
# 2025 Annual Report

www.anipharmaceuticals.com

## CORPORATE INFORMATION

### BOARD OF DIRECTORS

**Thomas Haughey**, Chairman of the Board
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.

**Patrick D. Walsh**, Director
Chairman, Alcami Corporation

### 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

### HEADQUARTERS

104 Carnegie Center Drive, Suite 300
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 21, 2026 via webcast through the link:
www.virtualshareholdermeeting.com/ANIP2026

### INVESTOR RELATIONS

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

### INDEPENDENT AUDITORS

Ernst & Young LLP
99 Wood Avenue South
Iselin, NJ 08830
Phone: (732) 516-4200

### 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

Ropes & Gray LLP
Pudential Tower
800 Boylston Street
Boston, MA 02199
Phone: (617) 951-7000

# 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, 2025**

## ☐ 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**<br>**Baudette, Minnesota** | **56623** |
| (Address of principal executive offices) | (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 30, 2025 was $1.3 billion (based upon the last reported sale price of $65.25 per share on June 30, 2025 on The Nasdaq Global Market).

As of February 20, 2026, 22,414,104 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 2026 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, 2025**
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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”). All statements other than statements of historical fact contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as “anticipates,” “may,” “will,” “should,” “could,” “expects,” “estimates,” “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 include, but are not limited to, statements concerning the following:

- our planned future operations, strategies and growth potential;
- our financial performance, including our estimates of our expenses and capital requirements, and our expectations regarding our revenue potential (including revenue from licensing, royalties and sales) of our products;
- our development pipeline, including the structure, focus, success, cost and timing of our development activities, including nonclinical studies and clinical trials, and the reporting of data from those activities;
- expected timeframes for the submission of new drug applications, abbreviated new drug applications, or supplemental new drug applications to the U.S. Food and Drug Administration (the “FDA”);
- our expectations regarding the size of patient populations, market acceptance and clinical utility of our products and product candidates, if approved;
- our manufacturing capabilities and our ability to comply with significant regulations with respect to the manufacture of our products or, where applicable, our reliance on third parties to do the same;
- supply chain and inventory expectations, and our and our partners’ ability to meet anticipated demand;
- selling and marketing strategies and associated costs to support the sales of our branded products, including Purified Cortrophin® Gel (Repository Corticotropin Injection USP) (“Cortrophin Gel”) and ILUVIEN® ("ILUVIEN");
- the success of competing therapies that are or may become available;
- our strategic initiatives, including acquisitions, strategic alliances and collaborations, and our ability to realize the intended benefits of such initiatives;
- our ability to attract and retain key personnel;
- our expectations and uncertainties regarding future pricing, coverage and reimbursement for our products;
- the impact of new or modified laws or regulations, and the application or implementation thereof, including the One Big Beautiful Bill Act (the “Act”), and tax, healthcare and pharmaceutical laws and regulations in the U.S. and foreign jurisdictions;
- our ability to obtain, protect and enforce our intellectual property; and
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or the impact of global pandemics on our business.

Any forward-looking statements in this Annual Report on Form 10-K are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Forward-looking statements are inherently subject to known and unknown risks, uncertainties and other factors, some of which cannot be predicted or quantified, that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed under Part I, Item 1A, “Risk Factors” and elsewhere in this Annual Report on Form 10-K, as well as in our other periodic reports filed with the United States (“U.S.”) Securities and Exchange Commission (the “SEC”). Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for management to predict all risk factors, nor can we assess the impact of all risk factors on our 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. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Except as required by law, we assume no obligation to update or revise these forward-looking statements for any reason, even if new information becomes available in the future.

**NOTE REGARDING TRADEMARKS**

Cortenema®, Purified Cortrophin® Gel, Inderal® LA, ILUVIEN®, Inderal® XL, InnoPran XL®, Inzirqo®, Kionex®, Lithobid®, Reglan®, SOVUNA®, Tezruly®, Vancocin®, Veregen®, and YUTIQ® are registered trademarks subject to trademark protection and are owned by ANI Pharmaceuticals. Cortrophin-Zinc™ is a trademark owned by ANI Pharmaceuticals 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 is licensed to ANI Pharmaceuticals for U.S. sales of Oxistat® Lotion. Solely for convenience, trademarks referred to in this Annual Report on Form 10-K may appear without the ® or ™ symbols, but any such references are not intended to indicate, in any way, that we will not assert our rights or the right of the applicable licensor to these trademarks to the fullest extent under applicable law. This Annual Report on Form 10-K may also contain trademarks or trade names of other parties, and we do not intend our use or display of other parties' trademarks or trade names to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

## PART I

### Item 1. Business

ANI Pharmaceuticals is a diversified bio-pharmaceutical company. The Company's mission is “Serving Patients, Improving Lives” by developing, manufacturing, and commercializing therapeutics through its Rare Disease, Generics, and Brands businesses.

On September 16, 2024, the Company acquired Alimera Sciences, Inc. ("Alimera"). In connection with the acquisition, the Company added two new products, ILUVIEN® ("ILUVIEN") and YUTIQ® ("YUTIQ"). 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.

During March 2025, the FDA approved an expanded label for ILUVIEN to include an indication for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye ("NIU-PS") in addition to the then-current indication of Diabetic Macular Edema ("DME"). The Company is currently marketing ILUVIEN for both indications in the U.S. ILUVIEN was already approved for both DME and NIU-PS outside the U.S., including in seventeen European countries. During the second quarter of 2025, the Company transitioned promotional efforts in the U.S. from YUTIQ to ILUVIEN with its combined label of DME and NIU-PS.

The Company owns and operates three pharmaceutical manufacturing facilities, including two facilities in Baudette, Minnesota and one in East Windsor, New Jersey, which collectively are capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. The Company ceased operations at another manufacturing facility in Oakville, Ontario as of March 31, 2023. 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 "2024 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 principal under the term loan facility to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the acquisition. As of December 31, 2025, $74.9 million is available for borrowing on the revolving credit facility, subject to the satisfaction of certain conditions. The term loan and the revolving credit facility each 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 were 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.

As of December 31, 2025, our Generics portfolio included more than 120 products with a wide variety of indications. Our diversified 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. We expect that our robust pipeline will continue to yield approximately 10 to 15 new product launches per year. We expect to continue to expand our Rare Disease and Brands offerings by addressing unmet needs across indications and evaluating opportunities to enhance patient convenience.

### 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 spend significant time, effort and resources in expanding our Rare Disease and Brands segment which consists of our Rare Disease and Brands portfolio of products.

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

On February 28, 2025, the FDA approved a prefilled syringe format for Cortrophin Gel. This new presentation became available in 40 USP units/0.5 mL and 80 USP units/mL single-dose options through Cortrophin Gel’s established specialty pharmacy network during the second quarter of 2025. The prefilled syringe reduces administration steps for patients using Cortrophin Gel, which remains available in 5 mL and 1 mL vials.

During 2026, we plan to build a dedicated sales organization focused on acute gouty arthritis flares, an indication unique to Cortrophin Gel within the ACTH class. We anticipate that our dedicated sales force will focus on the appropriate patient population through podiatry and primary care physicians, while our existing sales organization will continue to focus on appropriate acute gouty arthritis flare patients seen by rheumatologists and nephrologists.

In September 2024, we acquired ILUVIEN and YUTIQ (together, the "Retina Franchise") in connection with the acquisition of Alimera. The acquisition of Alimera strengthened our Rare Disease business and expanded our footprint beyond the U.S. through Alimera’s direct marketing operations in Germany, the United Kingdom ("UK"), Portugal, and Ireland, as well as its partnerships in Europe, Asia, and the Middle East. We believe that the Retina Franchise is durable with high barriers to genericization and a clear role for patients in need of alternative therapeutic options. Importantly, the addition of Alimera expanded the reach of the ophthalmology sales team and we believe there will be significant overlap between high potential prescribers of Cortrophin Gel and the Retina Franchise.

As noted above, during March 2025, the FDA approved an expanded label for ILUVIEN (fluocinolone acetonide intravitreal implant) to include an indication for the treatment of chronic NIU-PS in addition to the then-current indication of DME. During the second quarter of 2025, we transitioned promotional efforts in the U.S. from YUTIQ to ILUVIEN with its combined label of DME and NIU-PS.

We plan to continue to expand our Rare Disease business, through a combination of organic growth and acquisitions. While we execute against our strategic initiatives that we believe will result in 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 Rare Disease and Brands segment is comprised of various branded products. We have grown our Brands portfolio of products through acquisitions. We have acquired the NDAs for and market Atacand, Atacand HCT, Arimidex, Casodex, Inderal LA, Inderal XL, InnoPran XL, Inzirqo, Lithobid, Oxistat, Vancocin, 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***

We plan to strengthen our Generics and Other segment through continued investment in our research and development capabilities 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 Pharma LLC ("Novitium") in 2021, which included Novitium's 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 ("PIV"), and competitive generic therapy (“CGT”) designation filings.

Additionally, we plan to continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses.

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 and competitive environment for that product. 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.

**Products**

A complete list of our generic and branded pharmaceutical products and descriptions is posted on our website, www.anipharmaceuticals.com. Information on, or accessible through, our website is not a part of, and is not incorporated into, this report or any other SEC filing.

**Manufacturing, Suppliers, and Raw Materials**

Our manufacturing procedures and operations must conform to FDA requirements and guidelines, generally referred to as current good manufacturing practice ("cGMP"), which govern all aspects of the production process. Our facilities, procedures, operations, and testing of products are subject to periodic inspection by the FDA, the U.S. Drug Enforcement Agency ("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 product specifications, cGMP and other FDA regulations. Our suppliers are subject to similar regulations and periodic inspections.

Several of our key products, including injectables, softgel capsules, Cortrophin Gel, and ILUVIEN, 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.

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 generally is required to be approved by the FDA through a prior approval supplement ("PAS"). Generally, the process of obtaining approval of a PAS can take between six and nine months, and could take an additional eight to ten months if additional information is required to be submitted by the FDA. 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. We do not have in-house manufacturing capabilities for the production of Cortrophin Gel or ILUVIEN, and thus we depend, and expect to continue to depend, exclusively on third-party contract manufacturers to manufacture and package these products.

***Government Regulation***

The research, development, testing, manufacturing, labeling, advertising, promotion, distribution, packaging, storage, exportation and marketing of our products are subject to extensive regulation by governmental authorities in the U.S. and in other countries in which we sell our products.

A new drug generally must be approved by the FDA or by comparable foreign regulatory authorities before it may be legally marketed in the U.S. and in foreign jurisdictions. Generally, prescription pharmaceutical products distributed in the U.S., whether branded or generic, must be approved by the FDA through the NDA, 505(b)(2) New Drug Application ("505(b)(2) NDA") or ANDA processes. Similar application processes exist in foreign jurisdictions. However, we also market certain of our products without approved NDAs or ANDAs (see "Regulation of Unapproved Products") below.

We, along with any third-party contractors, are required to comply with the various preclinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our products and product candidates. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources.

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 relating to our industry, as has occurred since 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, we cannot be certain 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.

***Regulation in the U.S.***

*The Drug Approval Process*

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 rate and extent at which the duplicate (or "generic") drug becomes available in the bloodstream (or other site of drug action) in healthy volunteers and thereby demonstrating "bioequivalence" to the RLD. An approved ANDA provides marketing authorization 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 process required to obtain FDA approval to market a new drug in the U.S. generally requires that a sponsor complete nonclinical laboratory tests, animal studies and formulation studies under the FDA's Good Laboratory Practice ("GLP") regulations and other applicable laws or regulations; for NDAs and 505(b)(2) NDAs, conduct clinical testing in humans pursuant to an investigational new drug application ("IND") and in accordance with FDA's Good Clinical Practices ("GCP"); develop manufacturing processes to ensure the product's identity, strength, quality, purity, and potency; prepare and submit a marketing application to the FDA, which includes information relating to product formulation, raw material suppliers, analytical testing, stability, manufacturing processes, packaging, labeling, and quality control; successfully undergo an FDA inspection of the manufacturing facility or facilities where the product is produced to assess compliance with cGMP and potential inspection of selected clinical investigation sites to assess compliance with GCPs; and receive FDA approval of the marketing application to permit commercial marketing of the product for particular indications for use.

*Clinical Trials*

Clinical trials involve the administration of an investigational product to human subjects under the supervision of qualified investigators. Clinical trials must be conducted in accordance with protocols detailing objectives, safety parameters, effectiveness criteria, human subject protections, and statistical analysis plans, as well as GCP requirements. Prior to initiating a clinical trial, the trial sponsor must submit the proposed clinical study protocol, together with nonclinical study results, manufacturing information, analytical data, and any available clinical data or literature, to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans and must become effective before human clinical trials may begin. Furthermore, each clinical trial must be reviewed and approved by an Institutional Review Board ("IRB") for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trial are minimized and are reasonable in relation to anticipated benefits.

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. Certain clinical trial information must be submitted within specified timeframes for publication on the www.clinicaltrials.gov website.

The purpose of a clinical trial is to generate the data necessary to demonstrate the safety of the product candidate for its intended use, establish the overall risk-benefit profile of the product candidate and provide an adequate basis for physician labeling.

*NDA Approval Process*

Following the completion of clinical trials, the results of nonclinical studies and clinical trials may be submitted to the FDA as part of an NDA, along with proposed labeling, chemistry, and manufacturing information to ensure product quality and other relevant data. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the product candidate to the satisfaction of the FDA. 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.

Before approving an NDA, the FDA will typically conduct a pre-approval inspection of the manufacturing facilities for the new product to determine whether the facilities comply with cGMP requirements and are adequate to assure consistent production of the product within required specifications. The FDA also may audit data from clinical trials to ensure compliance with GCP requirements. The FDA may refer applications for novel products or products which present difficult questions of safety or efficacy to an advisory committee of expert advisors for review, evaluation and a non-binding recommendation as to whether the application should be approved and under what conditions, if any.

After the FDA evaluates an NDA, it will grant marketing approval, request additional information or issue a complete response letter ("CRL") outlining the deficiencies in the submission. The CRL may require additional testing or information, including additional nonclinical or clinical data, for the FDA to reconsider the NDA. Even if such additional information and data are submitted, the FDA may decide that the NDA still does not meet the standards for approval. If the FDA grants approval, it issues an approval letter that authorizes commercial marketing of the product with specific prescribing information for specific indications.

*Abbreviated New Drug Application Development and Approval Process*

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"). To support marketing approval, an ANDA generally must contain information to show that the product candidate is the same as the approved product with respect to API, conditions of use, route of administration, dosage form, strength, and labeling, with certain permissible differences, and is the bioequivalent of the approved drug.

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.

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.

**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.

*Section 505(b)(2) NDA Development and Approval Process*

505(b)(2) NDAs permit the submission of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. This pathway enables the applicant to rely upon certain published nonclinical or clinical studies conducted for an approved product or the FDA's findings of safety and efficacy for a previously approved existing product. The FDA may require applicants to perform additional studies or measurements to support any changes from the approved product, such as changes in new dosage form, strength, route of administration, formulation, or indication. The FDA may then approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the Section 505(b)(2) application. While references to nonclinical and clinical data not generated by the applicant or for which the applicant does not have a right of reference are allowed, all development, process, stability, qualification, and validation data related to the manufacturing and quality of the new product must be included in a 505(b)(2) NDA.

*Impact of Regulatory and Patent Protections on 505(b)(2) NDA and ANDA Approval*

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 PIV 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 PIV 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 PIV 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.

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 505(b)(2) or ANDA. Also, if the NDA drug is a new chemical entity ("NCE"), the FDA may not approve a 505(b)(2) or 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 505(b)(2) or ANDA that relies on the new clinical investigation for three years. Certain 505(b)(2) NDAs may also be eligible for three-year exclusivity for new clinical investigations. 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.

*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, such as if the latter product is shown to be clinically superior to the orphan product.

*Post-Approval Requirements*

After marketing approval of a 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.

If there are any modifications to the drug, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

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 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. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, including a new REMS, revisions to an existing REMS, or the conduct of post-marketing studies to assess a newly discovered safety issue. Product approvals may be withdrawn for non-compliance with regulatory standards, or if problems occur following initial marketing.

The Prescription Drug Marketing Act 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 U.S. Products subject to the DSCSA must only be transferred to appropriately licensed purchasers. 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. Prescription drug promotional materials must be submitted to the FDA in conjunction with their first use. Physicians may prescribe drugs off-label but manufacturers cannot promote such uses unless they have been previously authorized by the FDA.

We also are subject to various federal, state and local laws targeting fraud and abuse in the healthcare industry, including anti-kickback and false claims laws such as the federal Anti-Kickback Statute (the "AKS") and the federal civil False Claims Act ("FCA"). These laws regulate our interactions with healthcare providers, including prescribers, patients, third party payors and other individuals and entities in the healthcare space, and our government reporting of drug pricing and product information.

With respect to anti-kickback laws, the AKS generally prohibits, among other things, a pharmaceutical manufacturer from directly or indirectly soliciting, offering, receiving, or paying any remuneration in cash or in kind where one purpose is either to induce the referral of an individual for, or the purchase or prescription of, a particular drug that is payable by a federal health care program, including Medicare or Medicaid. A person or entity does not need to have actual knowledge of the statute or a specific intent to violate the statute. A claim arising from a violation of the AKS also constitutes a false or fraudulent claim for purposes of the FCA. Analogous federal and state laws exist. For example, another healthcare anti-kickback statute prohibits certain payments related to referrals of patients to certain providers (such as clinical laboratories) and applies to services reimbursed by private health plans as well as government health care programs.

Federal and state false claims laws generally prohibit anyone from knowingly and willfully, among other activities, presenting, or causing to be presented for payment to third party payors (including Medicare and Medicaid) claims for drugs or services that are false or fraudulent . The FCA, which may be enforced by the federal government or by private individuals (known as "whistleblowers") bringing suit on behalf of the government, has been used extensively to challenge the activities of pharmaceutical companies. FCA allegations in such actions have included violations of the AKS, noncompliant reporting of prices or other information under government price reporting programs, improper promotion of uses not expressly approved by the FDA in a product's label, and causing the submission of false information by healthcare providers to government health care programs to obtain product coverage. False claims laws are not always limited to activities involving government programs or payors. For example, a federal healthcare fraud statute prohibits the knowing and willful execution of, or attempt to execute, a scheme to defraud a health care benefit program, including private health plans, or obtain, through false or fraudulent pretenses, money or property owned by, or under the custody or control of, such a health care benefit program.

Other laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and health care providers; require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; require disclosure to the government and/or public of financial interactions (so-called "sunshine laws") and/or require registration of pharmaceutical representatives. State laws may also require disclosure of pharmaceutical pricing information and marketing expenditures. Manufacturers must also submit information to the FDA on the identity and quantity of drug samples requested and distributed by a manufacturer during each year.

Violations of federal and state fraud and abuse and other laws may be punishable by criminal or civil sanctions, including fines and civil monetary penalties, and/or exclusion from federal health care programs (including Medicare and Medicaid). Compliance is challenging in light of the scope, complexity and lack of clarity in laws and their implementation. The scope of the federal and the various analogous state anti-kickback, false claims, and similar fraud and abuse laws vary, but is generally broad. Many of the fraud and abuse laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Federal and state authorities are paying increased attention to enforcement of these laws within the pharmaceutical industry, and private individuals have been active in alleging violations of the laws and bringing suits on behalf of the government under the FCA as evidenced by numerous significant settlements. In light of these considerations, our activities could be subject to scrutiny and the imposition of penalties under the laws. If we were subject to allegations concerning, or were convicted of violating, these laws, our business could be harmed. See **"Risk Factors —** ***We may become subject to federal and state false claims litigation brought by private individuals and the government."***

***Regulation of 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 Schedule II 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."***

***Regulation of Unapproved Products***

Four of our 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 cannot be certain 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 2025, are marketed without approved NDAs or ANDAs and we cannot be certain 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 U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other organizations is critical to the commercial success of our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Within the U.S., no uniform policy for coverage and reimbursement exists across all payors. Coverage and reimbursement can differ significantly from payor to payor and be subject to change at any time. Most of our products are eligible for coverage by various government health benefit programs, as well as purchase by government agencies. We participate in various government programs to obtain coverage for our products. Such participation requires us to determine, certify and submit complex pricing calculations to federal agencies and to offer discounts to government programs, as well as government and private purchasers, with penalties for non-compliance. Private insurers may also impose coverage and reimbursement restrictions.

***Medicaid.*** Medicaid is a joint federal and state program that is administered by the states for low income, disabled, and other defined categories of beneficiaries. Our products are eligible to be reimbursed by Medicaid as we participate in the Medicaid Drug Rebate Program, under which participating manufacturers must pay a rebate for each unit of product reimbursed by state Medicaid programs. The amount of the rebate for each product is set by law and includes an additional rebate if certain reported prices increase faster than inflation. State Medicaid programs and Medicaid managed care plans can seek additional "supplemental" rebates from manufacturers in connection with favorable coverage (e.g., positioning on formularies).

***Medicare.*** Medicare is a program administered by the federal government that provides healthcare coverage to individuals age 65 and over, as well as those with certain disabilities. Some of our products are eligible for reimbursement under Medicare Part B. Medicare Part B generally covers drugs that must be administered by physicians. Medicare Part B generally pays for such drugs under a payment methodology based on the average sales price ("ASP") of the drugs. Some of our products are eligible for reimbursement under Medicare Part D. Medicare Part D generally provides coverage for self-administered drugs (i.e., drugs that do not need to be injected or otherwise administered by a physician). Medicare Part D is administered by private prescription drug plans under contract with and approved by the federal government. Each drug plan establishes its own government-approved Medicare Part D formulary for prescription drug coverage and pricing, which the drug plan may modify from time-to-time. The drug plans negotiate pricing with manufacturers and may determine formulary placement based on consideration of the availability of manufacturer discounts. Since 2011, manufacturers of branded drugs (which include any drug marketed under an NDA) and biologics have been required to participate in Medicare Part D discount programs in order for their products to be eligible for coverage under Medicare Part D. Effective January 1, 2025, a new manufacturer discount program Medicare Part D Manufacturer Discount Program ("MDP") took effect, requiring manufacturers to pay a discount of 10% of the reimbursement in the initial phase of the Part D benefit and 20% in the catastrophic phase of the benefit. Additionally, as the result of recent changes, drug utilization under Medicare Part B and Part D may be subject to an additional rebate if the pricing increases more than inflation.

