ — |
| Interest rate swap | \$ 4,897 | \$ — | \$ 4,897 | \$ — |
| CG Oncology - Investment in equity securities | \$ 6,307 | \$ 6,307 | \$ — | \$ — |
| Liabilities | | | | |
| Contingent consideration, Novitium | \$ 10,854 | \$ — | \$ — | \$ 10,854 |
| Contingent Value Rights, Alimera | \$ 9,000 | \$ — | \$ — | \$ 9,000 |
| Accrued licensor payment | \$ 20,961 | \$ — | \$ — | \$ 20,961 |

| (in thousands) Description | Fair Value at December 31, 2023 | Level 1 | Level 2 | Level 3 |
|-------------------------------|------------------------------------|------------|----------|-----------|
| Assets | | | | |
| Money Market Fund | \$ 191,841 | \$ 191,841 | \$ — | \$ — |
| Interest rate swaps | \$ 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 and liabilities that are measured at fair value on a non-recurring basis.

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

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

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

Long-lived assets, including property and equipment, ROU assets, intangible assets, and goodwill, are measured at fair value on a non-recurring basis. During the years ended December 31, 2024 and 2023 there were \$7.6 million and \$0 of impairment charges recognized related to non-financial assets and liabilities measured at fair value on a non-recurring basis, respectively. During the year ended December 31, 2022, impairment losses of approximately \$0.1 million, were recognized in relation to ANDA assets.

Acquired Non-Financial Assets Measured at Fair Value

On September 16, 2024, the Company acquired ILUVIEN and YUTIQ in connection with the acquisition of Alimera. See Note 3 “Business Combination” in the notes to the consolidated financial statements.

On December 27, 2023, the Company acquired from Alvogen, Inc. the rights to certain pharmaceutical products for total cash consideration of \$2.0 million (Note 8), which launched commercially in early 2024. The transaction was accounted for as an asset acquisition and there were no transaction costs directly related to the acquisition. Intangible assets amounted to \$2.0 million as NDAs and product rights. The payment was allocated to the acquired intangible assets based on relative fair value, which was determined using Level 3 unobservable inputs. The intangible asset will be amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2024.

On August 14, 2023, the Company acquired one ANDA and registered patents and pending patent applications from Slayback Pharma Limited Liability Company for total consideration of \$3.0 million. The Company also acquired an NDA which has yet to be filed. The transaction was funded from cash on hand. The transaction was accounted for as an asset acquisition and the transaction costs directly related to the acquisition were capitalized. Intangible assets amounted to \$2.8 million as acquired ANDA intangible assets. The payment was allocated to the acquired intangible assets based on relative fair value, which was determined using Level 3 unobservable inputs. The ANDA will be amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2024, and therefore no impairment loss was recognized for the year ended December 31, 2024.

During the second quarter of fiscal 2023, the Company acquired two ANDAs and one pipeline product from the Chapter 7 Trustee for the estates of Akorn Holding Company and certain of its affiliates for total consideration of \$4.8 million. The transaction was funded from cash on hand. This transaction was accounted for as an asset acquisition and the transaction costs directly related to the acquisition were capitalized. The product portfolio included two commercial products and one pipeline product. The Company recognized \$4.3 million as acquired ANDA intangible assets. The payment was allocated to the acquired intangible assets and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. The ANDAs will be amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2024, and therefore no impairment loss was recognized for the year ended December 31, 2024.

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On July 21, 2022, ANI acquired four ANDAs from Oakrum Pharma, LLC for total consideration of \$8.0 million plus an immaterial amount for the purchase of finished goods inventory. The transaction was funded from cash on hand. ANI accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. The product portfolio included one commercial product, one approved product with a launch completed in September 2022 and two filed products, with approval pending. ANI recognized \$7.2 million as acquired ANDA intangible assets and \$1.2 million as research and development expense because certain of the generic products have significant remaining work required in order to be commercialized and the products do not have an alternative future use. The payment was allocated to the acquired intangible assets and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. ANI used the present value of the estimated cash flows related to the products, using a discount rate of 13% to determine the fair value of the acquired intangible assets and in-process research and development. The inventory acquired was immaterial. Contingent liabilities are accrued when they are both estimable and probable. ANI accrued \$0.2 million in contingent payments due to a third party upon the launch of a product completed in September 2022. This was accrued and recorded in the fair value of acquired intangible assets as it was probable at the acquisition date and has been paid in 2023. The ANDAs will be amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2024, and therefore no impairment loss was recognized for the year ended December 31, 2024.

13. 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 December 31, 2024 and 2023.

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

Public Offering

In May 2023, through a public offering, the Company 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.

Class C Special Stock

There were 11 thousand shares of class C special stock issued and outstanding as of December 31, 2024 and 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 the Company's 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 the Company's 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.

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Mezzanine Equity

PIPE Shares

Concurrently with the acquisition of Novitium, 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 agreed to purchase, 25,000 shares of the Company's 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 in the Company's control. The Company incurred \$0.2 million in issuance costs associated with the transaction.

The PIPE Shares accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and will also participate, on a pro-rata basis, in any dividends that may be declared with respect to the Company's common stock. The PIPE Shares are convertible into the Company's common shares at the conversion price of \$41.47 (i) beginning two years 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 Company's 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 December 31, 2024, the PIPE shares are currently convertible into a maximum of 602,901 shares of the Company's 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 the Company's common stock. The PIPE Shares will have voting rights, voting as one series with the Company's common stock, on as-converted basis, and will have separate voting rights on any (i) amendment to the Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (the “Certificate”) that adversely amends and relates solely to the terms of the PIPE Shares and (ii) issuance of additional Series A convertible preferred stock. In case of a change of control of the Company, the PIPE Shares will be redeemed at the greater of (i) the PIPE Shares’ purchase price plus any accrued and unpaid dividends thereon and (ii) the change of control transaction consideration that the holder of the PIPE Shares would have received if it had converted into the Company's common stock.

There were 25,000 shares of Series A convertible preferred stock outstanding as of December 31, 2024 and 2023.

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14. EARNINGS (LOSS) PER SHARE

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

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

Unvested restricted shares and Series A convertible preferred stock shares contain non-forfeitable rights to dividends, and therefore are considered to be participating securities; in periods of net income, the calculation of basic and diluted earnings (loss) per share excludes from the numerator net income (but not net loss) attributable to the unvested restricted shares and the common shares assumed converted from the preferred shares and excludes the impact of those shares from the denominator. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss was attributed entirely to common stockholders. As the Company has reported a net loss for the year ended December 31, 2024, diluted net loss per share attributable to common shareholders is the same as basic net loss per share attributable to common shareholders for this period.

Earnings (loss) per share for the years ended December 31, 2024, 2023, and 2022 are calculated for basic and diluted earnings (loss) per share as follows:

| (in thousands, except per share amounts) | Basic | | | Diluted | | |
|---|--------------------------|------------------|--------------------|--------------------------|------------------|--------------------|
| | Years Ended December 31, | | | Years Ended December 31, | | |
| | 2024 | 2023 | 2022 | 2024 | 2023 | 2022 |
| Net (loss) income available to common shareholders | \$ (20,147) | \$ 17,154 | \$ (49,521) | \$ (20,147) | \$ 17,154 | \$ (49,521) |
| Earnings allocated to participating securities | — | (1,679) | — | — | (1,663) | — |
| Net (loss) income available to common shareholders | <u>\$ (20,147)</u> | <u>\$ 15,475</u> | <u>\$ (49,521)</u> | <u>\$ (20,147)</u> | <u>\$ 15,491</u> | <u>\$ (49,521)</u> |
| Basic Weighted-Average Shares Outstanding | 19,318 | 18,001 | 16,260 | 19,318 | 18,001 | 16,260 |
| Dilutive effect of stock options, ESPP, and performance stock units | — | 193 | — | — | 193 | — |
| Diluted Weighted-Average Shares Outstanding | 19,318 | 18,194 | 16,260 | 19,318 | 18,194 | 16,260 |
| (Loss) earnings per share | \$ (1.04) | \$ 0.86 | \$ (3.05) | \$ (1.04) | \$ 0.85 | \$ (3.05) |

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, were 2.3 million, 2.4 million, and 2.6 million for the years ended December 31, 2024, 2023, and 2022, respectively. For the years ended December 31, 2024 and 2022, all potentially dilutive shares were anti-dilutive and excluded from the calculation of diluted loss per share because the Company reported a net loss.

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15. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, the Company commenced administration of the ANI Pharmaceuticals, Inc. 2016 ESPP. As of December 31, 2024, there are approximately 0.1 million shares of common stock available for issuance under the ESPP. Under the ESPP, participants can purchase shares of common 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.