***Federal Purchasers.*** Drug products are subject to discounted pricing when purchased by federal agencies via the Federal Supply Schedule ("FSS"). FSS participation is required for a drug product to be covered and reimbursed by certain federal agencies and for coverage under Medicaid, Medicare Part B and the Public Health Service ("PHS") 340B drug pricing program. FSS pricing is determined based, in part, on manufacturer-reported prices and is further negotiated periodically with the Department of Veterans Affairs. In addition, prices for drugs purchased by the Veterans Administration, Department of Defense (including drugs purchased by military personnel and dependents through the TRICARE retail pharmacy program), Coast Guard, and PHS are subject to a cap on pricing (known as the "federal ceiling price") and may be subject to an additional discount if pricing increases more than the rate of inflation.

***PHS 340B Drug Pricing Program.*** To maintain coverage of drugs under the Medicaid Drug Rebate Program, manufacturers are required to extend discounts to certain purchasers under the PHS 340B drug pricing program. Purchasers eligible for discounts include hospitals that serve a disproportionate share of financially needy patients, community health clinics and other entities that receive health services grants from the PHS.

More generally, in the U.S., third-party payors are increasingly seeking to control drug costs by examining the cost effectiveness of products and services in addition to their safety and efficacy, managing drug utilization and challenging the price of drugs. To obtain or maintain coverage and reimbursement for our products, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals. Third-party payors may limit coverage of product by, for example, only covering specific products on an approved list, or formulary, which might not include all of the FDA approved products for a particular indication. Some third-party payors may manage utilization of a particular product by requiring pre-approval (known as "prior authorization") for coverage of particular prescriptions (to allow the payor to assess medical necessity) or otherwise restricting coverage of a product even if used consistent with its approved indication. Our branded and generic products with other generic competition may be subject to increasing price erosion.

The containment of healthcare costs also has become a priority of federal, state and foreign governments. In the U.S., in recent years, the pharmaceutical industry has been a particular focus of such reform efforts and has been significantly affected by major legislative, administrative and executive initiatives. For example, the Inflation Reduction Act ("IRA") of 2022 included a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes included caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the previous coverage gap discount program) and a drug price negotiation program for certain high-spend Medicare Part B and D drugs. The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Beyond the IRA, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap. Additionally, changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers.

More recently, President Trump issued an executive order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another executive order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); to prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the U.S.; and to facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the executive orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government offering pharmaceutical direct-to-consumer channels has also been launched. Federal agencies are developing new drug pricing pilot programs, such as the GENEROUS model, which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and the proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted.

At the state level, individual states are increasingly implementing initiatives 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 measures to encourage importation from other countries and bulk purchasing. For example, certain states have formed Prescription Drug Affordability Boards that assert authority to set reimbursement rates and/or drug pricing in the state. States are also increasingly expanding or changing Medicaid supplemental rebate 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. These and other future state-level reform activities could negatively affect Medicaid coverage and reimbursement for our products.

In addition, health systems, hospitals and other healthcare organizations are increasingly using bidding procedures (directly or through group purchasing organizations) to determine what pharmaceutical products and which suppliers will be included in their prescription drug formularies or otherwise available. These measures could reduce the ultimate demand for our products or put pressure on our product pricing.

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, third party payors, and other purchasing customers pay for health care products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

*Other Healthcare Regulation*

Our business activities may be subject to other healthcare laws and regulations, including state laws regulating the manufacture and distribution of drugs and biologics, federal and state laws regulating the privacy and security of health information, and federal and state consumer protection laws.

***Regulation in the United Kingdom and European Union***

ILUVIEN was initially authorized in the United Kingdom on May 4, 2012, following a full stand-alone application under Article 8(3) of Directive 2001/83/EC (as amended) for the known active substance fluocinolone acetonide. At that time, Campharm Limited was the marketing authorization holder, with ownership subsequently transferred to Alimera Sciences Limited on September 26, 2012.

In the European Union, ILUVIEN received approval via the decentralized procedure, with the UK acting as the Reference Member State and Austria, France, Germany, Italy, Portugal and Spain acting as Concerned Member States. This process concluded positively on February 27, 2012. A subsequent wave of mutual recognition, finalized on June 26, 2014, extended approval to Belgium, Czech Republic, Denmark, Finland, Luxembourg, Norway, Poland, Republic of Ireland, Sweden, and the Netherlands. Following the UK's exit from the EU, the Republic of Ireland assumed the role of Reference Member State, overseeing ongoing management of the mutual recognition procedure.

The EU employs several procedures for granting marketing authorizations for medicinal products, ensuring consistent and efficient evaluation across Member States while accommodating national and regional requirements. The centralized procedure, managed by the European Medicines Agency ("EMA") and granted by the European Commission, is mandatory for certain categories of medicines, including those produced via biotechnology, orphan drugs, advanced therapies and treatments for viral diseases, cancer, autoimmune and immune disorders, neurodegenerative diseases and diabetes. It is optional for other new active substances that offer significant therapeutic, scientific or technical innovation, or are considered beneficial for public health at the EU level.

For products outside the scope of the centralized procedure, companies may pursue approval through the decentralized procedure—used for products not yet authorized in the EU, allowing simultaneous authorization in multiple Member States led by a Reference Member State—or through the mutual recognition procedure, which extends an existing national authorization to other Member States. The national procedure remains available for products intended for use exclusively within a single Member State.

In both the EU and UK, a post-authorization Risk Management Plan ("RMP") is required for all new medicinal products to ensure ongoing monitoring of safety and effective management of risks after a product is placed on the market. The RMP outlines identified and potential risks, plans for pharmacovigilance activities, and risk minimization measures. In the EU, RMPs are governed by Regulation (EU) No 726/2004 and Directive 2001/83/EC and are assessed by the EMA. In the UK, following Brexit, the Medicines and Healthcare products Regulatory Agency ("MHRA") requires submission of an RMP under the Human Medicines Regulations 2012, and the content and format remain closely aligned with EU standards, though the MHRA conducts its own independent assessment.

Drug pricing and market access in the EU Member States and the UK are determined at the national level, resulting in considerable variation. After obtaining marketing authorization, pharmaceutical companies must navigate individual national processes for pricing and reimbursement, typically involving health technology assessments, cost-effectiveness evaluations, budget impact assessments, and price negotiations with national authorities. Each country has its own agencies and criteria, leading to differences in timelines, pricing outcomes, and patient access. In the UK, the National Institute for Health and Care Excellence and health technology bodies in the devolved governments assess clinical and cost-effectiveness, making recommendations for reimbursement in the National Health System ("NHS"). Drug pricing is traditionally regulated in the UK through the Voluntary Scheme for Branded Medicines Pricing and Access ("VPAS") or the statutory scheme, both of which limit annual NHS expenditure growth on branded medicines and may require manufacturer rebates. The UK's new voluntary drug pricing system is the 2024 Voluntary Scheme for Branded Medicines Pricing and Access, replacing the old VPAS, running from 2024-2028, and negotiated by the UK Government, the NHS, and the pharmaceutical industry. It controls NHS spending by requiring drug companies to pay rebates (around 22.9% for 2025, dropping to 14.5% for 2026) on sales above a set growth level, plus extra for an £400m investment fund in clinical trials and manufacturing, aiming to balance access to innovation with a sustainable NHS and boost UK life sciences.

Generic medicinal products in the EU and the UK are authorized through a well-established regulatory pathway set out in Directive 2001/83/EC, as amended. Each reference medicinal product approved under Article 8(3) of Directive 2001/83/EC benefits from eight years of regulatory data protection, during which a generic applicant cannot cross-reference the originator's non-clinical and clinical data on safety and efficacy. This is followed by two years of marketing protection, during which a generic product cannot be placed on the market, resulting in a standard total protection period of ten years. This period may be extended to eleven years if, within the initial eight years, one or more new indications are approved, and these are deemed to offer a significant clinical benefit over existing therapies. To be authorized, a generic product must have the same qualitative and quantitative composition in active substance(s), the same pharmaceutical form, and must be demonstrated to be bioequivalent to the reference medicinal product. Otherwise, if there are differences in these aspects, additional preclinical and/or clinical data must be provided to address the lack of similarity between the generic and the reference medicinal product.

In the EU, orphan designation is granted based on an evaluation of disease prevalence, with the threshold set at fewer than 5 in 10,000 individuals. Additionally, the product must demonstrate a significant benefit over existing authorized treatments. Alternatively, orphan designation may be granted if there is evidence that the return on investment would be insufficient to justify the research and development of the product. The orphan designation must be reassessed and confirmed at the time of marketing authorization to ensure that the criteria for designation continue to be met; otherwise, the designation may be revoked, as confirmed by the rulings of the EU General Court in Bristol-Myers Squibb v. European Commission and European Medicines Agency, and Sanofi v. European Commission and European Medicines Agency that clarified that orphan designation can be withdrawn if the criteria are no longer satisfied at the time of marketing authorization. If orphan designation is maintained at the time of marketing authorization, the product is granted a period of 10 years of orphan market exclusivity, which may be extended to 12 years if data are generated in accordance with an agreed pediatric investigation plan, even if those data do not result in approval of a pediatric indication.

Regulation (EU) 2021/2282, known as the EU Health Technology Assessment ("HTA") Regulation, establishes a harmonized framework for evaluating certain health technologies across EU Member States. Effective from January 12, 2025, the regulation aims to improve the efficiency, consistency, and transparency of HTA processes, supporting evidence-based decision-making for pricing and reimbursement. However, it does not harmonize national pricing and reimbursement decisions, which remain under the authority of individual Member States. Instead, the regulation focuses on joint clinical assessments to streamline and strengthen the evidence base for national decision-making.

The EU Clinical Trials Regulation (Regulation (EU) No 536/2014), effective from January 31, 2022, harmonizes and streamlines the approval and oversight of clinical trials across Member States by introducing a centralized application process through the EU Clinical Trials Information System, coordinated scientific and ethical assessments, enhanced transparency through public access to trial data, and strengthened safety reporting requirements, thereby facilitating efficient multi-country trials and improving participant protection throughout the EU. Following its exit from the EU, the UK did not adopt the EU Clinical Trials Regulation and continues to apply the previous EU Clinical Trials Directive (2001/20/EC) through local rules. However, the UK has recently enacted new clinical trials regulations, the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024, which will take full effect from April 10, 2026. These reforms place patient safety and benefit at the center of all clinical trials, aim to cut duplication and unnecessary delays while maintaining robust safety oversight, and create a proportionate and flexible regulatory environment that reduces bureaucracy for lower-risk trials. The new framework is designed to cement the UK's position as a destination for international trials and provides a streamlined, agile, and responsive approach to support innovation in clinical research.

Recent legislative proposals in the EU to revise the existing regulatory framework for pharmaceuticals and biotechnology reflect the European Commission's commitment to modernizing and strengthening the sector. EU Pharma Package, proposed in April 2023, is the most significant overhaul of EU pharmaceutical legislation in 20 years. Its goals are to improve access to medicines, enhance supply security, support innovation, and address antimicrobial resistance. Major changes include streamlining and shortening regulatory procedures to accelerate market access; revising data and market exclusivity periods to incentivize innovation while promoting timely generic and biosimilar entry; strengthening environmental risk assessments for medicines; introducing measures to address shortages and improve supply chain resilience; enhancing transparency and harmonization in regulatory processes. The European Commission has announced plans for a dedicated Biotech Act as part of its broader strategy to boost biotechnology and biomanufacturing in Europe. While details are still emerging, the act is expected to simplify regulatory pathways for biotech products; support research, development, and manufacturing capacity; foster public-private partnerships and investment in biotechnology; address regulatory barriers and promote innovation in areas such as advanced therapies, synthetic biology, and biomanufacturing.

**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, 2025, we owned six 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 Pharmaceuticals US, Inc. (f/k/a pSivida US, Inc. or “EyePoint”). Pursuant to an amended and restated license agreement (the "A&R 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 trademarks for most of our branded products, including Cortenema, Cortrophin-Zinc, Inderal LA, Inderal XL, InnoPran XL, Inzirqo, Kionex, Lithobid, Reglan, SOVUNA, Tezruly, Vancocin, and Veregen. We license the trademarks 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 one patent set to expire in October 2026. Therefore, we consider the trademarks 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 names. 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 from time to time with third parties pursuant to 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 include national wholesalers, specialty pharmacies, retail pharmacy chains, distributors, mail order houses, group purchasing organizations, and hospitals and healthcare providers, which then sell our products to patients.

In recent years, the wholesale distributor network for our 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 year ended December 31, 2025, approximately 53% of our net revenues were attributable to three customers. For the years ended December 31, 2024 and 2023 approximately 64% and 70%, respectively, of our net revenues were attributable to four customers.

In the Rare Disease business, specifically for Cortrophin Gel, there is a limited distribution network and a select group of specialty pharmacies which dispenses product to appropriate patients. We contract and engage with the largest health insurance payers across the appropriate channels and classes of trade. For ILUVIEN, our sales personnel focus on physician offices, clinics, pharmacies and hospitals in the U.S. and in foreign 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 U.S. and internationally. Our products are distributed through the following channels:

- ***Wholesalers.*** We conduct business with the three major wholesalers in the U.S.: Cencora, Inc., Cardinal Health, and McKesson.
- ***Specialty Pharmacies.*** We contract with specialty pharmacies, such as CVS Specialty Pharmacy, Accredo Specialty Pharmacy, ASD Specialty Healthcare, Optum Specialty Pharmacy, and others to dispense our Rare Disease products, including Cortrophin Gel.
- ***Retail Pharmacy Chains.*** We conduct business with all the major retail chains in the U.S. including CVS, Kroger, Walmart, and Walgreens among others.
- ***U.S. and International Distributors.*** We have contracts with several major distributors in the U.S., including Anda, Smith Drug Company, Morris Dickson, CVS Caremark, Accredo, OptumRx, CuraScript and several other partners. We also have various agreements with international distributors for our ILUVIEN product.
- ***Group Purchasing Organizations.*** We have contracts with group purchasing organizations in the U.S., including 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, and Premier Inc., among others.
- ***Hospitals, Clinics, and Physicians.*** In our Rare Disease business, specifically for ILUVIEN, we contract with certain hospital systems, clinics, and physicians.

**Competition**

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.

Certain of our products face limited competition due to complexities in formulation, API sourcing, and materials handling and manufacturing, as well as 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.

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.

***Generics and Others Segment***

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.

Our principal competitors for our Generics portfolio of pharmaceutical products 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.

***Rare Disease and Brands Segment***

The majority of our Brands portfolio of pharmaceutical products faces competition from generic products and we expect these products to continue to face competition from generic products in the future. Our principal competitor for Cortrophin Gel is Acthar® Gel which is marketed by Keenova Therapeutics plc.

The principal competitors for ILUVIEN 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 European Economic Area ("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; PAVBLU® (aflibercept-ayyh) marketed by Amgen Inc.; and TRIESENCE® (triamcinolone acetonide injectable suspension) marketed by Harrow Eye, LLC.

*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; and TRIESENCE® (triamcinolone acetonide injectable suspension) marketed by Harrow Eye, LLC.

**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 2026, we have 970 employees, of which 753 are in the U.S., 148 in India, 30 in the UK, 19 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 we believe 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.

Furthermore, we do not tolerate discrimination or harassment of any kind against anyone (including because of gender, gender identity, race, ethnicity, or sexual orientation), 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 2025). 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.

We believe that no one should go without medicines that they need. We maintain the ANI Rare Disease Patient Assistance Program, Inc. for the purpose of providing certain medicine for free to patients in the U.S. who do not have prescription drug or health insurance coverage and who, without assistance, cannot afford their medicine. In addition, ANI Pharmaceuticals has provided patient-related financial support to nonprofit organizations that are aligned with our 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*

Our 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 our 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. We have established a health and safety program with a focus on continuous improvement and employee engagement. Our 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.

Furthermore, our Employee Wellness Steering Committee is dedicated to creating a culture where every employee thrives —physically, mentally, and emotionally. The Steering Committee is committed to empowering our team by providing access to resources that promote overall well-being, foster a sense of belonging, and inspire purpose. Through continuous education, meaningful engagement, and ongoing improvement, the Steering Committee strives to cultivate an environment where our people are healthy, resilient, and compassionate. Additionally, our Employee Assistance Program offers mental/ psychological support and a variety of resources to support our employees.

*Environmental Stewardship and Sustainability*

We are committed to Serving Patients, Improving Lives, both directly though 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. Our Environmental, Social, and Governance ("ESG") Steering Committee was formed in October 2023 to oversee cross-functional initiatives. The ESG Steering Committee reports to our Board of Directors through our Nominating and Corporate Governance Committee ("N&CG Committee") and is committed to providing progress updates at least twice per year. The N&CG Committee is responsible for reviewing, monitoring, evaluating, and overseeing ANI's programs, policies and practices relating to ESG risks and opportunities, including climate, and assessing their impacts to support the sustainable growth of ANI's businesses.

**Available Information**

We file annual, quarterly and current reports, proxy statements and other information required by the Exchange Act, with the SEC. We make available free of charge on our website (www.anipharmaceuticals.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 – Governance" section are our Corporate Governance Guidelines, Code of Ethics and the charters for the Audit and Finance, Compensation, and N&CG 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. Below is a summary of the principal risks that could adversely affect our business, financial position and operating results:

- Our approved products, including Cortrophin Gel and ILUVIEN, may not achieve commercialization at levels of market acceptance that will allow us to maintain profitability;
- To the extent our ongoing and continuing efforts to commercialize Cortrophin Gel, ILUVIEN, and our other products for which we have received marketing approval are unsuccessful, our business, financial condition, and results of operations will be negatively impacted;
- 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 source third parties, which we cannot control and could result in us being unable to market and distribute products;
- If we fail to comply with broad and complex U.S. healthcare and other laws, as well as comparable laws and regulations in foreign jurisdictions, we could face substantial penalties and our business, operations, and financial condition could be adversely affected;
- 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;
- Any failure to comply with the complex reporting and payment obligations under the Medicaid Drug Rebate Program and other government pricing and price reporting programs may result in penalties and sanctions, which may have a material adverse effect on our business, financial position, and operating results;
- 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 accruals for the Medicare Manufacturer 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;
- We expect to spend significant 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 ILUVIEN and YUTIQ 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, including any cybersecurity incidents, 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 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;
- Future acquisitions and investments could disrupt our business and harm our financial position and operating results;
- Public health outbreaks, epidemics, or pandemics 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;
- Four of our products are marketed without approved NDAs or ANDAs and we cannot be certain 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;
- The FDA does not provide guidance on safety labeling for products that are marketed without approved NDAs or ANDAs, which could increase our potential liability with respect to failure-to-warn claims for these products;
- If the 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;
- Pharmaceutical product quality standards are steadily increasing on all products as set forth by the FDA and other governmental agencies, 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;
- The successful commercialization of our products depends on adequate coverage and reimbursement from third party payors;
- 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;
- U.S. healthcare reform initiatives may materially and adversely affect our business, financial position, and operating results;
- The international nature of our operations, including those resulting from our acquisition of Alimera and its international operations, will subject us to political and economic risks and increase our exposure to potential liability under anti-corruption, trade protection, tax, and other laws and regulations;
- Our policies regarding returns, allowances and chargebacks, as well as 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 operating results;
- Our 2024 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;
- We incurred certain risks relating to the Notes 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 and ILUVIEN, may not achieve commercialization at levels of market acceptance that will allow us to maintain 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 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 maintain 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 commercialize in the future.

Even if we are able to obtain regulatory approvals for our pharmaceutical products, if we fail to predict the demand for such products accurately, or if 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:

- relative convenience and ease of administration of our products;
- our products' pricing relative to that of our competitors;
- our marketing effectiveness relative to that of our competitors;
- timing of our market entry;
- publicity and health authority communications concerning our products or competing products and treatments;
- 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.

***To the extent our ongoing and continuing efforts to commercialize Cortrophin Gel, ILUVIEN, and our other products for which we have received marketing approval are unsuccessful, our business, financial condition and results of operations will be negatively impacted.***

We have 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 other indications. In 2025, a significant portion of our net product revenues were derived from the sale of Cotrophin Gel, and we expect that sales of Cortrophin Gel will continue to account for a significant portion of our net product revenues in future years. As a result, our business is dependent on our ability to sustain and grow revenues from sales of Cortrophin Gel, and we are accordingly subject to risks relating to the commercial success of Cotrophin Gel, including the risk that physicians, payors or patients will perceive the cost of Cortrophin Gel to outweigh the benefits of treatment; that we may be unable to maintain and increase sales of Cotrophin Gel or continue to gain market share from competing products; and that we may be unable to obtain and sustain favorable access and reimbursement rates.