Stock Incentive Plan

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

As of December 31, 2024, approximately 2.0 million shares of common stock were available for issuance under the 2022 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 the Company’s stockholders at the 2022 Annual Meeting of Stockholders (the “Annual Meeting”) held on April 27, 2022. Prior to this approval, the Company granted equity-based incentive awards under the Sixth Amended and Restated 2008 Stock Incentive Plan (the “2008 Plan”), which was renamed, amended and restated to the 2022 Plan. The 2022 Plan, among other things, increased the number of shares reserved for issuance thereunder by 1,150,000 shares. On May 23, 2023, the Company’s stockholders approved an amendment to the 2022 Plan (such amendment, the “2023 Stock Plan Amendment”). Subject to adjustment, the 2023 Stock Plan Amendment increased the number of shares reserved for issuance under the 2022 Plan by 750,000 shares.

From time to time, the Company may grant stock options to employees through an inducement grant outside of the 2022 Plan to induce prospective employees to accept employment with us (the “Inducement Grants”). The options are granted at an exercise price equal to the fair market value of a share of the 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 the stockholder approved equity plan as permitted under the Nasdaq Stock Market listing rules.

The cost of equity-based service awards are measured based on the grant-date fair value of the award. The cost is recognized ratably over the period during which an employee is required to provide service in exchange for the award or the requisite service period. Stock-based compensation expense is recognized ratably over the vesting periods of the awards.

The following table summarizes stock-based compensation expense incurred for ESPP expense incurred under the 2016 Employee Stock Purchase Plan, stock options, restricted stock awards, performance-based restricted stock units, and Inducement Grants and included in the consolidated statements of operations:

| (in thousands) | Years Ended December 31, | | |
|--------------------------------------|--------------------------|------------------|------------------|
| | 2024 | 2023 | 2022 |
| Selling, general, and administrative | \$ 26,534 | \$ 19,036 | \$ 13,316 |
| Research and development | 1,533 | 910 | 751 |
| Cost of sales | 1,277 | 706 | 532 |
| | <u>\$ 29,344</u> | <u>\$ 20,652</u> | <u>\$ 14,599</u> |

Income tax benefits of approximately \$2.8 million, \$3.3 million, and \$1.7 million were recognized for stock-based compensation-related tax deductions in the 2024, 2023, and 2022 consolidated statements of operations, respectively.

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Stock Options

Outstanding stock options granted to employees and consultants generally vest over a period of four years and have 10-year contractual terms. Outstanding stock options granted to non-employee directors generally vest over a period of one to four years and have 10-year contractual terms.

There were no grants of stock options during 2024. For 2023, and 2022, the fair value of each option grant was estimated using the Black-Scholes option-pricing model, using the following assumptions:

| | Years Ended December 31, | |
|---------------------------------|---------------------------------|---------------|
| | 2023 | 2022 |
| Expected option life (years) | 6.25 | 5.50 - 6.25 |
| Risk-free interest rate | 4.1% | 1.7% - 2.8% |
| Expected stock price volatility | 49.0% | 48.4% - 50.0% |
| Dividend yield | — | — |

The Company uses the simplified method to estimate the expected option life of options. The risk-free interest rate used is the yield on a U.S. Treasury note as of the grant date with a maturity equal to the estimated life of the option. The calculated estimated volatility rate is based on ANI's historical stock price. The Company has not issued a cash dividend on the common shares in the past nor does the Company have any current plans to do so in the future; therefore, an expected dividend yield of zero was used.

A summary of stock option activity under the 2022 Plan and Inducement Grants during the years ended December 31, 2024, 2023, and 2022 is presented below:

| (in thousands, except per share and remaining term data) | Option Shares | Weighted Average Exercise Price | Fair Value | Weighted Average Remaining Term (years) | Aggregate Intrinsic Value |
|---|----------------------|--|-------------------|--|----------------------------------|
| Outstanding December 31, 2021 | 988 | \$ 45.56 | | 6.6 | \$ 6,786 |
| Granted | 36 | 34.52 | \$ 16.82 | | |
| Exercised | (23) | 30.03 | | | 153 |
| Forfeited | (47) | 36.91 | | | |
| Expired | (47) | 55.07 | | | |
| Outstanding December 31, 2022 | 907 | \$ 45.47 | | 5.6 | \$ 3,868 |
| Granted | 3 | 41.84 | \$ 22.12 | | |
| Exercised | (189) | 44.09 | | | 2,894 |
| Forfeited | (21) | 33.45 | | | |
| Expired | (11) | 55.15 | | | |
| Outstanding at December 31, 2023 | 689 | \$ 46.05 | | 4.9 | \$ 8,370 |
| Exercised | (102) | 43.80 | | | 2,001 |
| Expired | (3) | 50.88 | | | |
| Outstanding at December 31, 2024 | 584 | \$ 46.42 | | 3.9 | \$ 7,190 |
| Exercisable at December 31, 2024 | 551 | \$ 47.15 | | 3.8 | \$ 6,500 |

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As of December 31, 2024, there was \$0.4 million of total unrecognized compensation cost related to non-vested stock options granted under the 2022 Plan and Inducement Grant. The cost is expected to be recognized over a weighted-average period of 0.50 years. During the year ended December 31, 2024, ANI received \$4.5 million in cash from the exercise of stock options and recorded approximately \$0.2 million tax provision related to these exercises. During the year ended December 31, 2023, ANI received \$8.3 million in cash from the exercise of stock options and recorded a \$0.2 million tax provision related to these exercises. During the year ended December 31, 2022, ANI received \$0.7 million in cash from the exercise of stock options and recorded a \$0.1 million tax provision related to these exercises.

Restricted Stock Awards

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

Shares of common stock delivered to employees and directors will be unrestricted upon vesting. During the vesting period, the recipient of the restricted stock 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 the Company's stock on the date of grant.

A summary of RSA activity under the Plan during the years ended December 31, 2024, 2023, and 2022 is presented below:

| (in thousands, except per share and remaining term data) | Shares | Weighted Average Grant Date Fair Value | Weighted Average Remaining Term (years) |
|--|--------|--|--|
| Unvested at December 31, 2021 | 707 | \$ 36.52 | 2.8 |
| Granted | 748 | 32.76 | |
| Vested | (245) | 36.99 | |
| Forfeited | (69) | 38.08 | |
| Unvested at December 31, 2022 | 1,141 | \$ 33.86 | 2.6 |
| Granted | 674 | 43.30 | |
| Vested | (383) | 34.59 | |
| Forfeited | (81) | 38.10 | |
| Unvested at December 31, 2023 | 1,351 | \$ 38.11 | 2.4 |
| Granted | 708 | 57.22 | |
| Vested | (485) | 37.99 | |
| Forfeited | (119) | 45.05 | |
| Unvested at December 31, 2024 | 1,455 | \$ 46.89 | 2.3 |

As of December 31, 2024, there was \$55.7 million of total unrecognized compensation cost related to non-vested RSAs granted under the Plan, which is expected to be recognized over a weighted-average period of 2.3 years.

Performance-Based Restricted Stock Units

Awards may also be issued in the form of PSUs. PSUs represent the right to receive a number of shares of Company common stock, contingent upon the achievement of specified performance objectives during a specified performance period. PSUs granted to date vest over a three-year performance period.

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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%. At each reporting period, the Company analyzes progress on the performance goals to assess the likelihood of achievement.

The estimated grant date fair value per share of the MPRSUs was \$85.65 and was calculated using a Monte Carlo simulation model. Based on the Company's analysis, the 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. Based on the Company's analysis, the 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 28, 2023 Performance-Based Restricted Stock Units Grant

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

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

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A summary of PSU activity under the Plan during the years ended December 31, 2024 and 2023 is presented below:

| (in thousands, except per share and remaining term data) | Shares | Weighted Average Grant Date Fair Value | Weighted Average Remaining Term (years) |
|--|--------|--|--|
| Unvested at December 31, 2022 | — | \$ — | — |
| Granted | 85 | 41.84 | |
| Vested | — | — | |
| Forfeited | (1) | 41.84 | |
| Unvested at December 31, 2023 | 84 | 41.84 | 2.0 |
| Granted | 74 | 56.10 | |
| Vested | — | — | |
| Forfeited | (8) | 48.06 | |
| Unvested at December 31, 2024 | 150 | \$ 48.52 | 1.6 |

As of December 31, 2024, there was \$7.2 million of total unrecognized compensation cost related to non-vested PSUs granted under the Plan, which is expected to be recognized over a weighted-average period of 1.6 years.

16. INCOME TAXES

The foreign current and foreign deferred (benefits) expenses below represent our tax (benefit) expense from Canada, India, United Kingdom, Ireland, Portugal, and Germany jurisdictions.

The Company is required to establish a valuation allowance for deferred tax assets if, based on the weight of all available evidence, it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible. The Company considers the projected future taxable income and tax planning strategies in making this assessment.

As of December 31, 2024 and 2023, the consolidated valuation allowance was \$9.5 million and \$0.4 million, respectively, primarily related to deferred tax assets for net operating losses in the UK and and U.S. state jurisdictions. The Company recorded a valuation allowance of approximately \$7.5 million in connection with the acquisition of Alimera, and recorded an additional increase in the valuation allowance of approximately \$1.5 million during the three months ended December 31, 2024.

(Loss) income before taxes consisted of the following:

| (in thousands) | As of December 31, | | |
|---|--------------------|-----------|-------------|
| | 2024 | 2023 | 2022 |
| Domestic | \$ (24,618) | \$ 19,124 | \$ (64,913) |
| Foreign | 2,406 | 748 | 2,248 |
| (Loss) income before income tax (benefit) expense | \$ (22,212) | \$ 19,872 | \$ (62,665) |

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Total income tax (benefit) expense for income taxes consists of the following for the years ended December 31:

| (in thousands) | As of December 31, | | |
|--|--------------------|-----------------|--------------------|
| | 2024 | 2023 | 2022 |
| Current income tax expense | | | |
| Federal | \$ 13,714 | \$ 9,117 | \$ 152 |
| State | 2,231 | 3,534 | 249 |
| Foreign | 1,876 | 26 | 66 |
| Total | 17,821 | 12,677 | 467 |
| Deferred income tax benefit | | | |
| Federal | (17,876) | (7,601) | (13,382) |
| State | (3,906) | (3,946) | (1,722) |
| Foreign | (1,217) | (29) | (128) |
| Total | (22,999) | (11,576) | (15,232) |
| Change in valuation allowance | 1,488 | (8) | (4) |
| Total (benefit) expense for income taxes | <u>\$ (3,690)</u> | <u>\$ 1,093</u> | <u>\$ (14,769)</u> |

The difference between the expected income tax (benefit) expense from applying U.S. Federal statutory tax rates to the pre-tax (loss) income and actual income tax (benefit) expense relates primarily to the effect of the following:

| | As of December 31, | | |
|--|--------------------|--------------|---------------|
| | 2024 | 2023 | 2022 |
| US Federal statutory rate | 21.0 % | 21.0 % | 21.0 % |
| State taxes, net of Federal benefit | 2.5 % | 4.8 % | 3.2 % |
| Foreign taxes | (3.0)% | 0.0% | 0.1 % |
| Change in valuation allowance | (6.7)% | 0.0% | — % |
| Stock-based compensation | (6.5)% | 10.8 % | (1.4)% |
| Non-deductible costs | (8.8)% | 2.1 % | (0.5)% |
| Change in state apportionment factors, state and foreign rates | 4.0 % | (11.8)% | (0.1)% |
| Research and experimentation and charitable credits | 14.1 % | (19.0)% | 1.4 % |
| Transfer pricing and other | — % | (2.4)% | (0.1)% |
| Effective income tax rate | <u>16.6 %</u> | <u>5.5 %</u> | <u>23.6 %</u> |

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Deferred income taxes reflect the net tax effects of differences between the bases of assets and liabilities for financial reporting and income tax purposes. Deferred income tax assets and liabilities consisted of the following:

| (in thousands) | As of December 31, | |
|--|--------------------|------------------|
| | 2024 | 2023 |
| Deferred tax assets: | | |
| Accruals and advances | \$ 16,318 | \$ 12,470 |
| Stock-based compensation | 7,373 | 6,013 |
| Accruals for chargebacks and returns | 23,427 | 17,358 |
| Inventories | 5,234 | 4,569 |
| Intangible assets | — | 40,193 |
| Net operating loss carryforwards | 27,254 | 2,900 |
| Capitalized research expenditures | 19,836 | 11,294 |
| Interest expense carryforwards | 6,400 | 5,132 |
| Debt instruments | 9,590 | — |
| Other assets | 5,305 | 2,318 |
| Total deferred tax assets | \$ 120,737 | \$ 102,247 |
| Deferred tax liabilities: | | |
| Depreciation | \$ (6,710) | \$ (5,658) |
| Intangible assets | (12,537) | — |
| Other liabilities | (6,934) | (5,440) |
| Total deferred tax liabilities | \$ (26,181) | \$ (11,098) |
| Valuation allowance | (9,450) | (438) |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | <u>\$ 85,106</u> | <u>\$ 90,711</u> |

As of December 31, 2024, U.S. federal net operating loss carryforwards were approximately \$55.6 million and UK net operating losses of approximately \$50.8 million, primarily arose as a result of the acquisition of Alimera and the 2013 merger with BioSante Pharmaceuticals, Inc. Net operating loss carryforwards related to the 2024 acquisition are indefinite lived. Net operating loss carryforwards related to the 2013 merger, if not used, expire in annual increments through 2033. All of the net operating loss carryforwards are limited on an annual basis as prescribed by Section 382 of the U.S. Internal Revenue Code; the current annual limitation is approximately \$7.2 million per year. Additionally, as of December 31, 2024, the Company has total net operating losses in various states of \$5.7 million which begin to expire through 2042.

The Company is subject to income taxes in numerous jurisdictions in the U.S. and certain foreign jurisdictions. Significant judgement is required in evaluating tax positions and determining the expense for income taxes. The Company established liabilities for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These liabilities are established when the Company believe that certain positions might be challenged despite our belief that our tax return positions are fully supportable. We adjusts these liabilities in light of changing facts and circumstances, such as the outcome of a tax audit. The expense for income taxes includes the impact of changes to the liability that is considered appropriate. The Company has not identified any material uncertain income tax positions as of December 31, 2024 and 2023.

The Company is subject to income tax audits in all jurisdictions for which tax returns are filed. Tax audits by their nature are often complex and can require several years to complete. All of the Company's income tax returns remain subject to examination by tax authorities due to the availability of net operating loss carryforwards.

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17. COMMITMENTS AND CONTINGENCIES

Operating Leases

The majority of the Company's leases as of December 31, 2024 are classified as operating leases. Leases with an initial term of twelve months or less are not recorded on the balance sheet, and the Company does not separate lease and non-lease components of contracts. The Company's lease agreements do not provide for determination of the interest rate implicit in the lease. Therefore, the Company used a benchmark approach to derive an appropriate incremental borrowing rate. The Company's incremental borrowing rate is the rate of interest that the lessee would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. The Company benchmarked itself against other companies of similar credit ratings and comparable quality and derived an incremental borrowing rate, which was used to discount its lease liabilities. Rent expense is recognized on a straight-line basis over the lease term. Operating lease ROU assets are included in other non-current assets and operating lease liabilities are included in accrued expenses and other and other non-current liabilities in the consolidated balance sheets. The Company's lease agreements do not contain any material residual value guarantees or material restrictive covenants.

In April 2023, the Company entered into an agreement to lease additional warehouse space in East Windsor, New Jersey. The lease has a term of five years, and is classified as an operating lease. Additionally, during October 2023, the Company entered into an amendment for the Middleton, Wisconsin location which expanded the Company's square footage and also extended the termination date to December 2028.

In connection with the acquisition of Alimera, the Company acquired operating leases for office space in Alpharetta, Georgia, which has a remaining term of approximately five years. The Company also entered into a new lease agreement in Princeton, New Jersey, for office space which is expected to have a commencement date during 2025. The Princeton, New Jersey lease will have a remaining term of approximately 10 years.

As of December 31, 2024, there are 15 operating leases for facilities and office equipment with remaining terms expiring from 2025 through 2029 and a weighted average remaining lease terms of 3.8 years and 3.9 years, as of December 31, 2024 and 2023, respectively. Many of the operating leases have fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. The weighted average incremental borrowing rates as of December 31, 2024 and 2023 is 8.10% and 8.12%, respectively.

Lease expense consisted of the following for the years ended December 31:

| (in thousands) | 2024 | 2023 | 2022 |
|-----------------------|-----------------|-----------------|---------------|
| Operating lease costs | \$ 2,122 | \$ 2,031 | \$ 701 |
| Finance lease costs | 43 | — | — |
| Variable lease costs | 261 | 221 | 236 |
| Total lease costs | <u>\$ 2,426</u> | <u>\$ 2,252</u> | <u>\$ 937</u> |

The table below reconciles the fixed component of the undiscounted cash flows for each of the first five years and the total remaining years to the operating lease liabilities recorded on the Consolidated Balance Sheet as of December 31, 2024:

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(in thousands)

| | |
|--|----------|
| 2025 | \$ 2,084 |
| 2026 | 1,779 |
| 2027 | 1,793 |
| 2028 | 1,024 |
| 2029 | 534 |
| Thereafter | — |
| Total minimum lease payments | \$ 7,214 |
| Less: effects of discounting | (1,022) |
| Present value of future minimum lease payments | 6,192 |
| Less: current lease liability, included in accrued expenses and other | (1,799) |
| Non-current lease liability, included in other non-current liabilities | \$ 4,393 |

Finance Leases

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

As of December 31, 2024, a schedule of maturity of lease liabilities under finance leases, together with the present value of minimum lease payments is as follows:

(in thousands)

| | |
|--|--------|
| Future payments: | |
| 2025 | \$ 302 |
| 2026 | 205 |
| 2027 | 24 |
| Total minimum lease payments | \$ 531 |
| Less: effects of discounting | (135) |
| Present value of future minimum lease payments | 396 |
| Less: current lease liability, included in accrued expenses and other | (240) |
| Non-current lease liability, included in other non-current liabilities | \$ 156 |

As of December 31, 2024, the weighted average remaining lease terms of the Company's financing leases was 1.7 years. As of December 31, 2024 the weighted average discount rate used to determine the financing lease liabilities was 10.7%.