In addition, we have received approval from the FDA for ILUVIEN for the treatment of NIU-PS in addition to DME, for which ILUVIEN was already approved. To the extent we receive FDA approval to commercialize other products in the future, we expect to devote significant time and money towards commercialization effects in the U.S, including building out our sales force and developing a patient support program. In addition, we are expanding our commercialization efforts with respect to Cortrophin Gel to include a 1 mL vial, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares. Additionally, on February 28, 2025, the FDA approved a prefilled syringe format for Cortrophin Gel. This new presentation became available in 40 USP units/0.5 mL and 80 USP units/mL single-dose options through Cortrophin Gel's established specialty pharmacy network during the second quarter of 2025. The prefilled syringe reduces administration steps for patients using Cortrophin Gel, which remains available in 5 mL and 1 mL vials. The ability for us to generate significant net product revenues from ILUVIEN, our Cortrophin Gel products or any other products for which we receive marketing approval 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 our approved products are approved for sale;
- successfully establishing and maintaining manufacturing capabilities with our third-party suppliers and contract manufacturers and manufacturing adequate commercial quantities of our approved products at acceptable cost and quality levels, including maintaining cGMP and quality systems regulation standards required by various regulatory agencies;
- broad acceptance of the products for which we have received marketing approval by physicians and patients, as well as our ability to gain market access share in the healthcare community;
- the acceptance of pricing and placement of the products for which we have received marketing approval on payers' formularies and the associated tiers;
- effectively competing with other products that are approved and available to patients for the same conditions, as well as other products that are in development or may be developed in the future as treatment options;
- continued demonstration of safety and efficacy of the products for which we have received marketing approval in comparison to competing products or treatment options;
- our ability to comply with ongoing regulatory obligations and continued regulatory review of the products for which we have received marketing approval, 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; 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 or continue to successfully commercialize ILUVIEN, Cortrophin Gel or any other products for which we receive marketing approval, which would negatively impact our business, financial condition and results of operations. In addition, sales of our products that have received marketing approval 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 such products, 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 was 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 adverse impact on our 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, 2025, approximately 17%, of our raw materials and API purchases were from one domestic supplier. During the year ended December 31, 2024, approximately 12% of our API purchases were from one domestic supplier. During the year ended December 31, 2023, no single vendor represented more than 10% of our API purchases. 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 condition, and operating results. We source the raw materials and API 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 generally is required to be approved by the FDA through a PAS. The process of obtaining approval of a PAS can take between six and nine months, and could take an additional eight to ten months if additional information is required to be submitted by the FDA. 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. From time to time, we have experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections, and we may experience future disruptions in the supply of certain imported API due to trade tensions or embargoes, geopolitical tensions and macroeconomic conditions. Any disruptions in our API supply, and particularly with respect to the API used to manufacture Cortrophin Gel and ILUVIEN, could have a material adverse effect on our business, financial condition and operating results.

***Our manufacturing facilities or those of our third-party manufacturers or suppliers may fail to meet regulatory requirements. Failure to meet cGMP requirements could increase production costs or impact supply of our products.***

All facilities where prescription drugs are manufactured, tested, packaged, stored, or distributed must comply with FDA cGMPs. All of our products are manufactured, tested, packaged, stored and distributed according to cGMP regulations, which govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of drug products. Poor control of cGMP production processes can lead to product quality failures that can impact our ability to supply product, resulting in cost overruns, which could be extensive. Such production process issues include: failure to meet target production costs and yields, facility and equipment failures, raw material failures, failure to meet product release specifications, including stability of the product, quality assurance system failures, operator error, equipment malfunction, and shortages of qualified personnel, as well as noncompliance with strictly enforced federal, state and foreign 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, financial condition and operating results.

***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, if any of our contract manufacturers or distributors fails to comply with federal, state, and local laws and regulations, or if any of our 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 have commercialized or are seeking to commercialize. Some of these products, including injectables, softgel capsules, Cortrophin Gel, as well as ILUVIEN, are products that we cannot currently manufacture in our facilities. As a result, we have contracted with third-party contract manufacturers to manufacture these 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. 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. Our reliance on contract manufacturers reduces our control over these activities but does not relieve us of our responsibility to ensure compliance with all required regulations. If a contract manufacturer does not successfully carry out its contractual duties, meet expected deadlines or manufacture our products in accordance with regulatory requirements, or if there are disagreements between us and a contract manufacturer, we may need to enter into an appropriate replacement third-party relationship, which may not be readily available or available on acceptable terms, and which may cause additional delay or increased expense in our ability to commercialize our products. 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.

Any of these situations could materially and adversely harm our business and financial condition. We cannot be certain 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.

***If we fail to comply with broad and complex U.S. healthcare and other laws, as well as comparable laws and regulations in foreign jurisdictions, we could face substantial penalties and our business, operations and financial condition could be adversely affected.***

Within the U.S., the marketing of pharmaceutical products and related arrangements with healthcare providers, third-party payors, patients and other third parties in the healthcare industry are subject to a wide range of federal and state healthcare laws and regulations that may constrain our business and/or financial arrangements. These laws include:

- the AKS, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving, or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid;
- federal civil and criminal false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower, or qui tam actions, as well as civil monetary penalty laws can impose criminal and civil penalties, assessments, and exclusion from participation for various forms of frauds and abuse involving the federal healthcare programs, such as Medicare and Medicaid;
- the federal Health Insurance Portability and Accountability Act of 1996, as amended, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also establishes requirements related to the privacy, security, and transmission of individually identifiable health information which apply to many healthcare providers, physicians, and third-party payers with whom we interact;
- the federal Food, Drug and Cosmetic Act, which, among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use, and regulates the distribution of samples;
- federal laws that require pharmaceutical manufacturers to calculate, report, and certify certain complex product prices and other data to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement of the manufacturers' drugs under government healthcare programs, which data may be used in the calculation of reimbursement and/or discounts on approved products;
- the so-called federal "sunshine law" or Open Payments program, which requires manufacturers of drugs, devices, biologics and medical supplies covered under certain government health benefit programs to report to CMS information related to "payments and other transfers of value" to teaching hospitals, physicians, and other healthcare practitioners, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- state laws and regulations analogous to federal laws, including anti-kickback or related laws, some of which apply regardless of whether products or services are covered by government health benefit programs or private insurance, false claims laws, laws prohibiting consumer protection and unfair competition laws, and laws governing privacy, security, and breaches of health information in certain circumstances, many of which differ in significant ways from federal laws and across states and are often not preempted by federal law, thus complicating compliance efforts; and
- state laws that require pharmaceutical companies to comply with specific compliance standards, restrict financial interactions between pharmaceutical companies and healthcare providers, report drug product pricing information, financial interactions with health care providers, or marketing expenditures, and/or require the registration of pharmaceutical sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage, and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Efforts to ensure that our activities comply with applicable healthcare laws and regulations will involve substantial costs. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations, and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with such laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal, and administrative penalties, damages, fines, exclusion from participation in federal health care programs such as Medicare and Medicaid, the curtailment or restructuring of our operations, and other actions. Further, defending against any such actions can be costly, time-consuming, and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including FDA and CMS, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, either in the U.S. or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, our business could be materially harmed.

***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. The CCPA provides for civil penalties for violations, as well as a private right of action in connection with certain data breaches, and establishes a regulatory agency authorized to implement and enforce the CCPA. In addition, almost 20 other states 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.

We are in the process of adopting and implementing our policies with respect to information subject to applicable data privacy laws and transfer restrictions. 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.

***The success of our business 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 pursuant to 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, with the advent of changes in federal law, as individuals become eligible for coverage under these programs or lose eligibility for such coverage, Medicaid utilization of our products could change, resulting in a corresponding change 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.

***Any failure to comply with the complex reporting and payment obligations under the Medicaid Drug Rebate Program and other government pricing and price reporting programs may result in penalties and sanctions, which may have a material adverse effect on our business, financial position, and operating results.***

The U.S. laws and regulations regulating the Medicaid Drug Rebate Program and other government pricing and price reporting programs are complex, vary across drug products and programs, continue to evolve and are often subject to interpretation by agencies and courts. These interpretations may change over time, and complex methodologies and related assumptions used in making calculations under these programs are subject to review and challenge. Any inaccuracies in our prior reporting may lead to recalculations and restatements, which may increase our historic liability. Further, civil monetary or other penalties may be applied if we fail to pay required rebates or other amounts, if we are found to have knowingly submitted false pricing or product information to the government, or if we are found to have made other misrepresentations or errors in our pricing. Government agencies also could decide to terminate our relevant government agreements, in which case federal government reimbursement would not be available under Medicaid or Medicare Part B for our products.

***Our accruals for rebates under the Medicare Manufacturer Discount Program have increased due to growth and acquisitions. Increases in Medicare Manufacturer Discount rebates, and further legislative changes to the Medicare Manufacturer Discount Program, could decrease our revenues from product sales, which in turn could have a material adverse effect on our business, financial position, and operating results.***

Our accruals for the rebates under the Medicare Manufacturer 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 Part D program, which is largely 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 accruals with respect to these anticipated rebates have grown. Increases in Medicare Manufacturer Discount rebates, and further legislative changes to the Medicare Manufacturer 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 significant 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. While we believe 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 contain "failure to supply" clauses that require us to reimburse the customer for the difference between our contract price and the price the customer would be forced to pay to procure the substitute product in the event we fail 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.

***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 clinical 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. The results of preclinical studies and early clinical trials of our product candidates may not predict results of later-stage clinical trials, and results in one indication may not predict results for the same product candidate in another indication. Differences in trial design between early-stage clinical trials and later-stage clinical trials raise challenges for extrapolating the results of earlier clinical trials to later clinical trials.

In addition, delays occur when a clinical trial is suspended, put on clinical hold or terminated by the trial sponsor, the FDA or other regulatory bodies, or the IRBs of the institutions in which such trials are being conducted. Suspensions and terminations are imposed due to a number of factors, including failure to conduct a clinical trial in accordance with regulatory requirements or trial protocols, failure to conduct the trial in accordance with GCPs or applicable regulatory guidelines, failed inspections of clinical trial operations or trial sites by the FDA or other regulatory bodies, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Clinical trials frequently are delayed or terminated as a result of ambiguous or negative interim results or unanticipated adverse events. If trials or tests are not positive or are only modestly positive or if there are safety concerns, we may be required to repeat or conduct additional clinical trials or preclinical studies for our product candidates beyond those that we currently contemplate, we may be delayed in or prevented from obtaining marketing approval or may obtain marketing approval in some countries and not in others, we may obtain approval for indications or patient populations that are not as broad as intended or desired or obtain approval with significant use or distribution restrictions or safety warnings, be subject to post-marketing testing requirements, or be subject to increased pricing pressure. Further, the FDA or other regulatory bodies may disagree with our clinical trial design and our interpretation of data from clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Further, the outcome of continuing post-marketing clinical trials, such as 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.

***Any significant adverse events or undesirable side effects caused by our products may impact regulatory approval or market acceptance, or result in significant negative consequences.***

If we or others identify undesirable side effects caused by any product that we develop or commercialize, several potentially significant negative consequences could result, including the interruption, delay or suspension of clinical trials, the suspension or withdrawal of approvals and licenses, the addition of warning labels, changes to the way a product is administered, the requirement to conduct further clinical trials, lawsuits or increased liability for harm to patients and their children and reputational harm to us. Any of these events could prevent us from obtaining or maintaining regulatory approvals or achieving or maintaining market acceptance of any products we develop or commercialize. Additionally, the FDA or other regulatory bodies could require us to adopt REMS for any product to ensure that the benefits of treatment outweigh the risks for each potential patient, which may include, among other things, a medication guide outlining the risks of the product for distribution to patients, a communication plan to health care practitioners, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry.

***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 or those of our partners, negatively affect our ability to service and interact with our clients, and adversely affect the value of our assets. Adverse weather conditions and natural disasters may also affect our or 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 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 our 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.

***Our current and potential future use of artificial intelligence and machine learning may not be successful and introduces emerging risks and challenges to our business.***

We have implemented certain artificial intelligence ("AI") technologies into our operations with the goal of improving efficiency, and may further expand our use of AI as the technology continues to evolve. However, the use, development, and integration of AI and machine learning technologies present risks and challenges that could materially and adversely affect our business, financial condition, and results of operations.

AI algorithms may be flawed, datasets may be insufficient or biased, and ineffective AI development or deployment could lead to compliance violations, cybersecurity risks, breaches of confidentiality and privacy obligations, noncompliance with applicable laws and regulations, threats to intellectual property rights, and the misuse of personally identifiable information, including protected health information. AI and machine learning technologies may also contribute to novel and urgent cybersecurity risks, including through the use by third parties of such technologies to launch more automated, targeted, and coordinated attacks.

Additionally, the regulatory framework for AI and machine learning technologies is rapidly evolving, and it is possible that new laws and regulations will be adopted, or that existing laws and regulations may be interpreted in ways that would affect our business. Several jurisdictions, including Europe and the U.S., have proposed or enacted laws governing AI, and we may be required to commit significant resources to modify and maintain business practices to comply with any applicable regulations concerning the use of AI, the nature of which cannot be determined at this time.

Developing, testing, and deploying AI systems may increase our operating costs due to the nature of the computing costs involved in such systems. Our efforts to develop, acquire, or integrate these technologies may involve significant time, costs, and other resources, and may divert our management team's attention and focus from executing on other elements of our strategy. We may also face increased competition from other companies that are using AI, some of which may develop more effective methods to deploy these technologies than we or any of our business partners have, which could impair our ability to compete effectively.

**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. A second U.S. patent relating to ILUVIEN will expire in November 2028, and a second U.S. patent relating to YUTIQ will expire in January 2028. We do not expect that any 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 and November 2028 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 trademarks for most of our branded products, including, Cortenema, Purified Cortrophin Gel, Cortrophin-Zinc, ILUVIEN, Inderal LA, Inderal XL, InnoPran XL, Inzirqo, Lithobid, Reglan, Vancocin, Veregen, and YUTIQ. We license the trademarks 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 A&R 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 and Ocumension Therapeutics ("Ocumension").

Our ability to pursue the development and commercialization of our products depends upon the continuation of our agreements with EyePoint. The A&R 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 A&R 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 A&R 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, financial condition and operating results.

***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 current 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 agreement 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.

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 A&R 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.

***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. Unauthorized parties or rogue insiders may also attempt to gain access to our systems or facilities through fraud or other forms of deception targeted at our customers, associates, suppliers and service providers. Any such incidents could compromise our networks and the information stored there could be accessed, misused, publicly disclosed, lost, stolen or rendered, permanently or temporarily, inaccessible. 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. Further, any security breach incident could expose us to risks of regulatory and law enforcement investigations, enforcement actions, litigation (including class claims) and liability and could result in negative publicity, any of which could significantly harm our reputation and relationships with our customers and adversely affect our business, financial condition, operating results, liquidity and stock price. Insurance policies that may provide coverage with regard to such incidents may not cover any or all of the resulting financial losses. 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 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 against us 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.

***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 U.S., that cover the UK and much of Europe and the Middle East. We have not historically conducted any operations or marketed any of our products outside the U.S. As a result of the closing of the Merger, the percentage of our revenues generated outside of the U.S. has increased materially, and our 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 components 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 continued making 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 U.S.;
- 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 requires additional oversight by our compliance and marketing teams. We plan to spend significantly more time and invest in additional resources to ensure compliance with regulatory regimes outside the U.S. Similarly, there are often supply chain risks that are specific to a given region, and our expansion outside the U.S. 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. We cannot be certain 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 EEA and the UK, 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 UK 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 U.S. 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 capabilities 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 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, in order to support the transition to of NIU-PS to ILUVIEN, in July 2024, the Company extended its partnership with 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.

Additionally, we may experience lengthy delays if we need to change a third-party supplier or manufacturer, which could have a material impact on our business, financial condition and operating results. 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 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 have adversely affected and may in the future adversely affect our business.***

Public health outbreaks, epidemics, or pandemics (actual or threatened) 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 three customers representing 22%, 17%, and 14% of our net revenues, respectively, during the year ended December 31, 2025. As of December 31, 2025, accounts receivable from these three customers was approximately 64% 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 required to make 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 2025, are marketed without approved NDAs or ANDAs and we cannot be certain 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.***

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 cannot be certain 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 of 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. 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.

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.

***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 schedule II 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 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-nitrosdimethylamine ("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 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.

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 U.S. 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.

***Inadequate funding for the FDA, DEA, the SEC and other government agencies, including from government shutdowns, or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.***

Inadequate funding for the FDA and other government agencies, in addition to potentially shifting priorities under the current presidential administration, could hinder the ability of the FDA or other government agencies to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business, financial position and operating results. Without appropriation of funding to federal agencies, our business operations related to our product development activities for the U.S. market could be impacted. The ability of the FDA to review and approve new products, to provide feedback on clinical trials and development programs, to meet with or engage in other informal interactions with sponsors and to otherwise review regulatory submissions can be affected by a variety of factors, including government budget and funding levels; the ability to hire and retain key personnel and accept the payment of user fees; and statutory, regulatory, and policy changes, among other factors. Similarly, the DEA's regulation of controlled substances can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency may and have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since the start of the current presidential administration in 2025, U.S. policy changes have been implemented at a rapid pace and additional changes are likely. It is difficult to predict how executive actions that may be taken under the current administration may affect the FDA, the DEA, or other agencies' ability to exercise their regulatory authority. Any disruptions at the FDA and other agencies that impose constraints on the FDA's ability to engage in routine oversight and product review activities may slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies or to otherwise respond to regulatory submissions, which would adversely affect our business. For example, the current administration has discussed several changes to the reach and oversight of the FDA, which could affect its relationship with the pharmaceutical industry, transparency in decision making and ultimately the cost and availability of prescription drugs. The FDA may pursue legislative, regulatory or policy changes regarding the standards or processes for approving our products or product candidates that we may be unable to satisfy. Additionally, over the last several years, the U.S. government has shut down multiple times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. For example, the current administration previously announced plans to reduce the number of federal employees by establishing voluntary termination programs, by position eliminations or by involuntary terminations. Reductions in workforce, particularly in the review or inspection divisions, could extend NDA review timelines, delay or prevent pre-approval inspections, and limit opportunities for FDA feedback on pending applications. In addition, as a result of the government shutdown, the FDA staff many be unable to process and review regulatory submission in a timely manner or at all. A significant reduction in the FDA's workforce or budget, changes in the FDA's regulatory and oversight priorities or activities, or a prolonged government shutdown could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***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 ("FCA"), imposes civil liability and criminal fines on individuals or entities that among other acts, knowingly submit, or cause to be submitted, false or fraudulent claims for payment to the government. 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. These suits have increased significantly in recent years because the FCA 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, 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, in both the branded and generic markets, 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.

***The successful commercialization of our products depends on adequate coverage and reimbursement from third party payors.***

Significant uncertainty exists as to the coverage and reimbursement status of pharmaceutical products. In the U.S. and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other organizations is critical to the commercial success of our products. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Within the U.S., no uniform policy for coverage and reimbursement exists across all payors. Coverage and reimbursement can differ significantly from payor to payor and be subject to change at any time. Third-party payors are increasingly seeking to control drug costs by examining the cost effectiveness of products and services in addition to their safety and efficacy; managing drug utilization and challenging the price of drugs. To obtain or maintain coverage and reimbursement for our products, we may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost-effectiveness of our product. These studies will be in addition to the studies required to obtain regulatory approvals. Third-party payors may limit coverage of product by, for example, only covering specific products on an approved list, or formulary, which might not include all of the FDA approved products for a particular indication. Some third-party payors may manage utilization of a particular product by requiring pre-approval (known as "prior authorization") for coverage of particular prescriptions (to allow the payor to assess medical necessity) or otherwise restricting coverage of a product even if used consistent with its approved indication. Our Branded and Generic products with other generic competition may be subject to increasing price erosion. We are required to offer discounted pricing to government health benefit programs, government purchasers and certain private purchasers in order to be eligible for coverage under government health care programs. Price concessions may need to be offered to private third party payors to obtain favorable coverage or to purchasers to achieve sales.

***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.

The U.S. government has enacted the 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. 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, 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 international markets 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 U.S. 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 U.S. 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.

***U.S. healthcare reform initiatives may materially and adversely affect our business and operating results.***

In the U.S., 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. For example, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, collectively, ACA, was enacted and includes measures that have significantly changed the way healthcare is financed by both governmental and private insurers. Those reform efforts are likely to continue and may increase the difficulty and cost for us to commercialize our products successfully.

In the U.S., in recent years, the pharmaceutical industry has been a particular focus of healthcare reform efforts and has been significantly affected by major legislative, administrative and executive initiatives. For example, the Inflation Reduction Act (IRA) of 2022 included a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes included caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the previous coverage gap discount program) and a drug price negotiation program for certain high-spend Medicare Part B and D drugs. The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Beyond the IRA, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap, and changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers.

More recently, President Trump issued an executive order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another executive order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the U.S.; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the executive orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government offering pharmaceutical direct-to-consumer channels has also been launched. Federal agencies are developing new drug pricing pilot programs, such as the GENEROUS model, which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and the proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted.

At the state level, individual states are increasingly implementing initiatives 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 measures to encourage importation from other countries and bulk purchasing. For example, certain states have formed Prescription Drug Affordability Boards that assert the authority to set reimbursement rates and/or drug pricing in the state. States are also increasingly expanding or changing Medicaid supplemental rebate 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. These activities and any additional flexibility afforded the states could negatively affect Medicaid coverage and reimbursement for our products.

In addition, health systems, hospitals and other healthcare organizations are increasingly using bidding procedures (directly or through group purchasing organizations) to determine what pharmaceutical products and which suppliers will be included in their prescription drug formularies or otherwise available. These measures could reduce the ultimate demand for our products or put pressure on our product pricing.

Furthermore, other broader legislative changes have been adopted that could have an adverse effect upon, and could prevent, our products' commercial success. For example, the Budget Control Act of 2011, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and remains in effect through 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

The nature and extent of future healthcare reforms cannot be predicted. There is significant uncertainty regarding the nature or impact of any drug pricing or broader healthcare reform implemented at the federal or state level and the extent to which such action may be subject to litigation or other challenges. Ongoing efforts to contain or reduce costs of healthcare and/or impose price controls may adversely affect the demand for our products and our ability to achieve or maintain profitability.

***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 UK, 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 operating results and our ability to satisfy our debt obligations.