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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 Estrogen with Methyltestosterone (“EEMT”), Opium Tincture, Thyroid Tablets, and Hyoscyamine are marketed without approved NDAs or ANDAs. 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. During the years ended December 31, 2024, 2023, and 2022, net revenues from the commercial sales of these products totaled \$22.4 million, \$22.4 million, and \$14.2 million, respectively. Before acquisition of Hyoscyamine, contract manufacturing revenues for Hyoscyamine, for the years ended December 31, 2024, 2023, and 2022 were \$0.1 million, \$1.9 million and \$2.6 million, respectively.

The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled “Marketed New Drugs without Approved NDAs or ANDAs.” Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness.

The Company believes that, so long as it complies with applicable manufacturing standards, the FDA will continue to operate on a risk-based approach and will not take action against us. However, the Company can offer no assurance that the FDA will continue to follow this approach or that it will not take a contrary position with any individual product or group of products. If the FDA were to move away from the risk-based approach to enforcement against marketing of unapproved products, ANI may be required to seek FDA approval for these products or withdraw such products from the market. If the Company decides to withdraw the products from the market, net revenues for generic pharmaceutical products could decline materially, and if the Company decides to seek FDA approval, it would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that it would receive such approval.

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 the Company believes that it 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. The Company intends to vigorously prosecute and/or defend these matters, as appropriate; however, from time to time, ANI may settle or otherwise resolve these matters on terms and conditions that it believes are in the Company's 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.

Unless otherwise disclosed, the Company is unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. The Company records accruals for loss contingencies to the extent it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

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From time to time, the Company may also be 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, ANI will disclose such matters.

Furthermore, like many pharmaceutical manufacturers, the Company is periodically exposed to product liability claims. The prevalence of these claims could limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial condition, and operating results. Recent trends in the product liability and director and officer insurance markets is to exclude matters related to certain classes of drugs. Our policies have been subject to such exclusions which place further potential risk of financial loss on us.

Legal fees for litigation-related matters are expensed as incurred and included in the consolidated statements of operations under the selling, general, and administrative expense line item.

Commercial Litigation

On December 3, 2020, class action complaints were filed against the Company on behalf of putative classes of direct and indirect purchasers of the drug Bystolic. On December 23, 2020, six individual purchasers of Bystolic, CVS, Rite Aid, Walgreen, Kroger, Albertsons, and H-E-B, filed complaints against the Company. On March 15, 2021, the plaintiffs in these actions filed amended complaints. All amended complaints were substantively identical. The plaintiffs in these actions alleged that, beginning in 2012, Forest Laboratories, the manufacturer of Bystolic, entered into anticompetitive agreements when settling patent litigation related to Bystolic with seven potential manufacturers of a generic version of Bystolic: Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, Watson, and various of their corporate parents, successors, subsidiaries, and affiliates. ANI itself was not a party to patent litigation with Forest concerning Bystolic and did not settle patent litigation with Forest. The plaintiffs named the Company as a defendant based on the Company's January 8, 2020 Asset Purchase Agreement with Amerigen. Under the terms of the 2020 Asset Purchase Agreement, Amerigen agreed to indemnify ANI for certain liabilities relating to Bystolic, including liabilities that arose prior to closing of the asset purchase. The complaints alleged that the 2013 patent litigation settlement agreement between Forest and Amerigen violated federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs alleged they paid higher prices as a result of delayed generic competition. Plaintiffs sought damages, trebled or otherwise multiplied under applicable law, injunctive relief, litigation costs and attorneys' fees. The complaints did not specify the amount of damages sought from the Company or other defendants and the Company. The cases were consolidated in the United States District Court for the Southern District of New York. On April 23, 2021, the Company and other defendants filed motions to dismiss the amended complaints. On January 24, 2022, the court dismissed all claims brought by the plaintiffs without prejudice. The court granted the plaintiffs until February 22, 2022 to file amended complaints, which were filed in federal court in the Southern District of New York, on that date. The newly amended complaints contained substantially similar claims. On April 19, 2022, the Company and other defendants filed motions to dismiss the newly amended complaints. After full briefing and oral argument, on February 21, 2023, the court granted the Company and the defendants' motion to dismiss all actions with prejudice. Plaintiffs filed an appeal in the Second Circuit. On May 13, 2024, the Second Circuit affirmed the district court's judgment, dismissing plaintiffs' claims with prejudice.

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On March 4, 2024, ANI commenced a civil action against CG Oncology, Inc. f/k/a Cold Genesys, Inc. (“CG Oncology”) in the Superior Court of the State of Delaware (“Delaware Action”). ANI’s complaint alleges that, under an Assignment and Technology Transfer Agreement dated as of November 15, 2010 (the “November 2010 Agreement”), CG Oncology is liable to pay ANI a running royalty of 5% of the worldwide net sales of cretostimogene made by CG Oncology or any affiliate or sublicensee thereof; and that in February 2024, CG Oncology wrongfully repudiated its royalty obligation to ANI. On April 2, 2024, CG Oncology filed an answer and counterclaim (the “CGON Answer and Counterclaim”) and concurrently moved for judgment on the pleadings or, in the alternative, for partial summary judgment (the “Motion for Summary Judgment”). CG Oncology’s Motion for Summary Judgment seeks judgment declaring that the November 2010 Agreement does not “oblige CGON to pay royalties after expiration of the latest-running assigned patent.” CG Oncology also seeks judgment awarding compensatory damages and punitive damages on counterclaims for alleged breach of the November 2010 Agreement and for alleged misappropriation of trade secrets under federal and Delaware state law. On April 22 and 25, 2024, ANI filed its reply to CG Oncology’s counterclaims, denying any liability to CG Oncology and asserting additional counterclaims against CG Oncology (“Reply Counterclaims”) for alleged breach of the November 2010 Agreement and, in the alternative, for unjust enrichment. ANI’s Reply Counterclaims seek judgment (i) declaring that, under Section 3.3 of the November 2010 Agreement, CG Oncology is contractually obligated to pay ANI 5% of the worldwide net sales of cretostimogene made by CG Oncology or any affiliate or sublicensee thereof; (ii) dismissing CG Oncology’s counterclaims with prejudice; (iii) awarding ANI compensatory damages as provided by law, including damages grounded in restitution and unjust enrichment; (iv) in the event of a judgment in ANI’s favor on ANI’s fourth counterclaim for unjust enrichment, ordering CG Oncology to re-transfer to ANI ownership of all assets that ANI sold to CG Oncology under the November 2010 Agreement, including, without limitation, all data and documentation comprising IND 12154; and (v) in the event of a judgment in ANI’s favor on ANI’s fourth counterclaim for unjust enrichment, imposing a constructive trust on all fruits of CG0070-related assets that ANI sold to CG Oncology under the November 2010 Agreement including, without limitation, all data and documentation comprising IND 12154 and any other IND that CG Oncology may have for CG0070. On May 15, 2024, CG Oncology filed a reply to ANI’s counterclaims, which generally maintains the positions in the CGON Answer and Counterclaim. The parties are currently engaged in pretrial fact discovery. On August 22, 2024, the court heard the parties’ oral arguments in a hearing on CG Oncology’s Motion for Summary Judgment. On November 18, 2024, the court issued its decision denying CG Oncology’s Motion for Summary Judgment. The deadline for submitting amendments or supplements to the pleadings has passed. The court entered the case management order on January 16, 2025 and trial is scheduled to commence on July 21, 2025. ANI intends to vigorously pursue this matter.

On March 5, 2024, a complaint was filed against ANI by Acella Pharmaceuticals, LLC, in the United States District Court of Minnesota, asserting, among other things, false advertising under the Lanham Act, and unfair trade practices and false advertising under Minnesota law, relating to ANI’s natural desiccated thyroid tablets USP. The complaint seeks injunctive relief, actual and consequential damages, disgorgement of profits, and attorneys’ fees and costs. On April 16, 2024, ANI filed an answer to Acella’s complaint, denying all claims, and asserting certain affirmative defenses, and counterclaims against Acella for false advertising of its thyroid product marketed as NP Thyroid® Tablets, under the Lanham Act, common law unfair competition and unfair and deceptive trade practices and false advertising under Minnesota and Georgia law. ANI seeks injunctive relief, compensatory damages, punitive damages and attorneys’ fees and costs. On May 17, 2024, Acella filed a motion to dismiss ANI’s counterclaims. On June 7, 2024, ANI filed an amended answer to Acella’s complaint and counterclaims. Acella filed a motion to dismiss ANI’s amended counterclaims on July 31, 2024. A hearing was held on September 11, 2024 on Acella’s motion to dismiss. On December 18, 2024, the court issued an order denying Acella’s motion. The parties have been unable to reach a settlement and have agreed to an extension for fact discovery until July 1, 2025. Trial is currently scheduled to begin as early as April 2026. ANI disputes any liability in this matter and intends to defend this lawsuit vigorously.

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Patent Litigation

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

On December 27, 2024, a complaint was filed against Novitium by Athena Bioscience, LLC ("Athena") in the United States District Court for the District of Delaware, asserting, among other things, that Novitium's proposed tramadol hydrochloride solution drug product, which is subject to Novitium's Abbreviated New Drug Application, infringes certain U.S. patents owned by Athena. The complaint seeks damages, injunctive relief, attorneys' fees and costs. Novitium disputes any liability in this matter.

Ranitidine Related Litigation

Federal Court Multi District Litigation

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

ANI and Novitium dispute any liability in this matter.

State Court Personal Injury Litigation

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

California. The pending cases in California state court naming generic ranitidine manufacturers were transferred to an existing civil case coordination docket for pretrial proceedings (JCCP) in Alameda County. On September 21, 2023, plaintiffs filed a master complaint in the JCCP alleging strict liability, negligent failure to warn and general negligence, but not naming any generic defendants. Plaintiffs filed an amended master complaint on April 29, 2024 and filed a second amended master complaint on July 2, 2024. Defendants filed omnibus demurrers to the complaint. Novitium is named in one third wave case. The court heard arguments for the demurrers on August 22, 2024 and issued its final ruling on August 28, 2024, allowing some counts to survive. The surviving counts as to generic defendants include strict liability (manufacturing defect) and general negligence (storage and transport, failure to warn and product containers). Novitium filed its answer to the second amended master complaint on September 6, 2024. Discovery is currently ongoing.

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In December 2023, the Keller Postman firm filed approximately 200 individual plaintiff short form complaints that name generic defendants. Novitium is named in 29 of the short form complaints which reference the claims for the master complaint, but Novitium has not been served. ANI is not named. On February 1, 2024, the generic defendants filed an omnibus demurrer challenging the sufficiency of the Keller Postman complaints, largely on the basis of preemption. On April 23, 2024, the California court sustained the demurrer in part, dismissing all design defect claims against the generic defendants with prejudice on preemption grounds, but the court otherwise granted plaintiffs an opportunity for leave to amend their other claims against the generic defendants. Plaintiffs filed amended short form complaints on September 20, 2024 and defendants filed responses on October 6, 2024. Pleadings are now closed and discovery is currently ongoing.

Pennsylvania. In September 2022, two complaints were filed naming Novitium as a defendant in Pennsylvania state court, Philadelphia County. On February 16, 2023, the Pennsylvania plaintiffs filed a consolidated long-form complaint against the generic defendants, Plaintiffs v. Actavis, et. al. Civil Action No. 1364. The long-form complaint names Novitium as a defendant. The long form complaint asserts causes of action for negligence, failure to warn, negligent storage and transportation, breach of express warranties, breach of implied warranties, negligent misrepresentation, fraud, strict products liability, wrongful death and survivor actions, and loss of consortium. The complaint includes a prayer for punitive damages. The generic defendants filed their preliminary objections to Plaintiffs' consolidated long-form generic complaint on March 20, 2023. The court dismissed all claims related to failure to warn/design defects on preemption grounds. The court also sustained the generics' preliminary objections relating to the counts of strict liability-design defect and breach of implied warranty to the extent Pennsylvania substantive law applies, effectively dismissing the generic defendants from the case unless and until a non-resident plaintiff names a generic in a short form complaint. Out of an abundance of caution, however, the generics, including Novitium, all filed answers to the long form complaint in June 2023. In January 2024, plaintiffs filed short form complaints naming generic defendants, including Novitium in one complaint. Generic defendants filed joint preliminary objections to the short form complaints based on preemption. The deadline for filing responses to these objections has passed. In addition, Novitium was not named in any amended short form complaint filed by plaintiffs

ANI and Novitium dispute any liability in these matters.

18. 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 and an aggregate purchase price of \$25.0 million on November 19, 2021. The Chairman of the Company's board of directors is an operating partner of Ampersand Capital Partners, an affiliate of the PIPE Investor.

Novitium

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

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A summary of payments to related parties is presented below:

| (in thousands) | Years Ended December 31, | | |
|--------------------------------|--------------------------|------------------|-----------------|
| | 2024 | 2023 | 2022 |
| Scitus Pharma Services | \$ 2,759 | \$ 3,646 | \$ 2,075 |
| SS Pharma LLC | 1,244 | 8,235 | 3,669 |
| Esjay Pharma LLC | 115 | — | 101 |
| SThree Chemicals Pvt Ltd | 11,428 | — | — |
| Nuray Chemical Private Limited | — | — | 1,110 |
| | <u>\$ 15,546</u> | <u>\$ 11,881</u> | <u>\$ 6,955</u> |

As of December 31, 2024, the outstanding balances due to Scitus was \$0.9 million. There was no outstanding balance due to SS Pharma, SThree, Nuray, or Esjay at December 31, 2024.

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.

19. SEGMENT REPORTING

An operating segment is defined as a component of an entity that engages in business activities from which it may recognize revenues and incur expense, its operating results are regularly reviewed by the entity's chief operating decision maker ("CODM") to make decisions about resources to be allocated to the segment and assess its performance, and its discrete financial information is available. The CODM for the Company is the Chief Executive Officer. The Company does not aggregate its operating segments for reporting purposes, and therefore, the reportable segments are the same as its operating segments.

Following the acquisition of Alimera and during the fourth quarter of 2024, the Company reorganized the segment information that is regularly provided to the chief operating decision maker which caused the identification of significant segment expenses to change. Therefore, the Company recasted prior period segment information to conform to the current-period presentation in accordance with the segment guidance at ASC 280-10-50-34.

The Company is now organized into two operating segments as follows:

- **Rare Disease and Brands** – Consists of two reporting units, Rare Disease and Brands. The Rare Disease unit consists of operations related to the development, manufacturing and marketing of proprietary branded pharmaceutical products, with a strategic focus on products used in the treatment of patients with rare disease conditions and consists of operations related to Cortrophin Gel, and from September 16, 2024, through December 31, 2024, ILUVIEN and YUTIQ. In addition, the Brands reporting unit includes a portfolio of approximately 16 brand products that are principally sold in highly genericized markets.

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- **Generics and Other** – Consists of operations related to the development, manufacturing, and marketing of generic pharmaceutical products including those sold through traditional wholesale and retail sales channels, sales of contract manufactured products, royalties on contract manufactured products, product development services, and other. As of December 31, 2024, this reporting segment was comprised of over 100 product families.

The CODM evaluates the performance of the Company as two operating segments based on revenues and Operating income (loss), exclusive of corporate expenses and other expenses not directly allocated or attributable to an operating segment. These expenses include, but are not limited to, certain management, legal, accounting, human resources, insurance, and information technology expenses, and transaction and integration expenses related to the acquisition of Alimera and other acquisitions.

The Company does not manage assets of the Company by operating segment and the 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:

| | Year Ended December 31, 2024 | | | |
|--|------------------------------|----------------------------|---------------------------------|--------------------|
| | Generics and Other | Rare Disease and Brands | Corporate and Unallocated | Total |
| Net Revenues | \$ 320,034 | \$ 294,342 | \$ — | \$ 614,376 |
| Cost of sales (excluding depreciation and amortization) | (168,371) | (81,839) | — | (250,210) |
| Research and Development | (30,519) | (14,062) | — | (44,581) |
| Selling, general, and administrative | (5,120) | (125,972) | (118,544) | (249,636) |
| Depreciation and amortization | — | — | (67,731) | (67,731) |
| Fair value adjustment | — | — | 619 | 619 |
| Gain on sale of building | — | — | 5,347 | 5,347 |
| Intangible asset impairment charge | — | — | (7,600) | (7,600) |
| Operating Income (Loss) | \$ 116,024 | \$ 72,469 | \$ (187,909) | \$ 584 |
| Unrealized gain on investment in equity securities | \$ — | \$ — | \$ 6,307 | 6,307 |
| Interest expense, net | — | — | (17,602) | (17,602) |
| Other expense, net | — | — | (4,033) | (4,033) |
| Loss on extinguishment of debt | — | — | (7,468) | (7,468) |
| Income (Loss) Before Expense (Benefit) for Income Taxes | \$ 116,024 | \$ 72,469 | \$ (210,705) | \$ (22,212) |