***The international nature of our operations, including those resulting from our acquisition of Alimera and its international operations, will subject us to political and economic risks and increase 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.

***Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.***

Significant political, trade, or regulatory developments in the jurisdictions in which we sell our products are difficult to predict and may create periods of volatility in such markets which may have a material adverse effect on us. Recent changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, the current presidential administration has commenced activities to renegotiate, or potentially terminate, certain existing bilateral or multi-lateral trade agreements and treaties with foreign countries, and the administration has imposed or threatened tariffs on U.S. trading partners. Related to these actions, certain foreign governments, including China, have instituted or threatened to impose retaliatory reciprocal tariffs on certain U.S. goods. On February 20, 2026, the U.S. Supreme Court ruled that certain tariffs announced throughout 2025, including those on global imports from China, Canada and Mexico, were impermissible. This decision creates uncertainty about the immediate path forward for many supply chains, including that the process and likelihood for obtaining potential tariff refunds remains unclear. Further, not all tariffs announced throughout 2025 will be impacted by this U.S. Supreme Court decision and new tariffs have, and may continue to be, implemented through other legal authorities.

Historically, tariffs have led to increased trade and political tensions, between not only the U.S. and China, but also between the U.S. and other countries in the international community. It remains unclear what the current administration or foreign governments will or will not do with respect to tariffs or other international trade agreements and policies. A trade war or other governmental action related to tariffs or international trade agreements or policies has the potential to disrupt our research activities, affect our suppliers, increase the cost of materials purchased to manufacture our products, impact our ability to sell our products outside the U.S. or to sell our products outside the U.S. at competitive prices and/or to affect the U.S. or global economy or certain sectors thereof and, thus, could adversely impact our business. Currently, we import a portion of our APIs, raw materials and excipients from countries outside of the U.S., including China and India. These tariffs or any new or additional tariffs on goods imported to the U.S. from China, India, or other countries, could increase the cost of some of our products and reduce our margins. Similarly, retaliation tariffs on U.S. products imported into the EU or other non-U.S. markets, could increase the cost of some of our products and reduce our margins. Political tensions and general uncertainty as a result of shifting trade policies could reduce trade volume, investment, technological exchange, and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including, but not limited to, U.S. and China and India trade policies, could have a material adverse effect on our financial condition or results of operations.

***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 U.S. 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 2025 did not result in an impairment charge related to goodwill, we cannot be certain 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 $0.8 million, $7.6 million, and zero in the years ended December 31, 2025, 2024, and 2023, respectively.

***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 and 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. 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 use in assessing 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, as well as 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, 2025, we had approximately $629.1 million of indebtedness and other liabilities on a consolidated basis. Subject to the limitations in the 2024 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 the 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 2024 Credit Agreement, the indenture governing our Notes and the agreements governing our other indebtedness.

In connection with the completion of the Merger, we entered into the 2024 Credit Agreement consisting of a $325.0 million term loan and a $75.0 million revolving credit facility. The 2024 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 the 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 2024 Credit Agreement, as well as the 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 Notes and indebtedness incurred under the 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 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 Notes may dilute the ownership interests of our stockholders. Upon conversion of the Notes, we will generally have the right to elect to settle our conversion obligation in excess of the principal amount of any converted 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 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 Notes may encourage short-selling by market participants because the conversion of the Notes could be used to satisfy short positions, or anticipated conversion of the 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 Notes for cash following a fundamental change or to pay the cash amounts due upon maturity or conversion of the Notes, and our other indebtedness limits our ability to repurchase the Notes or to pay the cash amounts due upon their maturity or conversion.***

Holders of the Notes may, subject to limited exceptions, require us to repurchase their Notes upon the occurrence of a fundamental change (as defined in the indenture governing the Notes) at a cash repurchase price generally equal to the principal amount of the Notes to be repurchased, plus accrued and unpaid interest, if any. Upon maturity of the Notes, we must pay the outstanding principal amount and accrued and unpaid interest in cash, unless they have been previously repurchased, redeemed or converted. In addition, all conversions of 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 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 Notes or to pay the cash amounts due upon their maturity or conversion. The 2024 Credit Agreement contains restrictive covenants that limit our ability to repay other indebtedness. Our failure to repurchase Notes or to pay the cash amounts due upon their maturity or conversion when required will constitute a default under the indenture governing the 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 Notes.

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

Certain provisions in the Notes and the indenture governing the 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 Notes will have the right to require us to repurchase their 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 Notes and the indenture governing the 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 Notes or holders of our common stock may view as favorable.

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

Because we must settle at least a portion of our conversion obligation with respect to the Notes in cash, the conversion of the Notes could materially and adversely affect our financial position and liquidity. Before June 1, 2029, holders of the Notes will have the right to convert their Notes only upon the occurrence of certain events. From and after June 1, 2029, holders of the Notes may convert their 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 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 Notes could adversely affect our reported financial condition and results.***

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

In addition, the shares of common stock underlying the Notes are reflected in our diluted earnings per share using the "if converted" method. Under that method, if the conversion value of the Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all of the 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 Notes will not be added back to the numerator of the diluted earnings per share calculation for these purposes. However, if reflecting the Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the Notes does not exceed their principal amount for a reporting period, then the shares of common stock underlying the 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 Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the Notes as a current, rather than a long-term, liability. This reclassification could be required even if no holders of our Notes actually convert their Notes and could materially reduce our reported working capital.

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

In connection with the pricing of the 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 Notes and/or offset any potential cash payments we are required to make in excess of the principal amount of converted 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 Notes (and are likely to do so during any observation period related to a conversion of Notes). This activity could also cause or avoid an increase or a decrease in the market price of our common stock or the 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 closures of Silicon Valley Bank and Signature Bank in March 2023, and First Republic Bank in May 2023. 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**

***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 cannot be certain 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 U.S. ("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.

***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 the population is small and where two of our three current manufacturing facilities are located, 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.

***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. The stock market in general and the market for biotechnology companies in particular have experienced extreme price and volume volatility that has often been unrelated to the operating performance of particular companies. 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 that is intended to address certain costs that we may incur in the event that we experience a cybersecurity incident.

We have invested in relevant tools and technologies to protect our data and business partners. Our Security Operations Team continuously monitors risks specific to us and 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. Following our acquisition of Alimera, we prioritized the integration and adoption of consistent policies and procedures related to information security, data privacy, and cybersecurity practices, with a strong focus on aligning security and privacy standards across our organization.

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 a 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 have not identified any cybersecurity incidents that have materially affected affect our business strategy, results of operations or financial condition, or are reasonably likely to materially affect the Company, including any cybersecurity incidents involving our vendors' facilities or systems. Please refer to "***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.***" in Item 1A of this Annual Report on Form 10-K.

***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 led by our VP of Technology provides periodic reports to our Board of Directors, as well as the Chief Executive Officer and Audit Committee as necessary. The current VP of Technology has more than 20 years of experience in cybersecurity, while possessing the required subject matter expertise, skills, experience, and industry certifications expected of an individual assigned to these duties. 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 primary corporate offices are located at 210 Main Street West, Baudette, Minnesota 56623. The manufacturing facility at this location, 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 also own a separate manufacturing facility in Baudette, Minnesota 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. 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.

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. In February 2024, we entered into an agreement for the sale of the Oakville site for a purchase price of $19.2 million Canadian Dollars, or approximately $14.2 million, based on the then-current exchange rate. On March 28, 2024, we completed the sale of the Oakville manufacturing site (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, our commercial headquarters, pursuant to a lease agreement entered into in August 2025, which includes certain employees in our corporate, legal, human resources, finance and accounting, IT, business functions, and Rare Disease operations. The current lease will expire in November 2035.

We also lease spaces for warehouse and packaging activities in East Windsor, New Jersey, and for research and development activities in Chennai, India. During 2023, we 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. The Company has subleased the entire space to a subtenant which expires in December 2032.

Internationally, we lease office space in Dublin, Ireland, Berlin, Germany, and Hook, UK. Our leases for the two facilities in Ireland expire in 2026 and 2027. Our lease for the office space in Berlin, Germany expires in 2027. We entered into the Hook, UK lease in December 2024 and it expires in December 2034. Additionally, we have an agreement for the usage of 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 20, 2026, there were approximately 360 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 special 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") accrued dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and also participated, on a pro-rata basis, in any dividends that would have been declared with respect to our common stock. We paid all PIPE Share dividends in cash. There were no shares of PIPE Shares outstanding as of December 31, 2025 as all of the PIPE Shares were converted to common shares during the third quarter of fiscal 2025, as the conditions for the conversion had been satisfied.

There were also approximately 11,000 shares of Class C special stock issued and outstanding as of December 31, 2025. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of our assets upon liquidation, dissolution, or winding-up the Company.

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.

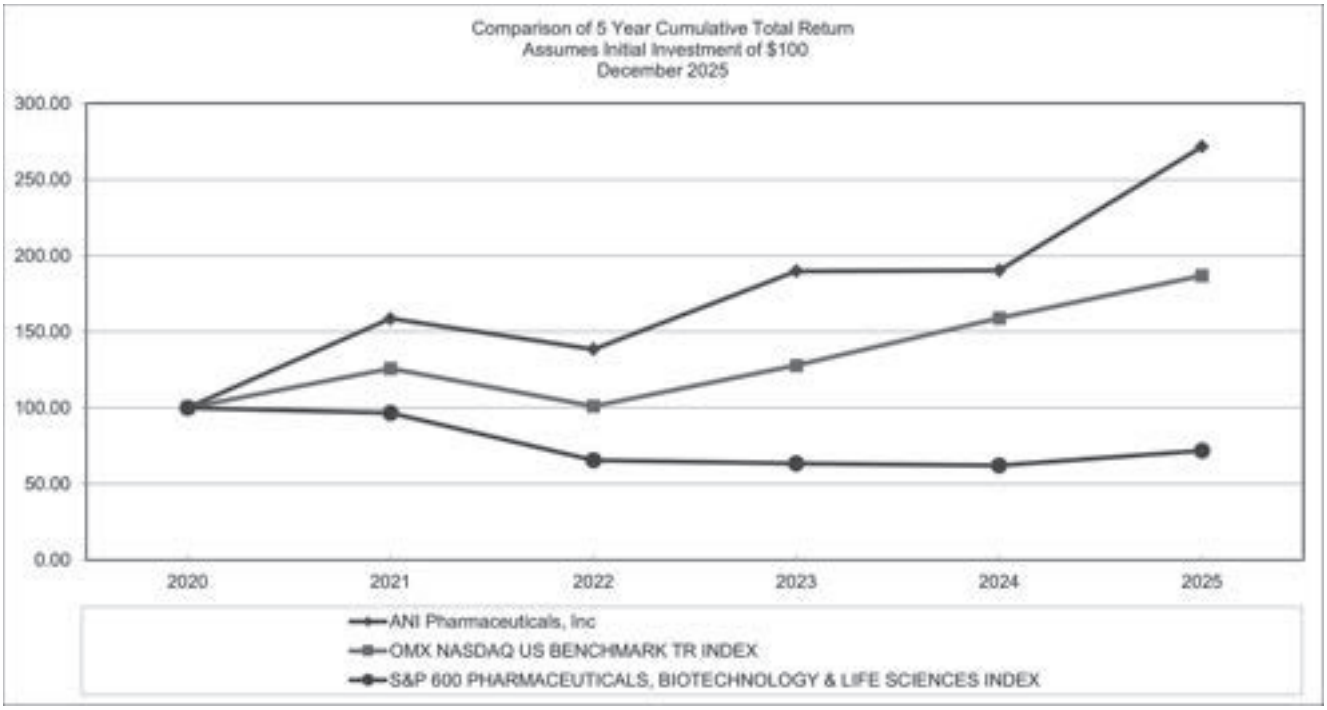
**Issuer Purchases of Equity Securities**

| 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, 2025 | — | $ — | — | $ — |
| November 1 - November 30, 2025 | 5,730 | $ 84.02 | — | $ — |
| December 1 - December 31, 2025 | 1,594 | $ 81.51 | — | $ — |
| Total | 7,324 | $ 83.47 | — | |

[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, 2020, 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, as actual results may differ materially from those contained in any forward-looking statements.*

*This section generally discusses 2025 and 2024 items and year-to-year comparisons between 2025 and 2024. Discussions of 2024 items and year-to-year comparisons between 2024 and 2023 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, 2024, filed with the SEC on February 28, 2025.*

**Executive Overview**

ANI Pharmaceuticals is a diversified bio-pharmaceutical company. The Company's mission is "Serving Patients, Improving Lives" by developing, manufacturing, and commercializing therapeutics through its Rare Disease, Generics, and Brands businesses.

On September 16, 2024, the Company acquired Alimera. 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"). Subsequent to the acquisition of Alimera, we expanded the label for ILUVIEN to include an indication for chronic NIU-PS in addition to its then-current indication in DME in the U.S.

The Company owns and operates three pharmaceutical manufacturing facilities, including two facilities in Baudette, Minnesota, and one in East Windsor, New Jersey, which collectively are capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. The Company ceased operations at another manufacturing facility in Oakville, Ontario as of March 31, 2023. 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 then-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 "2024 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 ($74.9 million of which remains undrawn), which may be used for revolving credit loans, swingline loans and letters of credit.

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 were 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.

On September 16, 2024, ANI drew the full $325.0 million of principal under the 2024 Credit Agreement, with proceeds used to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the acquisition. As of December 31, 2025, the revolving credit facility remains undrawn, and $74.9 million is available for borrowing, subject to the satisfaction of certain conditions. The 2024 Credit Agreement and the revolving credit facility mature on September 16, 2029.

**Recent Developments**

***Purchase of SWK Royalty***

Pursuant to a Royalty Purchase Agreement dated as of December 17, 2020, EyePoint sold its right to receive royalty payments on future sales of ILUVIEN to SWK Funding LLC ("SWK") under the existing collaboration agreement entered into in July 2017 between EyePoint and the Company (the "RPA Transaction"). In connection with the RPA Transaction, the Company agreed to pay such royalty payments directly to SWK (see Note 11 "Goodwill and Intangible Assets" to the notes to the consolidated financial statements).

On June 19, 2024, Alimera entered into a letter agreement with SWK, pursuant to which the parties agreed to a lower fixed royalty payment of 3.125% (the "Alternative Royalty") on combined sales of ILUVIEN and YUTIQ. The letter agreement included a buy-out of the Alternative Royalty at Alimera's option at any time during the period within six (6) months after a change of control of Alimera, after which SWK would have no further right to receive any payments under the letter agreement or the RPA (the "Buy-Out Option"). On March 17, 2025, the Company exercised the Buy-Out Option and paid SWK $17.3 million with cash on hand, and as such, no further royalty is due to SWK on net revenues after January 1, 2025.

***Acquisition of Alimera Sciences, Inc.***

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 (each as defined below), but excluding any treasury shares or shares owned by the Company, merger subsidiaries 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 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 (as defined therein) 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 Merger, 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 ("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). See Note 3 "Business Combination" to the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K for further information on the acquisition.

***Capital Structure***

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

The PIPE Shares accrued dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and participated, on a pro-rata basis, in any dividends that would be declared with respect to the Company's common stock. The PIPE Shares were convertible into common shares at the conversion price of $41.4662 (i) beginning two years after their issuance date, at the election of ANI, if the volume-weighted average price of the common stock for any 20 trading days out of 30 consecutive trading days exceeds 170% of the conversion price, or (ii) at any time after issuance, at the election of the PIPE Investor.

On August 14, 2025, the PIPE Investor converted 5,000 PIPE Shares into 120,580 shares of common stock based on the conversion price of $41.4662 per share. On September 26, 2025, the Company elected mandatory conversion of the remaining 20,000 outstanding PIPE Shares into 482,320 shares of common stock based on the conversion price of $41.4662 per share, as the conditions for conversion had been satisfied. There were no shares of Series A Convertible Preferred Stock outstanding as of December 31, 2025.

Refer to the Liquidity and Capital Resources below for further discussion of changes to our capital structure during 2025 and 2024.

***Product Launches***

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

***General***

Impacts to our 2025 and 2024 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:

| | Year Ended December 31, | |
|---|---|---|
| (in thousands) | **2025** | **2024** |
| Net Revenues | $ 883,366 | $ 614,376 |
| Operating Expenses | | |
| Cost of sales (excluding depreciation and amortization) | 341,310 | 250,210 |
| Research and development | 51,664 | 44,581 |
| Selling, general, and administrative | 317,745 | 249,636 |
| Depreciation and amortization | 91,417 | 67,731 |
| Contingent consideration fair value adjustment | (31,012) | (619) |
| Loss (gain) on disposal of assets | 382 | (5,347) |
| Intangible asset impairment charge | 767 | 7,600 |
| Operating Income | 111,093 | 584 |
| Unrealized gain on investment in equity securities | 2,824 | 6,307 |
| Interest expense, net | (20,060) | (17,602) |
| Other income (expense), net | 1,934 | (4,033) |
| Loss on extinguishment of debt | — | (7,468) |
| Income (Loss) Before (Benefit) Expense for Income Taxes | 95,791 | (22,212) |
| Income tax expense (benefit) | 17,454 | (3,690) |
| Net Income (Loss) | $ 78,337 | $ (18,522) |

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, | |
|---|---|---|
| | **2025** | **2024** |
| Net Revenues | 100.0 % | 100.0 % |
| Operating Expenses | | |
| Cost of sales (excluding depreciation and amortization) | 38.6 % | 40.7 % |
| Research and development | 5.8 % | 7.3 % |
| Selling, general, and administrative | 36.0 % | 40.6 % |
| Depreciation and amortization | 10.3 % | 11.0 % |
| Contingent consideration fair value adjustment | (3.5)% | (0.1)% |
| Loss (gain) on disposal of assets | — % | (0.9)% |
| Intangible asset impairment charge | 0.1 % | 1.2 % |
| Operating Income | 12.7 % | 0.2 % |
| Unrealized gain on investment in equity securities | 0.3 % | 1.0 % |
| Interest expense, net | (2.3)% | (2.9)% |
| Other income (expense), net | 0.2 % | (0.7)% |
| Loss on extinguishment of debt | — % | (1.2)% |
| Income (Loss) Before Expense (Benefit) for Income Taxes | 10.9 % | (3.6)% |
| Income tax expense (benefit) | 2.0 % | (0.6)% |
| Net Income (Loss) | 8.9 % | (3.0)% |

**Results of Operations for the Years Ended December 31, 2025 and 2024**

***Net Revenue***

| (in thousands) | Year Ended December 31, 2025 | 2024 | Change | % Change |
|---|---|---|---|---|
| **Rare Disease and Brands** | | | | |
| Cortrophin Gel | $ 347,778 | $ 198,085 | $ 149,693 | 75.6 % |
| ILUVIEN and YUTIQ | 74,868 | 31,514 | 43,354 | N/M |
| **Rare Disease total net revenues** | $ 422,646 | $ 229,599 | $ 193,047 | 84.1 % |
| Brands | 61,308 | 64,743 | (3,435) | (5.3)% |
| **Rare Disease and Brands total net revenues** | $ 483,954 | $ 294,342 | $ 189,612 | 64.4 % |
| **Generics and Other** | | | | |
| Generic pharmaceutical products | 384,110 | 301,004 | 83,106 | 27.6 % |
| Royalties and other pharmaceutical services | 15,302 | 19,030 | (3,728) | (19.6)% |
| **Generics and Other total net revenues** | $ 399,412 | $ 320,034 | $ 79,378 | 24.8 % |
| **Total net revenues** | $ 883,366 | $ 614,376 | $ 268,990 | 43.8 % |

***"N/M" - not meaningful percentage due to the acquisition of ILUVIEN and YUTIQ on September 16, 2024.***

We derive substantially all of our revenues from sales of our Rare Disease, Brands and Generics portfolios of pharmaceutical products, as well as from other sources of revenue such as royalties on net sales of certain products, and other pharmaceutical services. Essentially all of our Generics 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, 2025 were $883.4 million compared to $614.4 million for the same period in 2024, an increase of $269.0 million, or 43.8%, primarily as a result of the following:

- Net revenues from Rare Disease and Brands, which includes our rare disease and brands portfolios of pharmaceutical products, was $484.0 million during the year ended December 31, 2025, an increase of $189.6 million, compared to $294.3 million for the same period in 2024.
    - Net revenues for Rare Disease pharmaceutical products were $422.6 million during the year ended December 31, 2025, an increase of $193.0 million from $229.6 million for the same period in 2024. This increase was driven by increased volume of Cortrophin Gel from overall ACTH market growth and market share gains, and a full year of sales from ILUVIEN and YUTIQ. ILUVIEN and YUTIQ were acquired from Alimera in September 2024.
    - Net revenues for Brands portfolio of pharmaceutical products were $61.3 million during the year ended December 31, 2025, a decrease of $3.4 million compared to $64.7 million for the same period in 2024, driven by a net decrease in demand for certain products.

- Net revenues for Generic and Other pharmaceutical products were $399.4 million during the year ended December 31, 2025, an increase of 24.8% compared to $320.0 million for the same period in 2024, primarily as a result of the following:

    - Generic pharmaceutical products net revenues were $384.1 million during the year ended December 31, 2025, an increase of $83.1 million over the prior year. This increase was driven by the December 2024 launch of Prucalopride Tablets, which included CGT designation and corresponding 180 day exclusivity that expired in late June 2025, increased volumes from the benefit of new product launches during 2025, inclusive of a partnered generic product launched in Q3 2025, along with annualization of new product launches that occurred during 2024. The Company launched a total of 13 and 17 new products in 2025 and 2024, respectively. From a product perspective, in addition to the products cited above, the increase was principally driven by revenues from year over year increases in products such as Ketoconazole, Nitazoxanide, and Thyroid Tablets, among others.

    - Net revenues from royalties and other pharmaceuticals were down modestly between December 31, 2025 and the prior year due to fewer contract manufacturing shipments during the current year.