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| | Year Ended December 31, 2023 | | | |
|---|------------------------------|-------------------------|---------------------------|------------------|
| | Generics and Other | Rare Disease and Brands | Corporate and Unallocated | Total |
| Net Revenues | \$ 289,314 | \$ 197,502 | \$ — | \$ 486,816 |
| Cost of sales (excluding depreciation and amortization) | (152,739) | (28,774) | — | (181,513) |
| Research and Development | (28,197) | (6,089) | — | (34,286) |
| Selling, general, and administrative | (2,451) | (73,466) | (85,780) | (161,697) |
| Depreciation and amortization | — | — | (59,791) | (59,791) |
| Fair value adjustment | — | — | (1,426) | (1,426) |
| Restructuring activities | — | — | (1,132) | (1,132) |
| Operating Income (Loss) | \$ 105,927 | \$ 89,173 | \$ (148,129) | \$ 46,971 |
| Interest expense, net | — | — | (26,940) | (26,940) |
| Other expense, net | — | — | (159) | (159) |
| Income (Loss) Before Expense for Income Taxes | \$ 105,927 | \$ 89,173 | \$ (175,228) | \$ 19,872 |

| | Year Ended December 31, 2022 | | | |
|---|------------------------------|-------------------------|---------------------------|--------------------|
| | Generics and Other | Rare Disease and Brands | Corporate and Unallocated | Total |
| Net Revenues | \$ 235,237 | \$ 81,148 | \$ — | \$ 316,385 |
| Cost of sales (excluding depreciation and amortization) | (125,835) | (12,950) | — | (138,785) |
| Research and Development | (19,964) | (2,354) | — | (22,318) |
| Selling, general, and administrative | (3,963) | (55,306) | (64,775) | (124,044) |
| Depreciation and amortization | — | — | (56,972) | (56,972) |
| Fair value adjustment | — | — | (3,758) | (3,758) |
| Restructuring activities | — | — | (5,679) | (5,679) |
| Intangible asset impairment charge | — | — | (112) | (112) |
| Operating Income (Loss) | \$ 85,475 | \$ 10,538 | \$ (131,296) | \$ (35,283) |
| Interest expense, net | — | — | (28,052) | (28,052) |
| Other income, net | — | — | 670 | 670 |
| Income (Loss) Before Benefit for Income Taxes | \$ 85,475 | \$ 10,538 | \$ (158,678) | \$ (62,665) |

Geographic Information

The following depicts the Company's total revenue according to geographic location. The Company has ceased operations at the Oakville, Ontario, Canada location as of March 31, 2023. The revenue from the acquisition of Alimera is also included in the year ended December 31, 2024 in the table below. The majority of the assets of the Company are located in the United States. The Company's operations are also located in the United Kingdom, Ireland, India, and Portugal.

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

| (in thousands) Location of Operations | Years Ended December 31, | | |
|--|--------------------------|-------------------|-------------------|
| | 2024 | 2023 | 2022 |
| United States | \$ 604,989 | \$ 486,251 | \$ 312,427 |
| International | 9,387 | 565 | 3,958 |
| Total Revenue | <u>\$ 614,376</u> | <u>\$ 486,816</u> | <u>\$ 316,385</u> |

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

| (in thousands) | December 31, 2024 | December 31, 2023 |
|-----------------------------------|----------------------|----------------------|
| United States | \$ 54,730 | \$ 43,163 |
| International | 2,133 | 1,430 |
| Total property and equipment, net | <u>\$ 56,863</u> | <u>\$ 44,593</u> |

20. SUBSEQUENT EVENTS

On February 12, 2025, the Company granted RSA and PSU awards to officers and employees of the Company under the 2022 Plan. The Company granted 580,057 RSAs to employees and officers of the Company. These RSAs vest over four years. The Company granted 79,859 PSUs to employee and officers of the Company (74,421 to officers of the Company). PSU performance will be measured over three years from January 1, 2025 through December 31, 2027 and will cliff-vest contingent upon the achievement of specified performance objectives. PSUs granted to date vest over a three-year performance period. Additionally, on February 15, 2025, the Company granted 46,182 RSAs to new employees of the Company, which will vest over four years.

On February 27, 2025, the Company received written notice of non-renewal from EyePoint, effective May 31, 2025, of the YUTIQ Supply Agreement, dated May 17, 2023, by and among Alimera and EyePoint, under which EyePoint manufactures and supplies YUTIQ for ANI. The Company has submitted a PAS to the FDA seeking to add YUTIQ's indication of chronic NIU-PS to the ILUVIEN label.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Our management has carried out an evaluation, under the supervision and with the participation of our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of December 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.

Management’s Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company’s principal executive and principal financial officers and effected by a company’s board of directors, management, and other personnel to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our internal control over financial reporting includes those policies and procedures that:

- pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect transactions and dispositions of our assets
- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorizations of management and directors
- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of assets that could have a material effect on our consolidated financial statements

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) in Internal Control — Integrated Framework (2013). Based on this assessment, management has concluded that, as of December 31, 2024, our internal control over financial reporting is effective.

The scope of management's assessment of the effectiveness of internal control over financial reporting includes all of the Company's consolidated operations except for the operations of Alimera, which the Company acquired on September 16, 2024. Alimera's operations represent approximately 5% of the Company's consolidated revenues for the year ended December 31, 2024, and assets associated with Alimera's operations represent approximately 1% of the Company's consolidated assets, as of December 31, 2024.

Management has concluded that the Consolidated Financial Statements included in this Annual Report on Form 10-K present fairly, in all material respects, the Company’s financial position, results of operations and cash flows for the periods disclosed in conformity with U.S. GAAP.

Changes in Internal Control over Financial Reporting

On September 16, 2024, we completed the acquisition of Alimera. Other than the addition of Alimera's operations to our internal control over financial reporting and any related changes in control to integrate Alimera into ANI Pharmaceuticals, Inc., there has not been any change in the Company's internal control over financial reporting (as such term is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting. See Note 3 "Business Combination" of the consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information on this acquisition. There were no other changes in our internal control over financial reporting during the quarter ended December 31, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Trading Arrangements

During the fiscal quarter ended December 31, 2024, none of our directors or officers informed us of the adoption or termination of a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as those terms are defined in Regulation S-K, Item 408(a).

Non-Renewal of YUTIQ Supply Agreement

On February 27, 2025, the Company received written notice of non-renewal from EyePoint, effective May 31, 2025, of the YUTIQ Supply Agreement, dated May 17, 2023, by and among Alimera and EyePoint, under which EyePoint manufactures YUTIQ for ANI.

Under the YUTIQ Supply Agreement, EyePoint is responsible for manufacturing and exclusively supplying to the Company agreed-upon quantities of YUTIQ necessary for the Company to commercialize YUTIQ in the U.S. at certain cost plus amounts, subject to adjustments as set forth in the YUTIQ Supply Agreement. The YUTIQ Supply Agreement contains customary representations and warranties.

A copy of the YUTIQ Supply Agreement was filed as Exhibit 10.1 to the Alimera's Current Report on Form 8-K filed with the Securities and Exchange Commission on May 18, 2023. The above description of the YUTIQ Supply Agreement is qualified in its entirety by reference to such exhibit.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers, and Corporate Governance

The text of our Code of Ethics, which applies to our principal executive officer, principal financial officer, principal accounting officer or controller, and persons performing similar functions, is posted on our website, www.anipharma.com, under the "Governance" subsection of the "Investors" section of the site. We will disclose on our website amendments to, and, if any are granted, waivers of, our Code of Ethics for our principal executive officer, principal financial officer, or principal accounting officer, controller, or persons performing similar functions.

Information required by this item with respect to our directors will be set forth under the caption "Election of Directors" in our definitive proxy statement for our 2025 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Information required by this item with respect to our executive officers will be set forth under the caption "Executive Officers of the Company" in our definitive proxy statement for our 2025 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

To the extent required, information required by this item with respect to compliance with Section 16(a) of the Exchange Act will be set forth under the caption “Delinquent Section 16(a) Reports” in our definitive proxy statement for our 2025 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Information required by this item with respect to our audit committee, our audit committee financial expert, and any material changes to the way in which our security holders may recommend nominees to our Board of Directors will be set forth under the caption “Corporate Governance” in our definitive proxy statement for our 2025 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 11. Executive Compensation

Information required by this item with respect to executive compensation will be set forth under the caption “Executive Compensation” in our definitive proxy statement for our 2025 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Information required by this item with respect to security ownership of certain beneficial owners and management will be set forth under the captions “Security Ownership of Certain Beneficial Owners” and “Security Ownership of Directors and Executive Officers” and information relating to our equity compensation plans will be set forth under “Equity Compensation Plan Information” in our definitive proxy statement for our 2025 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Information required by this item with respect to certain relationships and related transactions and director independence will be set forth under the captions “Certain Relationships and Related Transactions” and “Corporate Governance” in our definitive proxy statement for our 2025 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services

Our independent registered public accounting firm is EisnerAmper LLP, West Palm Beach, Florida, Auditor Firm ID: 274.