***Cost of Sales (Excluding Depreciation and Amortization)***

| | Year Ended December 31, | | | |
|---|---|---|---|---|
| (in thousands) | **2025** | **2024** | **Change** | **% Change** |
| Cost of sales (excluding depreciation and amortization) | $ 341,310 | $ 250,210 | $ 91,100 | 36.4 % |

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

For the year ended December 31, 2025, cost of sales increased to $341.3 million from $250.2 million for the same period in 2024, an increase of $91.1 million or 36.4%. The increase is primarily due to significant net growth in sales volumes of pharmaceutical products and significant growth of royalty bearing products, including Cortrophin Gel and other products in our portfolio.

Cost of sales, as a percentage of net revenues, decreased to 38.6% for the year ended December 31, 2025, from 40.7% for the same period in 2024, primarily due to the non-recurrence of $13.6 million of inventory step-up related to the acquisition of Alimera during 2024.

During the years ended December 31, 2025 and 2024, 17% and 12%, respectively, of our raw material inventory purchases were from one domestic supplier.

***Other Operating Expenses, net***

| (in thousands) | Year Ended December 31, 2025 | 2024 | Change | % Change |
|---|---|---|---|---|
| Research and development | $ 51,664 | $ 44,581 | $ 7,083 | 15.9 % |
| Selling, general, and administrative | 317,745 | 249,636 | 68,109 | 27.3 % |
| Depreciation and amortization | 91,417 | 67,731 | 23,686 | 35.0 % |
| Contingent consideration fair value adjustment | (31,012) | (619) | (30,393) | 4910.0 % |
| Loss (gain) on disposal of assets | 382 | (5,347) | 5,729 | (107.1)% |
| Intangible asset impairment charge | 767 | 7,600 | (6,833) | (89.9)% |
| Total other operating expenses | $ 430,963 | $ 363,582 | $ 67,381 | 18.5 % |

For the year ended December 31, 2025, other operating expenses, net, increased to $431.0 million from $363.6 million for the same period in 2024, an increase of $67.4 million, or 18.5%, primarily as a result of the following factors:

- Research and development expenses increased from $44.6 million to $51.7 million, an increase of 15.9%, primarily due to a higher level of activity associated with ongoing and new projects to support future growth of our Generics and Rare Disease portfolios. Generics and Rare Disease expenses increased by approximately $6.0 million and $0.8 million, respectively, as compared to the year ended December 31, 2024.

- Selling, general, and administrative expenses increased from $249.6 million to $317.7 million, an increase of 27.3%, due to increased employment related costs, investment in Rare Disease sales and marketing infrastructure (including our new, larger ophthalmology sales and marketing team) and activities, legal expenses, and an overall increase in activities to support the growth of our business during the year ended December 31, 2025; offset by a decrease of approximately $16.0 million related to transaction and integration costs for the acquisition of Alimera, and $15.4 million related to severance and equity payments to former Alimera employees incurred during the year ended December 31, 2024, which did not recur during the year ended December 31, 2025.

- Depreciation and amortization expense was $91.4 million for the year ended December 31, 2025, compared to $67.7 million for the same period in 2024, an increase of approximately $23.7 million, primarily related to the increase in amortization expense of the acquired intangible assets, ILUVIEN and YUTIQ. Amortization expense for these assets totaled $32.9 million for the year ended December 31, 2025 compared to a partial year of amortization expense totaling $9.6 million for the year ended December 31, 2024, an increase of approximately $23.3 million. These assets were acquired in September 2024 from Alimera.

- We recognized a gain of $31.0 million for the year ended December 31, 2025 related to reductions in contingent consideration liabilities, which are measured at fair value. These reductions resulted from the adjustment of future forecasted cash flows and the corresponding decrease in expected future payments, including: (1) a $21.0 million reduction related to the accrued Alimera licensor payments; (2) a $7.6 million reduction related to the Alimera contingent value rights; and (3) a $2.6 million reduction in contingent consideration related to the acquisition of Novitium.

- We recognized a loss related to the disposal of certain manufacturing equipment of approximately $0.4 million during the year ended December 31, 2025, and 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.

- We recognized an impairment charge related to one definite-lived intangible asset of approximately $0.8 million during the year ended December 31, 2025. 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 fourth quarter of 2024.

***Other Expense, net***

| (in thousands) | Year Ended December 31, 2025 | 2024 | Change | % Change |
|---|---|---|---|---|
| Unrealized gain on investment in equity securities | $ 2,824 | $ 6,307 | $ (3,483) | (55.2)% |
| Interest expense, net | (20,060) | (17,602) | (2,458) | 14.0 % |
| Other income (expense), net | 1,934 | (4,033) | 5,967 | (148.0)% |
| Loss on extinguishment of debt | — | (7,468) | 7,468 | (100.0)% |
| Total other expense, net | $ (15,302) | $ (22,796) | $ 7,494 | (32.9)% |

For the year ended December 31, 2025, we recognized total other expense, net of $15.3 million as compared to total other expense, net of $22.8 million for the same period in 2024, a decrease of $7.5 million.

- We recorded an unrealized gain on investment in equity securities of approximately $2.8 million for the year ended December 31, 2025, compared to an unrealized gain of $6.3 million in the same period in 2024, which is based on the mark to market fair value of equity securities held in CG Oncology as of the balance sheet date.

- Interest expense, net, for the year ended December 31, 2025 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. Interest income earned on our bank balances and interest rate swaps decreased approximately $2.0 million and $1.4 million, respectively. This impact was partially offset by a decrease in interest expense related to our outstanding debt of approximately $1.1 million, compared to the prior year.

- Other income (expense), net for the years ended December 31, 2025 and 2024 consists primarily of unrealized foreign exchange gains related to our Alimera UK subsidiary. During 2024, other expense, net primarily consisted of 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, in addition to foreign exchange losses.

- We recorded a loss on debt extinguishment of approximately $7.5 million, comprised of the write-off of unamortized deferred financing fees related to the Credit Facility during 2024. On August 13, 2024, the Company entered into the Notes (as described in Note 7 “2.25% Convertible Senior Notes” in the Notes to the Consolidated Financial Statements). The proceeds of the Notes were used to repay the 2021 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 during the year ended December 31, 2025.

***Income Tax Expense (Benefit)***

| (in thousands) | Year Ended December 31, 2025 | 2024 | Change | % Change |
|---|---|---|---|---|
| Income tax expense (benefit) | $ 17,454 | $ (3,690) | $ 21,144 | 573.0 % |

Income tax expense (benefit) consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance. 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, 2025, our income tax expense was approximately $17.5 million. Our effective tax rate of approximately 18.2% of pre-tax income for the current year was determined based on our pre-tax income, statutory tax rates and the tax impacts of certain items including the UK valuation allowance, the U.S. federal research and development credit, certain non-deductible items such as contingent consideration and stock based compensation.

For the year ended December 31, 2024, our income tax benefit was approximately $3.7 million. Our effective tax rate of approximately 16.6% of pre-tax loss or the year ended December 31, 2024 was determined based on our pre-tax loss, statutory tax rates and the tax impacts of certain items including the U.S. federal research and development credit, certain non-deductible items, and stock based compensation.

**Liquidity and Capital Resources**

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

| (in thousands) | December 31, 2025 | December 31, 2024 |
|---|---|---|
| Cash and cash equivalents | $ 285,585 | $ 144,861 |
| Restricted cash | 36 | 33 |
| Accounts receivable, net | 281,082 | 221,726 |
| Inventories | 143,067 | 136,782 |
| Prepaid income taxes | 11,027 | 772 |
| Prepaid expenses and other current assets | 23,189 | 17,975 |
| Investment in equity securities | 9,131 | 6,307 |
| Total current assets | $ 753,117 | $ 528,456 |
| | | |
| Current debt, net of deferred financing costs | $ 17,268 | $ 9,172 |
| Accounts payable | 62,583 | 45,656 |
| Accrued royalties | 48,497 | 22,626 |
| Accrued compensation and related expenses | 37,897 | 37,725 |
| Accrued government rebates | 43,154 | 18,714 |
| Income taxes payable | 1,291 | 5,622 |
| Income taxes payable - foreign | 948 | 1,899 |
| Returned goods reserve | 49,504 | 39,274 |
| Current contingent consideration | 167 | 29 |
| Accrued expenses and other | 16,803 | 13,735 |
| Total current liabilities | $ 278,112 | $ 194,452 |

As of December 31, 2025 and 2024, we had $285.6 million and $144.9 million, respectively, in unrestricted cash and cash equivalents.

We are focused on expanding our business and product pipeline through acquisitions of products and companies as well as internal research and development. 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, 2025. We believe that our financial resources, consisting of net current working capital of approximately $475.0 million, anticipated future operating revenue and corresponding collections from customers, and available borrowings of under our revolving credit facility, of which $74.9 million is available as of December 31, 2025, 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 maintain profitability 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 three customers, which represented 22%, 17%, and 14% of our net revenues during the year ended December 31, 2025. As of December 31, 2025 accounts receivable from these three customers totaled approximately 64% of accounts receivable, net. Our net revenues were concentrated among four customers, which represented 25%, 16%, 12%, and 11% of our 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. 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 39% and 32% of our net revenues in 2025 and 2024, 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. In 2025, annual revenues of Cortrophin Gel reached a level by which we surpassed the highest royalty tier for incremental net sales. To the extent that we achieve higher revenues in future periods, our blended royalty rate will increase. During 2023, 2024 and 2025, the blended Merck royalty rate approximated 10%, the upper teens, and the low twenties, respectively. We currently anticipate the blended royalty rate to be in the high twenties in 2026. Solely for illustrative purpose, if annual net sales were to increase toward one billion dollars, the blended royalty rate would increase into the 30% range.

***Sources and Uses of Cash***

*The 2024 Credit Facility*

On August 13, 2024, the Company, as lead borrower, entered into the 2024 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 “2024 Credit Facility”).

The 2024 Credit Facility is 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 2024 Credit Facility matures on the date that is five years following the closing date of the 2024 Credit Agreement, provided that if any of the Notes remain outstanding on the date that is 91 days prior to the maturity date of the Notes, the 2024 Credit Facility will mature on such date unless certain terms are met.

At the Company’s option, loans under the 2024 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 2024 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 2024 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 Company 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 2024 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 2024 Credit Agreement.

On September 16, 2024 the Company drew the full $325.0 million of principal under the Term Loan A and used the proceeds to finance the acquisition of Alimera, including fees, costs and expenses incurred in connection with the transaction. As of December 31, 2025, $74.9 million is available for borrowing under the TLA Revolver subject to certain conditions. The TLA and the TLA Revolver mature on September 16, 2029. The 2024 Credit Facility contains certain contingent acceleration clauses, none of which have been triggered as of December 31, 2025. The contractual interest rate under the Term Loan A was approximately 6.33% at December 31, 2025.

*2.25% Convertible Senior Notes Due 2029*

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 e "Notes." Pursuant to the terms of the Purchase Agreement, the Company granted the Initial Purchasers an option to purchase up to an additional $41.3 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 were approximately $306.8 million. After payment of the cost of entering into the Capped Call transactions, the Company used the remainder of the net proceeds from the Notes offering, together with cash on hand, to repay the Company's 2021 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 "2021 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. 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.

*2021 Credit Agreement Debt Extinguishment*

The proceeds of the Notes were used to repay the 2021 Credit Agreement with Truist Bank and other lenders, 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 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 A&R 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.

Royalties are payable to EyePoint from 2025 to 2028 at 30% 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, and increasing annually thereafter (the "Accrued Licensor Payments"). There were no payments made in 2025, as the minimum threshold for payment was not met. Upon making the quarterly payments in the aggregate amount of $7.5 million in 2024, the licenses and rights granted to the Company automatically became perpetual and irrevocable.

**Equity Financing**

In May 2023, through a public offering, we completed the issuance and sale of 2,183,545 shares of our 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:

| | Year Ended December 31, | |
|---|---|---|
| (in thousands) | **2025** | **2024** |
| Operating Activities | $ 185,225 | $ 64,017 |
| Investing Activities | $ (34,321) | $ (404,719) |
| Financing Activities | $ (9,944) | $ 264,945 |

*Net Cash Provided by Operations*

Net cash provided by operating activities was $185.2 million for the year ended December 31, 2025, compared to net cash provided by operating activities of $64.0 million during the same period in 2024, an increase of $121.2 million. The increase in cash provided by operating activities primarily resulted from our net income of $78.3 million adjusted for non-cash items, and an increase in our working capital accounts driven by the growth of our business.

*Net Cash Used in Investing Activities*

Net cash used in investing activities for the year ended December 31, 2025 was $34.3 million, principally due to the payment for the exercise of the Buy-Out Option and purchase of other intangible assets of approximately $20.5 million and capital expenditures of approximately $13.8 million. 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) Provided by Financing Activities*

Net cash used in financing activities was $9.9 million for the year ended December 31, 2025, principally resulting from $12.2 million of treasury stock purchases for restricted stock vesting events, principal payments on our 2024 Credit Facility of $10.2 million, offset by proceeds received from stock option exercises and ESPP purchases of approximately $13.6 million. Net cash provided by financing activities for the year ended December 31, 2024 was $264.9 million, principally resulting from proceeds from the 2024 Credit Facility of $325.0 million, proceeds from the offering of the Notes of $316.3 million, tempered by the repayment of the 2021 Credit Facility of $292.5 million, purchase of the capped calls of $40.6 million, payments of debt issuance costs related to the Notes and 2024 Credit Facility of $17.4 million, $12.5 million paid the Company Members of Novitium, and $11.0 million of treasury stock purchase, and other items.

**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, 2025 are comprised of principal payments on debt, interest payments on debt, operating leases, purchase obligations, dividends, and contingent consideration.

***2024 Credit Agreement***

Our largest contractual obligation relates to our principal payments on our interest payments on our debt. As of December 31, 2025, the outstanding principal under our 2024 Credit Agreement was approximately $312.8 million. At the Company's option, loans under the 2024 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 2024 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 6.33% at December 31, 2025. See Note 6 "2024 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 2024 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, 2025, 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 the Indenture dated as of August 13, 2024 between the Company and the 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 leases are primarily operating leases 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 PIPE Shares accrued dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind. During the third quarter of 2025, all of the PIPE Shares were converted into shares of the Company, and as such, no dividends were payable in the fourth quarter of 2025 or in the future. 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 Merger Agreement, the Company paid $12.5 million of cash consideration to the Company Members for the achievement of the ANDA Filing Earn-Out. 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.

Pursuant to the terms of the Novitium Merger Agreement, the Company owes 20% of net profit generated by sales of certain 505(b)(2) Products, to the Company Members. The payments are due on a quarterly basis, within 45 calendar days of each quarter end, until the earlier to occur of (i) the sum of all such payments being equal to $21.5 million in the aggregate and (ii) the tenth anniversary of FDA approval of the applicable 505(b)(2) Product (the "505(b)(2) Earn-Out"). During the year ended December 31, 2025, the Company paid approximately $26 thousand for payment of the 505(b)(2) Earn-Out to the Company Members.

***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, 2025 was approximately $1.4 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 30% 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, and 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 automatically became perpetual and irrevocable. The present value of the remaining payments to EyePoint for years 2026 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, 2025 was zero. 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 Gel, 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 Annual Report on 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 $6.8 million for the year ended December 31, 2025.

*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 $7.8 million for the year ended December 31, 2025.

*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 $3.7 million for the year ended December 31, 2025.

*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 $8.7 million for the year ended December 31, 2025.

*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 $3.6 million for the year ended December 31, 2025.

***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, 2025 was approximately $62.5 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 $34.3 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 approximately $0.8 of impairment charges during the year ended December 31, 2025, related to one product for which the Company has ceased commercialization. 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 million in 2025, increasing annually thereafter. The fair value of the Accrued Licensor Payments was zero at December 31, 2025. 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. These changes resulted in a decrease of the fair value of the liability of approximately $21.0 million during the year ended December 31, 2025, as no further payments are anticipated to be made in fiscal 2026 to 2028.

***Novitium Contingent Consideration***

The fair value of the Novitium contingent consideration was $8.3 million and $10.9 million at December 31, 2025 and 2024, 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 $2.6 million during the year ended December 31, 2025.

***Alimera Contingent Value Rights***

The fair value of the Alimera Contingent Value Rights consideration was $1.4 million and $9.0 million at December 31, 2025 and 2024, respectively. 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 a gain recognized in our consolidated statement of operations of $7.6 million during the year ended December 31, 2025.

***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 awards and units are 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 expense incurred for ESPP, stock options, restricted stock awards, restricted stock units, performance-based restricted stock units, and Inducement grants included in our consolidated statements of operations:

| **(in thousands)** | **Years Ended December 31,** | | |
|---|---|---|---|
| | **2025** | **2024** | **2023** |
| Selling, general, and administrative | $ 33,982 | $ 26,534 | $ 19,036 |
| Research and development | 2,144 | 1,533 | 910 |
| Cost of sales | 1,803 | 1,277 | 706 |
| | $ 37,929 | $ 29,344 | $ 20,652 |

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 awards and units are recognized as expense on a straight-line basis over the employee's requisite service period.

Valuation of stock awards and units require 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 Income (Loss) Before Expense (Benefit) for Income Taxes would be affected by $3.8 million for the year ended December 31, 2025.

***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 UK, 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 income (loss) 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 the 2024 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 2024 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, 2025, the Company had approximately $312.8 million of debt outstanding under the 2024 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 $1.7 million based upon our unhedged portion of principal debt outstanding as of December 31, 2025. 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 2024 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, 2025 by approximately $2.9 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, 2025.

***Equity Investment Risk***

Our equity investment is held in the marketable equity securities of one publicly traded company, CG Oncology, Inc. As of December 31, 2025, the carrying value of our marketable equity securities was approximately $9.1 million. This equity investment 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 investment.

## 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, 2025 and 2024, 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, 2025, 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, 2025 and 2024, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2025, 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, 2025, 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 27, 2026 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, 2025, is approximately $143 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, which are utilized to estimate the expected chargeback 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.

/s/ EisnerAmper LLP

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

EISNERAMPER LLP
Iselin, New Jersey
February 27, 2026

## 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, 2025, 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, 2025, based on criteria established in the *Internal Control - Integrated Framework* (*2013*) issued by COSO.

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, 2025 and 2024, 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, 2025, and the related notes and our report dated February 27, 2026 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
Iselin, New Jersey
February 27, 2026

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

| | December 31, 2025 | December 31, 2024 |
|---|---|---|
| **Assets** | | |
| Current Assets | | |
| Cash and cash equivalents | $ 285,585 | $ 144,861 |
| Restricted cash | 36 | 33 |
| Accounts receivable, net of $171,803 and $127,824 of adjustments for chargebacks and other allowances at December 31, 2025 and 2024, respectively | 281,082 | 221,726 |
| Inventories | 143,067 | 136,782 |
| Prepaid income taxes | 11,027 | 772 |
| Prepaid expenses and other current assets | 23,189 | 17,975 |
| Investment in equity securities | 9,131 | 6,307 |
| Total Current Assets | 753,117 | 528,456 |
| Non-current Assets | | |
| Property and equipment, net | 62,476 | 56,863 |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | 69,072 | 85,106 |
| Intangible assets, net | 479,526 | 541,834 |
| Goodwill | 62,480 | 59,990 |
| Derivatives and other non-current assets | 13,706 | 12,220 |
| Total Assets | $ 1,440,377 | $ 1,284,469 |
| **Liabilities, Mezzanine Equity, and Stockholders' Equity** | | |
| Current Liabilities | | |
| Current debt, net of deferred financing costs | $ 17,268 | $ 9,172 |
| Accounts payable | 62,583 | 45,656 |
| Accrued royalties | 48,497 | 22,626 |
| Accrued compensation and related expenses | 37,897 | 37,725 |
| Accrued government rebates | 43,154 | 18,714 |
| Income taxes payable | 1,291 | 5,622 |
| Income taxes payable - foreign | 948 | 1,899 |
| Returned goods reserve | 49,504 | 39,274 |
| Current contingent consideration | 167 | 29 |
| Accrued expenses and other | 16,803 | 13,735 |
| Total Current Liabilities | 278,112 | 194,452 |
| Non-current Liabilities | | |
| Non-current debt, net of deferred financing costs and current component | 291,840 | 309,108 |
| Non-current convertible notes, net of deferred financing costs | 307,927 | 305,812 |
| Accrued licensor payments due | — | 20,961 |
| Non-current contingent consideration, net of current | 9,610 | 19,825 |
| Other non-current liabilities | 12,164 | 5,781 |
| Total Liabilities | $ 899,653 | $ 855,939 |
| Commitments and Contingencies (Note 17) | | |
| **Mezzanine Equity** | | |
| Convertible Preferred Stock, Series A, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2025 and 25,000 shares issued and outstanding at December 31, 2024 | — | 24,850 |
| **Stockholders' Equity** | | |
| Common Stock, $0.0001 par value, 66,000,000 shares authorized; 23,112,577 shares issued and 22,491,281 outstanding at December 31, 2025; $0.0001 par value, 33,333,334 shares authorized 21,537,707 shares issued and 21,108,152 shares outstanding at December 31, 2024 | 3 | 2 |
| Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at December 31, 2025 and 2024 respectively | — | — |
| Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2025 and 2024, respectively | — | — |
| Treasury stock, 621,296 shares of common stock, at cost, at December 31, 2025 and 429,555 shares of common stock, at cost, at December 31, 2024 | (33,249) | (21,040) |
| Additional paid-in capital | 596,036 | 519,653 |
| Accumulated deficit | (23,099) | (100,279) |
| Accumulated other comprehensive income, net of tax | 1,033 | 5,344 |
| Total Stockholders' Equity | 540,724 | 403,680 |
| Total Liabilities, Mezzanine Equity, and Stockholders' Equity | $ 1,440,377 | $ 1,284,469 |