Information required by this item with respect to principal accounting fees and services will be set forth under the caption “Ratification of Selection of Independent Registered Public Accountants” in our definitive proxy statement for our 2025 annual meeting, to be filed with the SEC pursuant to Regulation 14A no later than 120 days after the close of our fiscal year, and is incorporated herein by reference.

PART IV.

Item 15. Exhibits and Financial Statement Schedules

Documents filed as part of this report on Form 10-K:

(a) Financial Statements:

The consolidated balance sheets of the Registrant as of December 31, 2024 and 2023, the related consolidated statements of operations, statements of other comprehensive (loss) income, changes in stockholders’ equity, and cash flows for each of the years ended December 31, 2024, 2023, and 2022, the footnotes thereto, and the reports of EisnerAmper LLP, independent registered public accounting firm, are filed herewith.

(b) Financial Statement Schedules:

All schedules have been omitted because they are not applicable or the required information is included in the consolidated financial statements or notes thereto.

(c) Exhibits

Exhibits included or incorporated by reference herein: see Exhibit Index on page 155.

ANI PHARMACEUTICALS, INC.

**EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2024**

| Exhibit No. | Exhibit | Method of Filing |
|--------------------|--|--|
| 2.1 | Amended and Restated Agreement and Plan of Merger, dated as of April 12, 2013, by and among BioSante Pharmaceuticals, Inc., ANI Merger Sub, Inc. and ANIP Acquisition Company (1) | Incorporated by reference to Exhibit 2.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812) |
| 2.2 | Agreement and Plan of Merger dated March 8, 2021 by and among ANI Pharmaceuticals, Inc., Nile Merger Sub LLC, Novitium Pharma LLC, Esjay LLC, Chali Properties, LLC, Chad Gassert, Muthusamy Shanmugam and Thorappadi Vijayaraj and Shareholder Representative Services LLC as the representative of the Company Members | Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 9, 2021 (File No. 001-31812) |
| 2.3 | Agreement and Plan of Merger dated June 21, 2024, by and among ANI Pharmaceuticals, Inc., ANIP Merger Sup INC. and Alimera Sciences, Inc. (1) | Incorporated by reference to Exhibit 2.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2024 (File No. 001-31812) |
| 3.1 | Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of July 17, 2013, Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of June 1, 2012, and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 3.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013 (File No. 001-31812) |
| 3.2 | Second Amended and Restated Bylaws of ANI Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 3.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 6, 2023 (File No. 001-31812) |
| 3.3 | Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company, effective as of November 19, 2021. | Incorporated by reference to Exhibit 3.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 26, 2021 (File No. 001-31812) |
| 4.1 | Description of Securities | Incorporated by reference to Exhibit 4.1 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (File No. 001-31812) |
| 4.2 | Registration Rights Schedule to the Merger Agreement, effective as of November 19, 2021 | Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 26, 2021 (File No. 001-31812) |
| 4.3 | Indenture, dated as of August 13, 2024, between ANI Pharmaceuticals, Inc. and U.S. Bank Trust Company, National Association, as trustee | Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K filed on August 13, 2024 (File No. 001-31812) |
| 4.4 | Form of Certificate representing the 2.25% Convertible Senior Notes due 2029 (included as Exhibit A to Exhibit 4.3) | Incorporated by reference to Exhibit 4.2 to ANI's Current Report on Form 8-K filed on August 13, 2024 (File No. 001-31812) |

| Exhibit No. | Exhibit | Method of Filing |
|--------------------|--|--|
| 10.1* | Employment Agreement, entered into by the Company and Stephen P. Carey | Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K filed January 22, 2020 (File No. 001-31812) |
| 10.2* | Employment Agreement between Nikhil Lalwani and ANI Pharmaceuticals, Inc., dated July 24, 2020 | Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed August 3, 2020 (File No. 001-31812) |
| 10.3* | Employment Agreement between Muthusamy Shanmugam and the Company, dated as of March 8, 2021 and effective as of November 19, 2021. | Incorporated by reference to Exhibit 10.3 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 26, 2021 (File No. 001-31812) |
| 10.4* | Employment Agreement between and Christopher Mutz and the Company, dated February 10, 2021. | Incorporated by reference to Exhibit 10.26 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-31812) |
| 10.5* | Employment Agreement between Ori Gutwerg and the Company, dated January 15, 2021. | Incorporated by reference to Exhibit 10.27 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-31812) |
| 10.6* | Employment Agreement between Chad Gassert and the Company, dated March 8, 2021. | Incorporated by reference to Exhibit 10.28 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-31812) |
| 10.7* | Employment Agreement between Meredith Cook and the Company, dated June 21, 2022. | Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2022 (File No. 001-31812) |
| 10.8* | Employment Agreement between Krista Davis and ANI Pharmaceuticals, Inc. dated July 14, 2022. | Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 (File No. 001-31812) |
| 10.9 | Amendment No. 2 to Asset Purchase Agreement, dated as of July 10, 2015, Teva Pharmaceuticals, Inc. and ANI Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015 (File No. 001-31812) |
| 10.10 | Asset Purchase Agreement, dated as of September 18, 2015, between Merck Sharp & Dohme B.V. and ANI Pharmaceuticals, Inc. (2) | Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015 (File No. 001-31812) |
| 10.11 | Asset Purchase Agreement between Cranford Pharmaceuticals, LLC and ANI Pharmaceuticals, Inc. (2) | Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2016 (File No. 001-31812) |
| 10.12 | Asset Purchase Agreement between AstraZeneca AB, AstraZeneca UK Limited, and ANI Pharmaceuticals, Inc. (2) | Incorporated by reference to Exhibit 10.25 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (File No. 001-31812) |
| 10.13 | Asset Purchase Agreement between Amerigen Pharmaceuticals LTD. and ANI Pharmaceuticals, Inc. | Incorporated by reference to Exhibit 10.24 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (File No. 001-31812) |

| Exhibit No. | Exhibit | Method of Filing |
|--------------------|---|--|
| 10.14 | Credit Agreement, dated as of November 19, 2021 by and among the Company, certain of the Company's subsidiaries, as guarantors, Truist Bank, as Administrative Agent and other parties party thereto. | Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 26, 2021 (File No. 001-31812) |
| 10.15 | Equity Commitment and Investment Agreement, dated as of March 8, 2021, by and between the Company and Ampersand 2020 Limited Partnership | Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 9, 2021 (File No. 001-31812) |
| 10.16 | Sublicense Agreement, dated as of October 30, 2009, by and between ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., and Jazz Pharmaceuticals, Inc. (2) | Incorporated by reference to Exhibit 10.24 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-31812) |
| 10.17 | Master Product Development and Collaboration Agreement, dated as of July 11, 2011, by and among ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and RiconPharma LLC (2) | Incorporated by reference to Exhibit 10.25 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-31812) |
| 10.18 | Asset Purchase Agreement between Cranford Pharmaceuticals, LLC and ANI Pharmaceuticals, Inc. (2) | Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022 (File No. 001-31812) |
| 10.19 | Asset Purchase Agreement between Holmdel Pharmaceuticals, LP and ANI Pharmaceuticals, Inc. (2) | Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022 (File No. 001-31812) |
| 10.20* | ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan | Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A filed with the Commission on April 14, 2016 |
| 10.21* | ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan | Incorporated by reference Appendix A to ANI Pharmaceuticals, Inc.'s definitive proxy statement dated March 25, 2022 filed with the Securities and Exchange Commission on March 25, 2022 (File No. 001-31812) |
| 10.22* | Amended and Restated 2022 Stock Incentive Plan | Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A filed with the Commission on April 5, 2024 |
| 10.23* | Amended 2022 Stock Plan, Form of Restricted Stock Grant Agreement (Directors) | Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K filed on May 23, 2024 (File No. 001-31812) |
| 10.24* | Amended 2022 Stock Plan, Form of Restricted Stock Grant Agreement (Employees) | Incorporated by reference to Exhibit 10.3 to ANI's Current Report on Form 8-K filed May 23, 2024 (File No. 001-31812) |
| 10.25* | Amendment No. 2023-1 to ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan (including form of Performance Stock Unit Award Agreement) | Incorporated by reference to Exhibit 10.1 to ANI's Form S-8 filed on June 23, 2023 (File No. 001-31812) |