*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, | | |
|---|---|---|---|
| | **2025** | **2024** | **2023** |
| Net Revenues | $ 883,366 | $ 614,376 | $ 486,816 |
| | | | |
| Operating Expenses | | | |
| Cost of sales (excluding depreciation and amortization) | 341,310 | 250,210 | 181,513 |
| Research and development | 51,664 | 44,581 | 34,286 |
| Selling, general, and administrative | 317,745 | 249,636 | 161,697 |
| Depreciation and amortization | 91,417 | 67,731 | 59,791 |
| Contingent consideration fair value adjustment | (31,012) | (619) | 1,426 |
| Loss (gain) on disposal of assets | 382 | (5,347) | — |
| Restructuring activities | — | — | 1,132 |
| Intangible asset impairment charge | 767 | 7,600 | — |
| | | | |
| Total Operating Expenses, net | 772,273 | 613,792 | 439,845 |
| | | | |
| Operating Income | 111,093 | 584 | 46,971 |
| | | | |
| Other Expense, net | | | |
| Unrealized gain on investment in equity securities | 2,824 | 6,307 | — |
| Interest expense, net | (20,060) | (17,602) | (26,940) |
| Other income (expense), net | 1,934 | (4,033) | (159) |
| Loss on extinguishment of debt | — | (7,468) | — |
| Income (Loss) Before Expense (Benefit) for Income Taxes | 95,791 | (22,212) | 19,872 |
| | | | |
| Income tax expense (benefit) | 17,454 | (3,690) | 1,093 |
| | | | |
| Net Income (Loss) | $ 78,337 | $ (18,522) | $ 18,779 |
| | | | |
| Dividends on Series A Convertible Preferred Stock | (1,157) | (1,625) | (1,625) |
| | | | |
| Net Income (Loss) Available to Common Shareholders | $ 77,180 | $ (20,147) | $ 17,154 |
| | | | |
| **Basic and Diluted Income (Loss) Per Share:** | | | |
| Basic Income (Loss) Per Share | $ 3.50 | $ (1.04) | $ 0.86 |
| Diluted Income (Loss) Per Share | $ 3.32 | $ (1.04) | $ 0.85 |
| | | | |
| Basic Weighted-Average Shares Outstanding | 20,053 | 19,318 | 18,001 |
| Diluted Weighted-Average Shares Outstanding | 21,228 | 19,318 | 18,194 |

*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, | | |
|---|---|---|---|
| | **2025** | **2024** | **2023** |
| Net Income (Loss) | $ 78,337 | $ (18,522) | $ 18,779 |
| | | | |
| Other comprehensive income (loss), net of tax: | | | |
| Foreign currency translation adjustment | 116 | (644) | 44 |
| Loss on interest rate swap | (4,427) | (2,869) | (3,355) |
| Total other comprehensive loss, net of tax | (4,311) | (3,513) | (3,311) |
| Total comprehensive income (loss), net of tax | $ 74,026 | $ (22,035) | $ 15,468 |

*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, 2025, 2024, and 2023**
*(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, 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 | — | — | — | — | — | — | — |
| 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 | 25 | $ 2 | 21,538 | $ — | $ 519,653 | 430 | $ (21,040) | $ 5,344 | $ (100,279) | $ 428,530 |
| Stock-based Compensation Expense | — | — | — | — | — | 37,929 | — | — | — | — | 37,929 |
| Conversion of Series A Convertible Preferred Stock | (24,850) | (25) | 1 | 603 | — | 24,850 | — | — | — | — | 1 |
| Treasury Stock Purchases for Restricted Stock Vests | — | — | — | — | — | — | 191 | (12,209) | — | — | (12,209) |

| | 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 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Issuance of Common Shares upon Stock Option and ESPP Exercise | — | — | — | 258 | — | 13,604 | — | — | — | — | 13,604 |
| Issuance of Restricted Stock Awards | — | — | — | 729 | — | — | — | — | — | — | — |
| Issuance of Performance Stock Units | — | — | — | 80 | — | — | — | — | — | — | — |
| Restricted Stock Awards Forfeitures | — | — | — | (95) | — | — | — | — | — | — | — |
| Dividends on Series A Convertible Preferred Stock | — | — | — | — | — | — | — | — | — | (1,157) | (1,157) |
| Other comprehensive loss | — | — | — | — | — | — | — | — | (4,311) | — | (4,311) |
| Net Income | — | — | — | — | — | — | — | — | — | 78,337 | 78,337 |
| Balance, December 31, 2025 | $ — | — | $ 3 | 23,113 | $ — | $ 596,036 | 621 | $ (33,249) | $ 1,033 | $ (23,099) | $ 540,724 |

*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, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| Cash Flows From Operating Activities | | | |
| Net income (loss) | $ 78,337 | $ (18,522) | $ 18,779 |
| Adjustments to reconcile net income (loss) to net cash and cash equivalents provided by operating activities: | | | |
| Stock-based compensation | 37,929 | 29,344 | 20,652 |
| Deferred taxes | 14,237 | (21,913) | (11,740) |
| Depreciation and amortization | 91,417 | 67,731 | 59,791 |
| Unrealized gain on investment in equity securities | (2,824) | (6,307) | — |
| Non-cash operating lease expense | 1,759 | 1,526 | 1,269 |
| Non-cash interest | 1,356 | 642 | 3,922 |
| Contingent consideration fair value adjustment | (31,012) | (619) | 1,426 |
| Loss (gain) on disposal of assets | 382 | (5,347) | — |
| Loss on extinguishment of debt | — | 7,468 | — |
| Amortization of inventory step up | — | 13,599 | — |
| Asset impairment charges | 767 | 7,600 | — |
| Changes in operating assets and liabilities, net of acquisitions: | | | |
| Accounts receivable, net | (58,530) | (21,087) | 3,359 |
| Inventories | (5,961) | (21,287) | (5,841) |
| Prepaid expenses and other assets | (5,024) | 2,129 | (9,015) |
| Accounts payable | 15,156 | 479 | 7,552 |
| Accrued royalties | 25,871 | 6,350 | 6,969 |
| Income taxes | (15,531) | (1,415) | 11,991 |
| Accrued government rebates | 24,441 | 6,160 | 1,296 |
| Returned goods reserve | 10,229 | 9,102 | (3,722) |
| Accrued expenses, accrued compensation, and other | 2,226 | 8,384 | 12,271 |
| Net Cash and Cash Equivalents Provided by Operating Activities | 185,225 | 64,017 | 118,959 |
| Cash Flows From Investing Activities | | | |
| Acquisition of Alimera, net of cash acquired | — | (401,280) | — |
| Acquisition of product rights, intangible assets, and other related assets | (20,486) | (717) | (9,643) |
| Acquisition of property and equipment, net | (13,835) | (16,236) | (8,868) |
| Proceeds from the sale of building | — | 13,514 | — |
| Net Cash and Cash Equivalents Used in Investing Activities | (34,321) | (404,719) | (18,511) |
| 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 | (26) | (12,500) | (12,500) |
| Principal payments on borrowings | (10,156) | (3,531) | (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 | (1,157) | (1,625) | (1,625) |
| Proceeds from stock option exercises and ESPP purchases | 13,604 | 6,488 | 8,996 |
| Treasury stock purchases for restricted stock vests | (12,209) | (10,959) | (4,987) |
| Net Cash and Cash Equivalents (Used in) Provided by Financing Activities | (9,944) | 264,945 | 67,439 |
| Effect of Exchange Rate Changes on Cash, Cash Equivalents and Restricted Cash | (233) | (470) | — |
| Net Change in Cash, Cash Equivalents, and Restricted Cash | 140,727 | (76,227) | 167,887 |
| Cash and cash equivalents, beginning of year | 144,894 | 221,121 | 53,234 |
| Cash, cash equivalents and restricted cash, end of year | $ 285,621 | $ 144,894 | $ 221,121 |

| | Year Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| Reconciliation of cash, cash equivalents, and restricted cash, beginning of year | | | |
| Cash and cash equivalents | $ 144,861 | $ 221,121 | $ 48,228 |
| Restricted cash | 33 | — | 5,006 |
| Cash, cash equivalents, and restricted cash, beginning of year | $ 144,894 | $ 221,121 | $ 53,234 |
| | | | |
| Reconciliation of cash, cash equivalents, and restricted cash, end of year | | | |
| Cash and cash equivalents | $ 285,585 | $ 144,861 | $ 221,121 |
| Restricted cash | 36 | 33 | — |
| Cash, cash equivalents, and restricted cash, end of year | $ 285,621 | $ 144,894 | $ 221,121 |
| | | | |
| **Supplemental disclosure for cash flow information:** | | | |
| Cash paid for interest, net of amounts capitalized | $ 26,929 | $ 24,379 | $ 31,431 |
| Cash paid for income taxes, net of refunds received | $ 17,674 | $ 19,061 | $ 1,228 |
| Right-of-use assets obtained in exchange for lease obligations | $ 6,641 | $ — | $ 4,715 |
| | | | |
| **Supplemental non-cash investing and financing activities:** | | | |
| Purchase consideration for acquisition of Alimera | $ — | $ (8,322) | $ — |
| Conversion of convertible preferred stock into common stock | $ 24,850 | $ — | $ — |
| Property and equipment purchased and included in accounts payable | $ 1,050 | $ 529 | $ 328 |

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

## 1. DESCRIPTION OF BUSINESS AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

### Organization and Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (collectively, “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 therapeutics through its Rare Disease, Generics, and Brands businesses.

On September 16, 2024, the Company acquired Alimera Sciences, Inc. ("Alimera"). 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 the consolidated financial statements for further information on the acquisition.

During March 2025, the U.S. Food and Drug Administration (the “FDA”) approved an expanded label for ILUVIEN to include an indication for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye ("NIU-PS") in addition to the then-current indication of Diabetic Macular Edema ("DME"). The Company is currently marketing ILUVIEN for both indications in the U.S. ILUVIEN was already approved for both DME and NIU-PS outside the U.S., including in seventeen European countries. During the second quarter of 2025, the Company transitioned promotional efforts in the U.S. from YUTIQ to ILUVIEN with its combined label of DME and NIU-PS.

The Company owns and operates three pharmaceutical manufacturing facilities, including two facilities in Baudette, Minnesota and one in East Windsor, New Jersey, which collectively are capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. The Company ceased operations at another manufacturing facility in Oakville, Ontario as of March 31, 2023. 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 then-current exchange rate at closing of such transaction. The sale closed on March 28, 2024. See Note 4 "Restructuring Canada Operations" in the notes to the consolidated financial statements for further information.

The Company held its 2025 Annual Meeting of Stockholders (the "2025 Annual Meeting") on May 22, 2025. At the 2025 Annual Meeting, the stockholders of the Company approved an amendment to the Company's Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 33.3 million shares to 66.0 million shares.

### 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”).

Certain prior year amounts, such as prepaid income taxes, income taxes payable, and income taxes payable-foreign, have been reclassified for consistency to conform with current year presentation in the consolidated balance sheets. Such reclassifications had no effect on previously reported net income (loss), stockholders' equity, or cash flows.

### 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 Canada, 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 subsidiaries 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 its functional currency is Euros. The Canada-based subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar.

The results of any non-U.S. dollar transactions and balances are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income (loss). 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 year ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are accumulated as a separate component of shareholders' equity within accumulated other comprehensive income (loss), net of tax. Foreign currency transaction gains and losses include fluctuations related to long-term intercompany loans. Translation gains and losses on intercompany balances of a long-term investment nature are included in foreign currency translation adjustments in accumulated other comprehensive income (loss).

**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 has completed the final fair value determination of the assets acquired and liabilities assumed from Alimera, within the measurement period, which did not 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").

**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 is 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.

*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 Canada, the United Kingdom, 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 not material as of December 31, 2025 and 2024.

**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.

**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, 2025, 2024, and 2023.

**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, 2025, 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 the 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.

**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, 2025, $0.8 million of impairment charges were recognized on intangible assets. 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.

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. At December 31, 2025, there was no IPR&D recorded on the balance sheet, and as such no impairment testing was performed, and no impairment charges were recognized on IPR&D. During the year ended December 31, 2024, $4.0 million of impairment charges were recognized on IPR&D. During the year ended December 31, 2023, no impairment charges were recognized on IPR&D.

**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 Pharma Services Inc., 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, 2025 and 2024, and therefore no quantitative testing for impairment was required. No impairment loss related to goodwill was recognized in the years ended December 31, 2025, 2024, and 2023.

**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, restricted stock awards ("RSAs") and restricted stock units ("RSUs"), 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 vesting of PSUs is contingent upon the Company meeting both certain total shareholder return ("TSR") levels as compared to a select peer group over the over three years and 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 its income tax returns remain subject to examination by tax authorities due to the availability of net operating loss carryforwards.

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 income (loss)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, 2025 and 2024 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. 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 the consolidated statement of cash flows.

**Accrued Licensor Payments**

The terms of the Product Rights Agreement, dated May 17, 2023, 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 and 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. There were no amounts due and payable during the year ended December 31, 2025.

**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 the 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, 2025 or 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, 2025 and 2024 due to their short term nature. See Note 12 "Fair Value" in the notes to the consolidated financial statements for additional information.

**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 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 anticipates disclosing any impact of the adoption in the annual report on Form 10-K for the fiscal year ended December 31, 2027.

*Recently Adopted Accounting Pronouncements*

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires disclosure of disaggregated income taxes paid, prescribes standard categories for the components of the effective tax rate reconciliation, and modifies other income tax-related disclosures. The Company adopted ASU 2023-09 in the fourth quarter of 2025, with prospective application. The adoption of ASU 2023-09 has not had a material effect on the Company’s statements and disclosures. See Note 16 "Income Taxes" in the notes to the consolidated financial statements.

In November 2023, the FASB issued Accounting Standards Update 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 its customers generally pay 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:

| | Years Ended December 31, | | |
|---|---|---|---|
| **Products and Services (in thousands)** | **2025** | **2024** | **2023** |
| **Rare Disease and Brands** | | | |
| Cortrophin Gel | $ 347,778 | $ 198,085 | $ 112,117 |
| ILUVIEN and YUTIQ | 74,868 | 31,514 | — |
| **Rare Disease total net revenues** | $ 422,646 | $ 229,599 | $ 112,117 |
| Brands | 61,308 | 64,743 | 85,384 |
| **Rare Disease and Brands total net revenues** | $ 483,954 | $ 294,342 | $ 197,501 |
| **Generics and Other** | | | |
| Generic pharmaceutical products | $ 384,110 | $ 301,004 | $ 269,449 |
| Royalties and other pharmaceutical services | 15,302 | 19,030 | 19,866 |
| **Generics and Other total net revenues** | $ 399,412 | $ 320,034 | $ 289,315 |
| **Total net revenue** | $ 883,366 | $ 614,376 | $ 486,816 |

| | Years Ended December 31, | | |
|---|---|---|---|
| **Timing of Revenue Recognition (in thousands)** | **2025** | **2024** | **2023** |
| Performance obligations transferred at a point in time | $ 883,366 | $ 614,376 | $ 486,441 |
| Performance obligations transferred over time | — | — | 375 |
| Total | $ 883,366 | $ 614,376 | $ 486,816 |

In the years ended December 31, 2025 or 2024, the Company did not incur, and therefore did not defer, any material incremental costs to obtain or fulfill contracts. As of December 31, 2025, there were no contract assets recorded which were related to revenue recognized based on percentage of completion but not yet billed.

The Company recognized a decrease of $2.1 million of net revenue from performance obligations satisfied in prior periods during the year ended December 31, 2025, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales.

As of December 31, 2025, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $2.4 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, and
- 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 the Company's products by beneficiaries under such governmental programs. The two largest government programs are Medicaid and Medicare.

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 utilization 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 invoice has not been received, as well as an estimate for future claims that will be made when inventory in the distribution channel is sold through to Medicaid beneficiaries.

Many of the Company's products are also covered under Medicare. Through 2024, the Company participated in the Coverage Gap Discount Program ("CGDP"), under which it provided discounts on covered Part D drugs approved under NDAs that were dispensed to Medicare Part D beneficiaries in the coverage gap phase of the benefit. Beginning in 2025, the Company participates in the Medicare Part D Manufacturer Discount Program ("MDP"), which replaces the CGDP under the Inflation Reduction Act of 2022. Under the MDP, the Company is required to provide discounts on covered Part D drugs approved under NDAs or BLAs that are dispensed to Medicare Part D beneficiaries during the initial coverage and catastrophic phases of the benefit. This requirement applies to all covered Part D drugs approved under NDAs or BLAs, including products marketed as authorized generics.

Estimates for these discounts are based on historical experience with Medicare Part D utilization and discount invoicing patterns for applicable products. Medicare Part D discounts are billed quarterly for drugs dispensed to Medicare Part D 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 discount invoicing, Medicare Part D discount 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 beneficiaries.

To evaluate the adequacy of government rebate and discount reserves, the Company reviews these reserves on a quarterly basis against actual claims and invoicing data to ensure the liability is reasonably stated. The Company continually monitors the government rebate and discount reserve and adjusts estimates when it expects that actual obligations may differ from established accruals. Accruals for government rebates and discounts 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.

*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, 2025, 2024, and 2023:

| | Accruals for Chargebacks, Returns, and Other Allowances | | | | |
|---|---|---|---|---|---|
| (in thousands) | Chargebacks | Government Rebates | Returns | Administrative Fees and Other Rebates | Prompt Payment Discounts |
| Balance at December 31, 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 |
| Accruals/Adjustments | 677,311 | 78,276 | 37,333 | 86,620 | 35,993 |
| Credits Taken Against Reserve | (639,489) | (53,836) | (27,103) | (77,295) | (33,618) |
| Balance at December 31, 2025 (1) | $ 143,452 | $ 43,154 | $ 49,504 | $ 28,913 | $ 8,633 |

(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 national wholesalers, specialty pharmacies, retail pharmacy chains, other U.S. and international distributors, group purchasing organizations, and hospitals and healthcare providers.

During the year ended December 31, 2025, there were three customers that accounted for 10% or more of net revenues, made up of wholesale distributors. As of December 31, 2025, accounts receivable from these customers totaled 64% of accounts receivable, net. During the years ended December 31, 2024, and 2023, there were four customers that accounted for 10% or more of net revenues.

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

| | Years Ended December 31, | | |
|---|---|---|---|
| | 2025 | 2024 | 2023 |
| **Customer 1** | 17 % | 25 % | 31 % |
| **Customer 2** | 9 % | 11 % | 13 % |
| **Customer 3** | 14 % | 12 % | 13 % |
| **Customer 4** | 22 % | 16 % | 12 % |

## 3. BUSINESS COMBINATION

On September 16, 2024, the Company completed its 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 (the "Merger"), with Alimera surviving the Merger as a wholly owned subsidiary of the Company.

At the effective time of the Merger, each share of outstanding Alimera common stock (the "Alimera Common Stock"), including each Alimera RSA, Alimera PSU, Alimera RSU, and Alimera Warrant (each as defined below), but excluding any treasury shares or shares owned by the Company, Merger Sub 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 certain milestone payments 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, 2025. 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 Merger, all of the outstanding awards of restricted 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 ("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 cash 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 Consideration (as defined in the Merger Agreement) may receive a payment in connection with the payout of the CVRs (if any).

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

| (In thousands, except share price and exchange ratio) | Purchase Consideration |
|---|---|
| Alimera Common Stock outstanding | $ 53,971 |
| Alimera Warrants outstanding after exercise | 989 |
| Alimera Common Stock and Alimera 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 2024 Credit Facility (see Note 6 "2024 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, 2025, see Note 12 “Fair Value” in the notes to the consolidated financial statements.

The preliminary purchase price allocation, measurement period adjustments, and final purchase price allocation of the fair value of the Alimera acquisition is shown in the table below.

| (in thousands) | Preliminary Purchase Price Allocation | Measurement Period Adjustment | Final Purchase Price Allocation |
|---|---|---|---|
| Cash and cash equivalents | $ 9,247 | $ — | $ 9,247 |
| Accounts receivable | 38,605 | 175 | 38,780 |
| 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 | (84) | 114 |
| Derivative and other non-current assets | 1,224 | — | 1,224 |
| Total assets | $ 474,435 | $ (1,468) | $ 472,967 |
| | | | |
| Accounts payable | $ 8,001 | $ — | $ 8,001 |
| Accrued expenses and other | 11,396 | 976 | 12,372 |
| 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 | 1,828 | 39,760 |
| Accrued licensor payment, net of current | 21,316 | — | 21,316 |
| Other non-current liabilities | 2,364 | — | 2,364 |
| Total liabilities | $ 87,788 | $ 589 | $ 88,377 |
| | | | |
| Total fair value of consideration transferred | $ 418,849 | $ — | $ 418,849 |
| Less: fair value of net acquired identifiable assets and liabilities | 386,647 | (2,057) | 384,590 |
| Goodwill | $ 32,202 | $ 2,057 | $ 34,259 |

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.

Subsequent to the acquisition date, the Company has updated certain amounts above based upon information that was not known to the Company as of the acquisition date. The Company determined that the adjustments are considered measurement period adjustments under the accounting guidance. The Company recorded a net increase to goodwill of approximately $2.1 million as a result of the adjustments based on matters that existed at acquisition date but were not known to the Company at that time. Measurement period adjustments were recorded, from the acquisition date through the end of the measurement period. The purchase price allocation was finalized during the quarter ended September 30, 2025.

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. 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 amortization period (in years):

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

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.

During the second quarter of 2025, the Company transitioned promotional efforts in the U.S. from YUTIQ to ILUVIEN with its combined label of DME and NIU-PS, and as a result the Company combined the ILUVIEN and YUTIQ intangible assets. The Company concluded that there were no changes to expected future cash flows for the combined ILUVIEN definite-lived intangible asset. The fair value of the definite-lived intangible asset was not below its carrying value as of December 31, 2025.

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 $2.1 million and $18.1 million in transaction and integration costs during the year ended December 31, 2025 and 2024, respectively, 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 (the "Property").

For the year ended December 31, 2025 and 2024, there were no restructuring activities recorded in the consolidated statements of operations or the consolidated balance sheets.

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 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.

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 then-current 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 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. The land and building had a net carrying value of approximately $8.0 million, which was previously presented as assets held for sale on the consolidated balance sheets as of December 31, 2023.

## 5. 2021 CREDIT FACILITY

In connection with the acquisition of Novitium on November 19, 2021, the Company, as borrower, entered into a credit agreement (the “2021 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 “2021 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 "2021 Revolving Facility," and together with the 2021 Term Facility, the "2021 Credit Facility").

The Company incurred $14.0 million in deferred debt issuance costs associated with the 2021 Credit Facility. Costs allocated to the 2021 Term Facility were classified as a direct reduction to the current and non-current portion of the borrowings, depending on their nature. Costs allocated to the 2021 Revolving Facility were 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 2021 Revolving Facility.

***Extinguishment of the 2021 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 the consolidated financial statements). The proceeds of the Convertible Senior Notes and cash on-hand were used to repay the 2021 Credit Facility in its entirety, or 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 2021 Credit Facility as of August 13, 2024.

The following table sets forth the components of total interest expense related to the 2021 Credit Facility recognized in the accompanying consolidated statements of operations for the years ended December 31:

| (in thousands) | 2024 | 2023 |
|---|---|---|
| Contractual coupon | $ 16,644 | $ 30,692 |
| Amortization of deferred financing costs | 1,477 | 2,363 |
| Capitalized interest | (492) | (588) |
| | $ 17,629 | $ 32,467 |

## 6. 2024 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 "2024 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 "2024 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, 2025, $74.9 million is available for borrowing under the TLA Revolver. The TLA and the TLA Revolver mature on September 16, 2029. The 2024 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, 2025.

The cash interest rate and effective rate under the Term Loan A was approximately 6.33% and 6.69% per annum at December 31, 2025, respectively.

The 2024 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 2024 Credit Facility is subject to customary financial and nonfinancial covenants. As of December 31, 2025, the Company was in compliance with all covenants associated with the 2024 Credit Facility.

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 2024 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 $0.8 million of unamortized deferred debt issuance costs allocated to the TLA Revolver, $0.6 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:

| | Current | |
|---|---|---|
| **(in thousands)** | **2025** | **2024** |
| Current borrowing on debt | $ 18,281 | $ 10,156 |
| Deferred financing costs | (1,013) | (984) |
| Current debt, net of deferred financing costs | $ 17,268 | $ 9,172 |

| | Non-Current | |
|---|---|---|
| **(in thousands)** | **2025** | **2024** |
| Non-current borrowing on debt | $ 294,531 | $ 312,813 |
| Deferred financing costs | (2,691) | (3,705) |
| Non-current debt, net of deferred financing costs and current component | $ 291,840 | $ 309,108 |

The contractual maturity of the Term Loan A is as follows for the years ended December 31:

| **(in thousands)** | **2024 Term Loan A** |
|---|---|
| 2026 | $ 18,281 |
| 2027 | 24,375 |
| 2028 | 24,375 |
| 2029 | 245,781 |
| Total | $ 312,812 |

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)** | **2025** | **2024** | **2023** |
|---|---|---|---|
| Contractual coupon interest expense, 2021 Credit Agreement | $ — | $ (20,993) | $ (33,270) |
| Contractual coupon interest expense, 2024 Credit Agreement | (22,137) | (7,264) | — |
| Contractual coupon interest expense, Convertible Notes | (7,096) | (2,747) | — |
| Amortization of deferred financing costs | (3,329) | (2,624) | (2,364) |
| Interest expense | (32,562) | (33,628) | (35,634) |
| Capitalized interest related to Construction in Progress | 381 | 492 | 588 |
| Interest and dividend income on bank balances | 7,247 | 9,268 | 5,528 |
| Interest income on interest rate swap | 4,874 | 6,266 | 2,578 |
| Interest income | 12,502 | 16,026 | 8,694 |
| **Interest expense, net** | $ (20,060) | $ (17,602) | $ (26,940) |

## 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 were 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 2021 Credit Facility in its entirety. Refer to Note 5 "2021 Credit Facility" to the notes to the consolidated financial statements for the details of the extinguishment of the 2021 Credit Agreement.

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

***Conversion Options***

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

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

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

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

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

***Events of Default***

The Notes include customary provisions relating to the occurrence of "Events of Default" (as defined in the Indenture), including breaches of covenants, breaches of warranty, change of control, nonpayment, bankruptcy, assignment, foreclosure, cessation of business, and defaults under ancillary documents. Certain of the Events of Default are subject to notice and cure periods. As of December 31, 2025, 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, 2025 and 2024, the unamortized debt discount and debt issuance cost of the Notes was approximately $8.3 and $10.4 million, respectively, on the consolidated balance sheets. The effective interest rate during the year ended December 31, 2025 was 3.01%.

During the year ended December 31, 2025, 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, 2025, and were classified as long-term debt on the Company's consolidated balance sheet as of December 31, 2025.

As of December 31, 2025, the total estimated fair value (which represents a Level 2 valuation) of the Notes is approximately $413.0 million.

The Company recognized $7.1 million and $2.7 million of contractual coupon interest expense and $2.1 million and $0.8 million of interest expense related to the amortization of deferred financing costs for the years ended December 31, 2025 and 2024, respectively.

***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")-based interest rates underlying total borrowings under term facilities related to the 2021 Credit Agreement. The interest rate swap matures in December 2026. The Company amended its 2021 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 Loan A. Concurrent with the termination of the 2021 Credit Agreement and entry into the 2024 Credit Agreement with Truist Bank, the interest rate swap with a notional value of $168.6 million at origin on November 21, 2021 was novated and Truist Bank became the new counterparty.

On August 30, 2024, in connection with the entry into the 2024 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 Term Loan A. 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, 2025, 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, 2025, the fair value of the interest rate swap asset recorded in other non-current assets in the consolidated balance sheets is $1.6 million. As of December 31, 2025, $1.6 million was recorded in accumulated other comprehensive income (loss), net of tax in the consolidated balance sheets.

During the year ended December 31, 2025, the loss on fair value of the interest rate swaps, net of tax recorded in accumulated other comprehensive income (loss)in the consolidated statements of comprehensive income was approximately $4.4 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, 2025 and 2024, the Company recorded a reduction in interest expense of $4.9 million and $6.3 million in relation to the interest rate swaps, respectively. Included in these amounts for the years ended December 31, 2025 and 2024 are reclassifications out of accumulated other comprehensive income (loss)of $3.4 million of interest income and $0.8 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) | 2025 | 2024 |
|---|---|---|
| Raw materials | $ 74,363 | $ 67,174 |
| Packaging materials | 9,743 | 9,977 |
| Work-in-progress | 2,973 | 1,665 |
| Finished goods | 55,988 | 57,966 |
| Inventories | $ 143,067 | $ 136,782 |

### 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, 2025, approximately 17% of the Company's raw material inventory purchases were from one domestic supplier. During the year ended December 31, 2024, approximately 12% of the Company's raw material inventory purchases were from one domestic supplier. During the year ended December 31, 2023, no single vendor represented more than 10% of the Company's raw material inventory purchases.

## 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) | 2025 | 2024 |
|---|---|---|
| Land | $ 2,410 | $ 1,582 |
| Buildings | 25,833 | 24,438 |
| Machinery, furniture, and equipment | 76,043 | 68,697 |
| Leasehold improvements | 1,405 | 1,297 |
| Finance leases | 650 | 1,161 |
| Construction in progress | 8,825 | 4,568 |
| | 115,166 | 101,743 |
| Less: accumulated depreciation | (52,690) | (44,880) |
| Property and equipment, net | $ 62,476 | $ 56,863 |

Depreciation expense for the years ended December 31, 2025, 2024, and 2023 totaled $8.9 million, $7.4 million, and $7.5 million, respectively. During the years ended December 31, 2025, 2024, and 2023 there was $0.4 million, $0.5 million, and $0.6 million, respectively, of interest capitalized into construction in progress, respectively.

## 11. GOODWILL AND INTANGIBLE ASSETS

### Goodwill

As of December 31, 2025, 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 $34.3 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 years ended December 31, 2025 and 2024, and as a result, no impairment charges have been recognized. In addition to the qualitative impairment analysis performed at October 31, 2025, 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, 2025 to December 31, 2025. No goodwill impairment losses were recognized during the years ended December 31, 2025, 2024, and 2023.

### Intangible Assets

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

| | December 31, 2025 | | | December 31, 2024 | | | Remaining Weighted Average Amortization Period(1) |
|---|---|---|---|---|---|---|---|
| (in thousands) | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount | Gross Carrying Amount | Accumulated Amortization | Net Carrying Amount | |
| **Definite-Lived Intangible Assets:** | | | | | | | |
| Acquired ANDA intangible assets | $ 214,260 | $ (147,511) | $ 66,749 | $ 210,497 | $ (124,874) | $ 85,623 | 3.7 years |
| NDAs and product rights | 673,554 | (271,818) | 401,736 | 641,271 | (216,420) | 424,851 | 10.3 years |
| Marketing and distribution rights | 17,157 | (16,195) | 962 | 17,157 | (15,233) | 1,924 | 1.0 years |
| Customer relationships | 24,900 | (14,821) | 10,079 | 24,900 | (11,264) | 13,636 | 2.8 years |
| Total Definite-Lived Intangible Assets | 929,871 | (450,345) | 479,526 | 893,825 | (367,791) | 526,034 | 9.2 years |
| **Indefinite-Lived Intangible Assets:** | | | | | | | |
| In process research and development | — | — | — | 15,800 | — | 15,800 | Indefinite |
| Total Intangible Assets, net | $ 929,871 | $ (450,345) | $ 479,526 | $ 909,625 | $ (367,791) | $ 541,834 | |

(1) Weighted average amortization period as of December 31, 2025.

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 assets might be impaired.

Pursuant to a Royalty Purchase Agreement dated as of December 17, 2020, EyePoint Pharmaceuticals US, Inc. (f/k/a pSivida US, Inc. or "EyePoint") sold to SWK Funding LLC ("SWK") its right to receive royalty payments on future sales of ILUVIEN under an existing collaboration agreement entered into in July 2017 between EyePoint and the Company (the "RPA Transaction"). In connection with the RPA Transaction, the Company agreed to pay such royalty payments directly to SWK. On June 19, 2024, Alimera entered into a letter agreement with SWK, pursuant to which the parties agreed to a lower fixed royalty payment of 3.125% (the "Alternative Royalty") on combined sales of ILUVIEN and YUTIQ. The letter agreement included a buy-out of the Alternative Royalty at Alimera's option at any time during the period within six (6) months after a change of control of Alimera, after which SWK would have no further right to receive any payments under the letter agreement or the RPA (the "Buy-Out Option"). On March 17, 2025, the Company exercised the Buy-Out Option and paid SWK $17.3 million with cash on hand, and as such, no further royalty is due to SWK on net revenues beginning January 1, 2025, forward. The purchase of the Buy-Out Option was recorded as a definite-lived intangible asset, which will be amortized over a period of approximately twelve years, consistent with the useful lives of YUTIQ and ILUVIEN. The SWK definite-lived intangible asset is included in the "NDAs and product rights" in the table above.

During the year ended December 31, 2025, $15.8 million was reclassified from indefinite-lived IPR&D to definite-lived NDAs and Product Rights related to the commercialization of Tezruly and Inzirqo, and will be amortized over ten years. As of December 31, 2025 there was no IPR&D on the consolidated balance sheet, and there were no impairment losses recognized on IPR&D.

Additionally, approximately $3.8 million of acquired ANDA intangible assets were capitalized related to asset acquisitions during the year ended December 31, 2025, which will be amortized over their useful lives.

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. During the second quarter of 2025, the Company transitioned promotional efforts in the U.S. from YUTIQ to ILUVIEN with its combined label of DME and NIU-PS, and as result the Company combined the ILUVIEN and YUTIQ intangible assets. The Company concluded that there were no changes to expected future cash flows for the combined ILUVIEN definite-lived intangible asset.

The Company recognized approximately $0.8 million of impairment charges during the year ended December 31, 2025, related to one product for which the Company has ceased commercialization, and recognized approximately $3.6 million of impairment losses during the year ended December 31, 2024, related to certain definite-lived intangibles. There were no impairment losses recorded during the year ended December 31, 2023.

Amortization expense for definite-lived intangible assets was $82.5 million, $60.3 million, and $52.3 million for the years ended December 31, 2025, 2024, and 2023, 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, as described above, include IPR&D. Indefinite-lived intangible assets are not amortized, and the Company tests for impairment of indefinite-lived intangible assets annually as of October 31, 2025, 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.

No amounts were reclassified from indefinite-lived IPR&D to intangible assets during the year ended December 31, 2024. The Company recorded $4.0 million of impairment losses on IPR&D during the year ended December 31, 2024. There were no comparable reclassifications or impairment charges for the year ended December 31, 2023.

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

| **(in thousands)** | | |
|---|---|---|
| 2026 | $ | 69,640 |
| 2027 | | 60,573 |
| 2028 | | 54,582 |
| 2029 | | 48,343 |
| 2030 | | 37,727 |
| 2031 and thereafter | | 208,661 |
| Total | $ | 479,526 |

Expected amortization expense is an estimate. Actual amounts of amortization expense may differ due to 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 the Company's 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 2024 Credit Facility bears an interest rate that fluctuates with the changes in SOFR and because the variable interest rate approximates market borrowing rates available to the Company, the carrying value of the 2024 Credit Facility approximated its fair values at December 31, 2025 and 2024.

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

#### *Alimera Contingent Value Rights Agreement*

On September 16, 2024, prior to consummation of the Alimera acquisition, the Company entered into a CVR agreement, 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 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 the 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 Securities and Exchange Commission in its annual report 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. As a result of the decrease in forecast future revenue for 2026 and 2027, a corresponding decrease in the CVR liability was recorded. The fair value of the CVR liability was approximately $1.4 million as of December 31, 2025, a decrease of approximately $7.6 million from $9.0 million as of December 31, 2024, and is classified as non-current contingent consideration in the Company's consolidated balance sheet.

The following table presents the changes in the CVR liability classified as Level 3 for the years ended December 31, 2025 and 2024:

| | Year Ended December 31, | |
|---|---|---|
| **(in thousands)** | **2025** | **2024** |
| Beginning balance | $ 9,000 | $ — |
| CVR Agreement | — | 8,700 |
| Change in fair value | (7,572) | 300 |
| Ending balance | $ 1,428 | $ 9,000 |

***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 sheets, and are 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 was approximately $209.9 million and $84.3 million as of December 31, 2025 and 2024, respectively.

***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 "2024 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 the consolidated financial statements. As described in Note 8, the fair value of the interest rate swap was $1.6 million and $4.9 million at December 31, 2025 and 2024, 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, Inc. (Nasdaq: CGON) ("CG Oncology"). 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 was approximately $9.1 million and $6.3 million as of December 31, 2025 and 2024, based on a closing market price of $41.52 and $28.68 on December 31, 2025 and 2024, respectively. The change in fair value of the equity securities is classified on the consolidated statements of operations as unrealized gain on investment in equity securities, in the amounts of approximately $2.8 million and $6.3 million for the years ended December 31, 2025 and 2024, respectively. 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 (which period ran from December 1, 2021 through November 30, 2023), , 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 the inputs are not based on readily available market data. 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 related to the Novitium acquisition, dated as of March 8, 2021 (the "Novitium Merger Agreement"), on December 12, 2023, the Company paid $12.5 million of cash consideration to the holders of Novitium ownership interests ("Company Members"), for the achievement of the ANDA Filing Earn-Out, (as defined in the Novitium Merger Agreement). On February 22, 2024, the Company paid $12.5 million to Company Members of Novitium upon the achievement of the milestone. See Note 18 "Related Party Transactions" in the notes to the consolidated financial statements).

Pursuant to the terms of the Novitium Merger Agreement, the Company owes 20% of net profit generated by the sales of certain 505(b)(2) products (as defined in the Novitium Merger Agreement) to the Company Members through the earlier to occur of (i) the sum of all such payments being equal to $21.5 million in the aggregate and (ii) the tenth anniversary of the FDA approval of the applicable 505(b)(2) product (the "505(b)(2) Earn-Out"). The payments are due on a quarterly basis, within 45 calendar days of each quarter end. During the years ended December 31, 2025 and 2024, the Company has paid less than $0.1 million and zero, respectively, for payments of the 505(b)(2) Earn-Out to the Company Members, respectively.

The total fair value of the contingent consideration was approximately $8.3 million and $10.9 million as of December 31, 2025 and 2024, 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, 2025:

| Payment Type | Valuation Technique | Unobservable Input | Assumptions |
|---|---|---|---|
| Profit-based milestone payments | Probability-weighted discounted cash flow | Discount rate | 11.5% |
| | | Projected fiscal year of payment | 2026-2034 |

The following table presents the changes in contingent consideration balances classified as Level 3 balances for the years ended December 31, 2025 and 2024:

| | Year Ended December 31, | |
|---|---|---|
| **(in thousands)** | **2025** | **2024** |
| Beginning balance | $ 10,854 | $ 23,984 |
| Payment of Gross-Profit earn-out | (26) | (12,500) |
| Accrual of Gross-Profit earn-out | 108 | — |
| Change in fair value | (2,588) | (630) |
| Ending balance | $ 8,348 | $ 10,854 |

***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 had such rights pursuant to the A&R 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, for which Ocumension holds a license from EyePoint. Pursuant to the agreement, Alimera paid EyePoint an upfront payment of $75.0 million and also made four quarterly guaranteed payments to EyePoint totaling $7.5 million during the year ended December 31, 2024. Upon making the quarterly payments in the aggregate amount of $7.5 million in 2024, the licenses and rights granted to the Company became automatically perpetual and irrevocable. There are no quarterly guaranteed payments in 2025 and beyond.

Royalties are payable to EyePoint from 2025 to 2028 at 30% 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, and increasing annually thereafter. The Company did not make any royalty payments during 2025, as the minimum threshold of net sales that would trigger the requirement to make royalty payments was not met.

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. 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. These changes resulted in a decrease of the fair value of the liability of approximately $21.0 million as no further payments are anticipated to be made in fiscal 2026 to 2028.

The following table presents the changes in accrued licensor payments classified as Level 3 balances for the years ended December 31, 2025 and 2024:

| | Year Ended December 31, | |
|---|---|---|
| **(in thousands)** | **2025** | **2024** |
| Beginning balance | $ 20,961 | $ — |
| Accrued licensor payments | — | 25,000 |
| Payments | — | (3,750) |
| Change in fair value | (20,961) | (289) |
| Ending balance | $ — | $ 20,961 |

The following table presents financial assets and liabilities accounted for at fair value on a recurring basis as of December 31, 2025 and December 31, 2024, by level within the fair value hierarchy:

| **(in thousands)**<br>**Description** | **Fair Value at December 31, 2025** | **Level 1** | **Level 2** | **Level 3** |
|---|---|---|---|---|
| Assets | | | | |
| Money Market Fund | $ 209,891 | $ 209,891 | $ — | $ — |
| Interest rate swap | $ 1,646 | $ — | $ 1,646 | $ — |
| CG Oncology - Investment in equity securities | $ 9,131 | $ 9,131 | $ — | $ — |
| Liabilities | | | | |
| Contingent consideration, Novitium | $ 8,348 | $ — | $ — | $ 8,348 |
| Contingent Value Rights, Alimera | $ 1,428 | $ — | $ — | $ 1,428 |
| Accrued licensor payment | $ — | $ — | $ — | $ — |

| (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 swaps | $ 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 |

**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.

**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, 2025 and 2024 there were $0.8 million and $7.6 million 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, 2023, there were no impairment losses recognized in relation to any non-financial assets or liabilities measured at fair value.

**Acquired Non-Financial Assets Measured at Fair Value**

Acquired non-financial assets measured at fair value consists of certain assets, such as ANDAs or NDAs, acquired by the Company during the year ended December 31, 2025 and 2024, as discussed above, and assets and liabilities acquired from Alimera during the year ended December 31, 2024 (see Note 3 "Business Combination" in the notes to the consolidated financial statements).

## 13. MEZZANINE AND STOCKHOLDERS' EQUITY

***Authorized shares***

At the 2025 Annual Meeting, the stockholders of the Company approved an amendment to the Company's Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 33.3 million shares to 66.0 million shares.

The Company is authorized to issue up to 66.0 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, 2025.

There were 23.1 million and 22.5 million shares of common stock issued and outstanding as of December 31, 2025, respectively, and 21.5 million and 21.1 million shares of common stock issued and outstanding as of December 31, 2024, 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, 2025 and 2024. 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.

**Mezzanine Equity**

***PIPE Shares***

On March 8, 2021, concurrently with the acquisition of Novitium, and as financing for a portion of the acquisition, 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 were classified as mezzanine equity because the shares were mandatorily redeemable for cash upon a change in control, an event that would not have been solely in the Company's control. The Company incurred $0.2 million in issuance costs associated with the transaction.

The PIPE Shares accrued dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and participated, on a pro-rata basis, in any dividends that would have been declared with respect to the Company's common stock. The PIPE Shares were convertible into shares of the Company's common stock at the conversion price of $41.4662 (i) beginning two years after their issuance date, at the election of ANI (in which case the PIPE Investor must convert all of the PIPE Shares), if the volume-weighted average price of the Company's common stock for any 20 trading days out of 30 consecutive trading days exceeded 170% of the conversion price, and (ii) at any time after issuance, at the election of the PIPE Investor.