| Exhibit No. | Exhibit | Method of Filing |
|--------------------|--|--|
| 10.26* | Amendment No. 2024-2 to ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan | Incorporated by reference to Exhibit 10.24 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (File No. 001-31812) |
| 10.27* | ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan Sub-Plan for U.K. Employees | Incorporated by reference to Exhibit 10.4 to ANI's Quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2024 (File No. 001-31812) |
| 10.28* | ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan Notice of Restricted Stock Grant | Incorporated by reference to Exhibit 10.5 to ANI's Quarterly report on Form 10-Q for the fiscal quarter ended September 30, 2024 (File No. 001-31812) |
| 10.29* | Form of Restricted Stock Grant Agreement | Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement for the 2022 Virtual Annual Meeting filed on March 25, 2022 (File No. 001-31812) |
| 10.30* | Form of Stock Option Agreement | Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement for the 2022 Virtual Annual Meeting filed on March 25, 2022 (File No. 001-31812) |
| 10.31* | Inducement Stock Option Award Agreement, effective as of September 8, 2020, between ANI Pharmaceuticals, Inc. and Nikhil Lalwani | Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020 (File No. 001-31812) |
| 10.32* | ANI Pharmaceuticals, Inc. Executive Incentive Bonus Plan | Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed on February 28, 2022 (File No. 001-31812) |
| 10.33 | Amendment No. 1 to the Credit Agreement, dated as of July 3, 2023 by and among the Company, and Truist Bank, as Administrative Agent. | Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2023 (File No. 001-31812) |
| 10.34 | Underwriting Agreement, dated May 11, 2023, by and between ANI Pharmaceuticals, Inc. and Guggenheim Securities, LLC | Incorporated by reference to Exhibit 1.1 to ANI's Current Report on Form 8-K filed on May 12, 2023 (File No. 001-31812) |
| 10.35 | Assignment and Technology Transfer Agreement between BioSante Pharmaceuticals, Inc. and Cold Genesys, Inc., dated as of November 15, 2010 | Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2024 (File No. 001-31812) |
| 10.36 | Voting Agreement, dated June 21, 2024, by and among ANI Pharmaceuticals, Inc., Alimera Sciences, Inc. and Caligan Partners LP, Caligan Partners Master Fund LP and Caligan Partners CV VI LP | Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed on June 24, 2024 (File No. 001-31812) |
| 10.37 | Form of Capped Call Transaction Confirmation | Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed on August 13, 2024 (File No. 001-31812) |

| Exhibit No. | Exhibit | Method of Filing |
|--------------------|--|---|
| 10.38† | Credit Agreement, dated as of August 13, 2024, among ANI Pharmaceuticals, Inc., ANIP Acquisition Company, the guarantors party thereto., JPMorgan Chase Bank, N.A., as administrative agent, and other financial institutions as lenders | Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K filed on August 13, 2024 (File No. 001-31812) |
| 10.39 | Contingent Value Rights Agreement dated September 16, 2024, by and between ANI Pharmaceuticals, Inc. and Continental Stock Transfer & Trust Company | Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed on September 20, 2024 (File No. 001-31812) |
| 10.40 | Agreement of Purchase and Sale between ANI Pharmaceuticals Canada, Inc. and 1540700 Ontario Limited | Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed on February 23, 2024 (File No. 001-31812) |
| 10.41 | Purchase and Sale Agreement between ANI Pharmaceuticals Canada Inc. and Mastercom Inc. | Incorporated by reference to Exhibit 10.31 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (File No. 001-31812) |
| 10.42 | Amendment to Purchase and Sale Agreement between ANI Pharmaceuticals Canada Inc. and Mastercom Inc. | Incorporated by reference to Exhibit 10.32 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (File No. 001-31812) |
| 10.43 | Notice of Termination of Purchase and Sale Agreement between ANI Pharmaceuticals Canada Inc. and Mastercom Inc. | Incorporated by reference to Exhibit 10.33 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (File No. 001-31812) |
| 10.44 | Form of Indemnification Agreement | Incorporated by reference to Exhibit 10.34 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (File No. 001-31812) |
| 19.1 | ANI Pharmaceuticals, Inc. Insider Trading Policy | Filed herewith |
| 21 | List of subsidiaries | Filed herewith |
| 23.1 | Consent of EisnerAmper LLP | Filed herewith |
| 31.1 | Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14 | Filed herewith |
| 31.2 | Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14 | Filed herewith |
| 32.1 | Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | Furnished herewith |
| 97.1 | ANI Pharmaceuticals, Inc. Amended and Restated Clawback Policy | Incorporated by reference to Exhibit 97.1 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (File No. 001-31812) |

| Exhibit No. | Exhibit | Method of Filing |
|--------------------|--|-------------------------|
| 101 | The following financial information from this annual report on Form 10-K for the fiscal year ended December 31, 2024, formatted in Inline XBRL: (i) the audited consolidated Balance Sheets, (ii) the audited consolidated Statements of Operations, (iii) the audited consolidated Statements of Comprehensive Income, (iv) the audited consolidated Statements of Mezzanine Equity and Stockholders' Equity; (v) the audited consolidated Statements of Cash Flows, and (vi) Notes to consolidated Financial Statements. | Filed herewith |
| 104 | The cover page from the Company Annual Report on Form 10-K for the year ended December 31, 2024 formatted in inline XBRL (included in Exhibit 101) | Filed herewith |

(1) All exhibits to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. ANI will furnish the omitted exhibits to the SEC upon request by the SEC.

(2) Confidential treatment has been granted with respect to redacted portions of this document or certain information has been omitted from this exhibit in accordance with Regulation S-K Item 601(b)(10)(iv). The Company agrees to furnish supplementally a copy of any omitted information to the Securities and Exchange Commission upon its request.

* Management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K pursuant to Item 15(a).

† Certain schedules and certain exhibits to this exhibit have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished supplementally to the SEC upon request; provided, however, that the parties may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any document so furnished.

Item 16. Form 10-K Summary

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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.

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

Date: February 28, 2025

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

Date: February 28, 2025

Pursuant to the requirements the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

| Name | Capacity | Date |
|---|--|-------------------|
| <u>/s/ Nikhil Lalwani</u> Nikhil Lalwani | Director, President, and Chief Executive Officer (principal executive officer) | February 28, 2025 |
| <u>/s/ Stephen P. Carey</u> Stephen P. Carey | Senior Vice President, Finance and Chief Financial Officer (principal financial and accounting officer) | February 28, 2025 |
| <u>/s/ Muthusamy Shanmugam</u> Muthusamy Shanmugam | Director, Head of Research and Development and Chief Operating Officer of New Jersey Operations | February 28, 2025 |
| <u>/s/ Patrick D. Walsh</u> Patrick D. Walsh | Director and Chairman of the Board of Directors | February 28, 2025 |
| <u>/s/ Thomas J. Haughey</u> Thomas J. Haughey | Director | February 28, 2025 |
| <u>/s/ Matthew J. Leonard</u> Matthew J. Leonard | Director | February 28, 2025 |
| <u>/s/ Jeanne Thoma</u> Jeanne Thoma | Director | February 28, 2025 |
| <u>/s/ Antonio Pera</u> Antonio Pera | Director | February 28, 2025 |
| <u>/s/ Renee Tannenbaum</u> Renee Tannenbaum | Director | February 28, 2025 |

Company Profile

ANI Pharmaceuticals, Inc. (NASDAQ: ANIP) is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. Our objective is to build a sustainable and growing biopharmaceutical company serving patients in need and creating long-term value for our investors. Our overall strategy is enabled by an empowered, collaborative, and purposeful team with high performance-orientation that seeks to deliver on our purpose of “Serving Patients, Improving Lives.” For more information, please visit our website www.anipharma.com.

Cautionary Note Regarding Forward Looking Statements

This report, and the documents incorporated by reference herein, may contain forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995. These statements are based on the beliefs and assumptions of management. Although the Company believes that its plans, intentions, and expectations reflected in or suggested by these forward- looking statements are reasonable, the Company cannot assure you that it will achieve or realize these plans, intentions, or expectations. Forward-looking statements are inherently subject to risks, uncertainties, and assumptions. Generally, statements that are not historical facts, including 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, pipeline or potential markets for our products, selling and marketing strategies and associated costs to support the sales of our approved products, including Cortrophin Gel, ILUVIEN and YUTIQ, impact of accounting principles, litigation expenses, liquidity and capital resources, our indebtedness and liabilities, risks related to our acquisitions and investments are forward-looking statements. In some instances, these statements may be preceded by, followed by or include the words “anticipates,” “will,” “expects,” “plans,” “potential,” “future,” “believes,” “intends,” “continue,” other words of similar meaning, derivations of such words, and the use of future dates.

Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements which speak only as of the date hereof. You should understand that the following important factors, among others, could affect the Company’s future results and could cause those results or other outcomes to differ materially from those expressed or implied in the Company’s forward-looking statements: the ability of the Company to grow and manage growth profitably, maintain relationships with customers, compete within its industry and retain its key employees; the possibility that the Company may be adversely impacted by other economic, business, and/or competitive factors; the outcome of any legal proceedings that may be instituted against the Company or others; future exchange and interest rates; and other risks and uncertainties indicated in this report, including those under “Risk Factors” herein, and other filings that have been made or will be made with the SEC.

These and other factors that could cause actual results to differ from those implied by the forward- looking statements in this report are more fully described in the “Risk Factors” section. The risks described in “Risk Factors” are not exhaustive. New risk factors emerge from time to time and it is not possible for us to predict all such risk factors, nor can the Company assess the impact of all such risk factors on its business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements attributable to the Company or persons acting on its behalf are expressly qualified in their entirety by the foregoing cautionary statements. The Company undertakes no obligations to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