On August 14, 2025, the PIPE Investor converted 5,000 PIPE Shares into 120,580 shares of common stock based on the conversion price of $41.4662 per share. On September 26, 2025, the Company mandatorily converted the remaining 20,000 outstanding PIPE Shares into 482,320 shares of common stock based on the conversion price of $41.4662 per share, as the conditions for conversion had been satisfied.

There were no shares of Series A convertible preferred stock outstanding at December 31, 2025. There were 25,000 shares of Series A convertible preferred stock outstanding as of December 31, 2024.

**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 shares of common stock, consisting of shares issuable upon conversion of the Company's senior convertible notes, common stock options, shares to be purchased under the 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 shares of common stock 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 is attributed entirely to common stockholders.

As the Company reported a net loss for the year ended December 31, 2024, diluted net loss per share attributable to common shareholders was 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, 2025, 2024, and 2023 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, | | |
| | 2025 | 2024 | 2023 | 2025 | 2024 | 2023 |
| Net income (loss) available to common shareholders | $ 77,180 | $ (20,147) | $ 17,154 | $ 77,180 | $ (20,147) | $ 17,154 |
| Earnings allocated to participating securities | (6,963) | — | (1,679) | (6,611) | — | (1,663) |
| Net income (loss) available to common shareholders | $ 70,217 | $ (20,147) | $ 15,475 | $ 70,569 | $ (20,147) | $ 15,491 |
| Basic Weighted-Average Shares Outstanding | 20,053 | 19,318 | 18,001 | 20,053 | 19,318 | 18,001 |
| Dilutive effect of convertible senior notes, common stock options, ESPP, and performance stock units | | | | 1,175 | — | 193 |
| Diluted Weighted-Average Shares Outstanding | | | | 21,228 | 19,318 | 18,194 |
| | | | | | | |
| Earnings (loss) per share | $ 3.50 | $ (1.04) | $ 0.86 | $ 3.32 | $ (1.04) | $ 0.85 |

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, was 2.0 million, 2.3 million, and 2.4 million for the years ended December 31, 2025, 2024, and 2023, respectively. For the year ended December 31, 2024, all potentially dilutive shares were anti-dilutive and excluded from the calculation of diluted loss per share because the Company reported a net loss.

## 15. STOCK-BASED COMPENSATION

### Employee Stock Purchase Plan

In July 2016, the Company commenced administration of the ANI Pharmaceuticals, Inc. 2016 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.

During the 2025 Annual Meeting, the stockholders of the Company approved an amendment to the ESPP. Subject to adjustment, the Amended and Restated ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan, or Amended and Restated ESPP, authorized the issuance of an additional 500,000 shares.

As of December 31, 2025, there are approximately 0.5 million shares of common stock available for issuance under the Amended and Restated ESPP.

**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 pursuant to the Amended 2022 Stock Plan. During the 2025 Annual Meeting, the stockholders of the Company approved a further amendment to the Amended 2022 Stock Plan (such amendment, the "2025 Stock Plan Amendment"; and the Amended 2022 Stock Plan, after giving effect to the 2025 Stock Plan Amendment, the "Second Amended 2022 Stock Plan"). The 2025 Stock Plan Amendment authorized the issuance of an additional 750,000 shares pursuant to the Second Amended 2022 Stock Plan..

As of December 31, 2025, approximately 1.9 million shares of common stock were available for issuance under the Second Amended 2022 Stock Plan.

Equity-based service awards are granted under 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 under the 2008 Plan 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 Second Amended 2022 Stock Plan to induce prospective employees to accept employment (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. No Inducement Grants were issued to employees in 2023, 2024, or 2025.

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, stock options, restricted stock awards, restricted stock units, performance-based restricted stock units, and Inducement Grants and included in the consolidated statements of operations:

| **(in thousands)** | **Years Ended December 31,** | | |
|---|---|---|---|
| | **2025** | **2024** | **2023** |
| Selling, general, and administrative | $ 33,982 | $ 26,534 | $ 19,036 |
| Research and development | 2,144 | 1,533 | 910 |
| Cost of sales | 1,803 | 1,277 | 706 |
| Total | $ 37,929 | $ 29,344 | $ 20,652 |

Income tax benefits of approximately $1.4 million, $2.8 million, and $3.3 million were recognized for stock-based compensation-related tax deductions in the 2025, 2024, and 2023 consolidated statements of operations, respectively.

**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 2025 or 2024. For 2023, the fair value of each option grant was estimated using the Black-Scholes option-pricing model, using the following assumptions:

| | Year Ended December 31, |
|---|---|
| | 2023 |
| Expected option life (years) | 6.25 |
| Risk-free interest rate | 4.1% |
| Expected stock price volatility | 49.0% |
| 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 its shares of common stock 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 Second Amended 2022 Stock Plan and Inducement Grants during the years ended December 31, 2025, 2024, and 2023 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 at 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 |
| Exercised | (197) | 55.22 | | | $ 5,125 |
| Forfeited | (3) | 34.24 | | | |
| Expired | (33) | 68.71 | | | |
| Outstanding at December 31, 2025 | 351 | $ 39.53 | | 4.0 | $ 13,852 |
| Exercisable at December 31, 2025 | 349 | $ 39.53 | | 3.9 | $ 13,765 |

As of December 31, 2025, there was less than $0.1 million of total unrecognized compensation cost related to non-vested stock options granted under the Second Amended 2022 Stock Plan and Inducement Grant. The cost is expected to be recognized over a weighted-average period of 0.83 years. During the year ended December 31, 2025, the Company received $10.9 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, 2024, the Company received $4.5 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, 2023, the Company received $8.3 million in cash from the exercise of stock options and recorded a $0.2 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. 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. Upon vesting, unrestricted shares of common stock are delivered to employees and directors.

A summary of RSA activity under the Second Amended 2022 Stock Plan during the years ended December 31, 2025, 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 | 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 |
| Granted | 729 | 61.59 | |
| Vested | (552) | 43.44 | |
| Forfeited | (95) | 55.04 | |
| Unvested at December 31, 2025 | 1,537 | $ 54.59 | 2.3 |

As of December 31, 2025, there was $66.5 million of total unrecognized compensation cost related to non-vested RSAs granted under the Second Amended 2022 Stock Plan, which is expected to be recognized over a weighted-average period of 2.26 years.

**Restricted Stock Units**

Restricted stock units ("RSUs") are typically granted to international employees of the Company under the Amended 2022 Stock Plan, and generally vest over a period of four years. Each RSU will entitle the recipient to receive one unrestricted share of common stock upon vesting. The fair value of each RSU is based on the market value of the Company's stock on the date of grant. The Company began granting RSUs to certain employees during the year ended 2025, and there were no grants to employees during 2024 or 2023.

A summary of RSU activity under the Second Amended 2022 Stock Plan during the year ended December 31, 2025 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, 2024 | — | $ — | — |
| Granted | 23 | 70.09 | |
| Forfeited | (1) | 69.64 | |
| Unvested at December 31, 2025 | 22 | $ 70.12 | 3.4 |

As of December 31, 2025, there was $1.4 million of total unrecognized compensation cost related to non-vested RSUs granted under the Second Amended 2022 Stock Plan, which is expected to be recognized over a weighted-average period of 3.4 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.

***February 12, 2025 Performance-Based Restricted Stock Units***

On February 12, 2025, 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, 2025, and 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, 2025. The MPRSUs and PRSUs are also subject to the recipient's continued employment or service through December 31, 2027. 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.

On February 12, 2025, the Company granted 79,859 PSUs to employees and officers of the Company under the Second Amended 2022 Stock Plan (including 74,421 PSUs to officers of the Company). As described above, PSU performance will be measured over three-year performance period from January 1, 2025 through December 31, 2027 and will cliff-vest contingent upon the achievement of specified performance objectives. 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 $97.48 and was calculated using a Monte Carlo simulation model. These MPRSUs are included at 100% of the estimate number of shares at the end of the three-year performance period and are reflected under "Granted" in the table below.

The estimated grant date fair value per share of the PRSUs was $59.68 based on the closing price of the stock on the date of grant. These PRSUs are included at 100% of the estimated number of shares at the end of the three-year performance period and are reflected under "Granted" in the table below.

***February 14, 2024 Performance-Based Restricted Stock Units Grant***

On February 14, 2024, the Company granted 73,588 PSUs to officers and employees of the Company under the Second Amended 2022 Stock Plan (including 66,433 PSUs 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 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, 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 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.

A summary of PSU activity under the Second Amended 2022 Stock Plan during the years ended December 31, 2025, 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 | — | $ — | 0 |
| Granted | 85 | 41.84 | |
| Forfeited | (1) | 41.84 | |
| Unvested at December 31, 2023 | 84 | $ 41.84 | 2.0 |
| Granted | 74 | 56.10 | |
| Forfeited | (8) | 48.06 | |
| Unvested at December 31, 2024 | 150 | $ 48.52 | 1.6 |
| Granted | 80 | 59.68 | |
| Unvested at December 31, 2025 | 230 | $ 52.40 | 1.5 |

As of December 31, 2025, there was $8.5 million of total unrecognized compensation cost related to non-vested PSUs granted under the Second Amended 2022 Stock Plan, which is expected to be recognized over a weighted-average period of 1.5 years.

## 16. INCOME TAXES

The foreign current and foreign deferred (benefit) expense below represent the Company's tax (benefit) expense from Canada, India, United Kingdom, Ireland, Portugal, and Germany.

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, 2025 and 2024, the consolidated valuation allowance was $12.4 million and $9.5 million, respectively, primarily related to deferred tax assets for net operating losses in the UK and certain U.S. state jurisdictions.

In July 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted into law. For fiscal year 2025, the primary impact of the OBBBA to the tax provision was the accelerated expensing of domestic research and development activities which reduced the Company's deferred tax assets and reduced its current income tax liability. The OBBBA restored an EBITDA-based calculation permanently and it resulted in the reduction of deferred tax assets and additional tax-deductible interest expense.

Income (loss) before expense (benefit) for income taxes consisted of the following:

| | Years Ended December 31, | | |
|---|---|---|---|
| (in thousands) | 2025 | 2024 | 2023 |
| United States | $ 103,588 | $ (24,618) | $ 19,124 |
| Foreign | (7,797) | 2,406 | 748 |
| Income (loss) before expense (benefit) for income taxes | $ 95,791 | $ (22,212) | $ 19,872 |

Total income tax expense (benefit) for income taxes consists of the following for the years ended December 31:

| (in thousands) | 2025 | 2024 | 2023 |
|---|---|---|---|
| Current income tax expense (benefit) | | | |
| Federal | $ (3,011) | $ 13,714 | $ 9,117 |
| State | 5,533 | 2,231 | 3,534 |
| Foreign | 171 | 1,876 | 26 |
| Total current tax expense | 2,693 | 17,821 | 12,677 |
| Deferred income tax expense (benefit) | | | |
| Federal | 15,979 | (17,876) | (7,601) |
| State | (1,250) | (3,906) | (3,946) |
| Foreign | (2,942) | (1,217) | (29) |
| Total deferred tax expense (benefit) | 11,787 | (22,999) | (11,576) |
| Change in valuation allowance | 2,974 | 1,488 | (8) |
| Total expense (benefit) for income taxes | $ 17,454 | $ (3,690) | $ 1,093 |

The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the year ended December 31, 2025, updated for the new disclosure guidance within ASU 2023-09, which the Company has adopted prospectively.

| | Year Ended December 31, 2025 | |
|---|---|---|
| (in thousands) | Amount | Percentage |
| Tax expense at federal statutory rate | $ 20,116 | 21.0 % |
| State and local income tax, net of federal (national) income tax effect | 2,902 | 3.0 % |
| Foreign tax effects: | | |
| Foreign Tax Effects - United Kingdom - Valuation Allowance | 2,974 | 3.1 % |
| Foreign Tax Effects - United Kingdom - Other | (468) | (0.5)% |
| Foreign Tax Effects - Other foreign jurisdictions | (662) | (0.7)% |
| Tax Credits - Research and Experimentation | (3,771) | (3.9)% |
| Nontaxable or nondeductible items: | | |
| Nontaxable or Nondeductible Items - Executive compensation | 2,668 | 2.8 % |
| Nontaxable or Nondeductible Items - Equity compensation | (1,281) | (1.3)% |
| Nontaxable or Nondeductible Items - Contingent consideration | (5,992) | (6.3)% |
| Nontaxable or Nondeductible Items - Other | 989 | 1.0 % |
| Other adjustments | (21) | — % |
| Tax expense at effective rate | $ 17,454 | 18.2 % |

The following is a reconciliation of the statutory federal income tax rate to the Company's effective tax rate for the years ended December 31, 2024 and 2023, prior to the application of ASU 2023-09:

| | As of December 31, | |
|---|---|---|
| | **2024** | **2023** |
| US federal statutory rate | 21.0 % | 21.0 % |
| State taxes, net of federal benefit | 2.5 % | 4.8 % |
| Foreign taxes | (3.0)% | 0.0% |
| Change in valuation allowance | (6.7)% | 0.0% |
| Stock-based compensation | (6.5)% | 10.8 % |
| Non-deductible costs | (8.8)% | 2.1 % |
| Change in state apportionment factors, state and foreign rates | 4.0 % | (11.8)% |
| Research and experimentation and charitable credits | 14.1 % | (19.0)% |
| Transfer pricing and other | — % | (2.4)% |
| Effective income tax rate | 16.6 % | 5.5 % |

The components of deferred tax assets and liabilities as of December 31, 2025 and 2024, are as follows (in thousands):

| | As of December 31, | |
|---|---|---|
| **(in thousands)** | **2025** | **2024** |
| Deferred tax assets: | | |
| Accruals and advances | $ 18,944 | $ 16,318 |
| Stock-based compensation | 8,430 | 7,373 |
| Accruals for chargebacks and returns | 19,447 | 23,427 |
| Inventories | 6,614 | 5,234 |
| Net operating loss carryforwards | 28,148 | 27,254 |
| Capitalized research expenditures | — | 19,836 |
| Interest expense carryforwards | — | 6,400 |
| Debt instruments | 7,728 | 9,590 |
| Charitable contribution carryforward | 7,003 | — |
| Other assets | 7,718 | 5,305 |
| Total deferred tax assets | $ 104,032 | $ 120,737 |
| Less valuation allowance | (12,423) | (9,450) |
| Total net deferred tax assets | $ 91,609 | $ 111,287 |
| Deferred tax liabilities: | | |
| Depreciation | $ (6,336) | $ (6,710) |
| Intangible assets | (7,358) | (12,537) |
| Other liabilities | (8,843) | (6,934) |
| Total deferred tax liabilities | $ (22,537) | $ (26,181) |
| Deferred tax assets, net of deferred tax liabilities and valuation allowance | $ 69,072 | $ 85,106 |

As of December 31, 2025, the Company had U.S. federal net operating loss carryforwards of approximately $48.3 million and UK net operating loss carryforwards of approximately $61.9 million as a result of the acquisition of Alimera. Net operating loss carryforwards related to the Alimera acquisition are indefinite lived. State net operating loss carryforwards related to the 2013 merger with BioSante Pharmaceuticals, Inc., 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, 2025, the Company had tax effected total net operating losses in various states of $2.2 million which begin to expire through 2030.

The amounts of income tax paid by the Company, net of refunds, for the year ended December 31, 2025 were as follows:

| (in thousands) | | Amount |
|---|---|---|
| United States - federal | $ | 13,699 |
| United States - state and local - other | | 2,343 |
| United States - state and local - Pennsylvania | | 976 |
| Foreign | | 656 |
| Total | $ | 17,674 |

The Company is subject to income taxes in numerous jurisdictions in the U.S. and certain foreign jurisdictions. Significant judgment 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 its belief that its tax return positions are fully supportable. The Company 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, 2025 and 2024.

While the general IRS assessment statute of limitations is three years, the IRS can examine an original loss year return to verify a net operating loss deduction, even if it is beyond the three-year statute. This exception applies because a net operating loss deduction may affect the taxable income in other years, and the IRS retains the right to audit the original year to ensure the net operating loss was properly calculated.

## 17. COMMITMENTS AND CONTINGENCIES

### Operating Leases

The majority of the Company's leases as of December 31, 2025 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.

The Company entered into a new lease agreement for office space located in Princeton, New Jersey, for a term of approximately 10 years, following the lease commencement date of August 18, 2025. The office space serves as the Company's commercial headquarters, which includes certain employees in the Company's corporate, legal, human resources, business functions, and commercial operations. The Company recognized a right-of-use asset and a corresponding lease liability at the lease commencement date of approximately $5.2 million. The lease liability is initially measured at the present value of the lease payments, discounted using the lessee's incremental borrowing rate of approximately 7.4%. The lease agreement includes a rent-free period of three months, and is classified as an operating lease in the consolidated balance sheets.

In connection with the acquisition of Alimera, the Company acquired an operating lease for office space in Alpharetta, Georgia The lease for this space expires in December 2032 with an early termination option in December 2029 and an option to extend five years beyond December 2032. During 2025, the Company entered into an agreement to sublease the entire space to a subtenant, which agreement will expire in December 2032.

As of December 31, 2025, the Company has operating leases for facilities and office equipment with remaining terms expiring from 2026 through 2035 and a weighted average remaining lease terms of 6.5 years and 3.8 years, as of December 31, 2025 and 2024, 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 for the Company's lease obligations as of December 31, 2025 and 2024 are 7.74% and 8.10%, respectively.

Lease expense consisted of the following for the years ended December 31:

| **(in thousands)** | **2025** | **2024** | **2023** |
|---|---|---|---|
| Operating lease costs | $ 3,299 | $ 2,122 | $ 2,031 |
| Finance lease costs | 123 | 43 | — |
| Variable lease costs | 190 | 261 | 221 |
| Sublease income | (64) | — | — |
| Total lease costs | $ 3,548 | $ 2,426 | $ 2,252 |

The table below reconciles the fixed component of the undiscounted cash flows for each of the next five years and the total remaining years to the operating lease liabilities recorded on the consolidated balance sheet as of December 31:

| **(in thousands)** | |
|---|---|
| 2026 | $ 2,597 |
| 2027 | 2,835 |
| 2028 | 2,147 |
| 2029 | 1,679 |
| 2030 | 920 |
| Thereafter | 4,094 |
| Total minimum lease payments | $ 14,272 |
| Less: effects of discounting | (3,176) |
| Present value of future minimum lease payments | 11,096 |
| Less: current lease liability, included in accrued expenses and other | (1,923) |
| Non-current lease liability, included in other non-current liabilities | $ 9,173 |

**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, 2025, a schedule of maturity of finance lease liabilities, together with the present value of minimum lease payments, is as follows:

| **(in thousands)** | | |
|---|---|---|
| 2026 | $ | 150 |
| 2027 | | 8 |
| Total minimum lease payments | $ | 158 |
| Less: effects of discounting | | (6) |
| Present value of future minimum lease payments | | 152 |
| Less: current lease liability, included in accrued expenses and other | | (104) |
| Non-current lease liability, included in other non-current liabilities | $ | 48 |

As of December 31, 2025, the weighted average remaining lease terms of the Company's finance leases was 0.6 years. As of December 31, 2025 the weighted average discount rate used to determine the finance lease liabilities was 10.7%.

**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 FDA, the Centers for Medicare and Medicaid Services, the Central Drugs Standard Control Organization, the Narcotics Control Bureau ("NCB"), and India's Ministry of Health and Family Welfare. 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, 2025, 2024, and 2023, net revenues from the commercial sales of these products totaled $24.1 million, $22.4 million, and $22.4 million, respectively. Before the acquisition of Hyoscyamine, contract manufacturing revenues for Hyoscyamine, for the years ended December 31, 2024 and 2023 were $0.1 million and $1.9 million, respectively.

**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 has 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, the Company 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 the results of operations and/or cash flows in any given accounting period or on the Company's 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.

From time to time, the Company may also be involved in other pending proceedings for which, in the opinion of management and 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 the opinion of management, become material, the Company 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 the Company's coverage under future insurance policies or cause those policies to become more expensive, which could harm its 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. The Company's 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 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 sought judgment declaring that the November 2010 Agreement does not "oblige CGON to pay royalties after expiration of the latest-running assigned patent." On April 25, 2024, ANI filed a 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. On May 15, 2024, CG Oncology filed a reply to ANI's counterclaims, denying any liability to ANI and generally maintaining the positions taken in the CGON Answer and Counterclaim. On November 18, 2024, the court denied CG Oncology's Motion for Summary Judgment. On June 2, 2025, CG Oncology filed five motions for summary judgment seeking dismissal of all of ANI's claims and counterclaims, including breach of the royalty payment provision, breach of good faith performance, breach of the implied covenant of good faith, and in the alternative, unjust enrichment. Also on June 2, 2025, ANI filed a motion for partial summary judgment seeking dismissal of CG Oncology's counterclaims for unenforceability of the royalty payment provision under *Brulotte*, breach of good faith performance, breach of confidentiality and trade secret misappropriation. At a pretrial conference on July 16, 2025, the court granted CG Oncology's motion for partial summary judgment on its *Brulotte* counterclaim and affirmative defense, but allowed the case to proceed on ANI's counterclaim for unjust enrichment. The court also granted ANI's motion for partial summary judgment, dismissing CG Oncology's breach of confidentiality and trade secret misappropriation claims. The jury trial commenced in Delaware Superior Court on July 21, 2025. On July 29, 2025, a verdict was returned by the jury, finding that (1) the unenforceability of the royalty payment provision in the November 2010 Agreement did not affect the economic or legal substance of the transactions contemplated thereby in a manner that was materially adverse to ANI, and (2) awarding no damages to ANI on its unjust enrichment counterclaim. On August 12, 2025, ANI filed a motion for a new trial and for judgment as a matter of law. On September 10, 2025, CG Oncology filed its opposition to ANI's motion, and on October 8, 2025, ANI filed its reply to CG Oncology's opposition. A hearing date has been scheduled for April 10, 2026. ANI expects to continue to challenge this verdict through post-trial motions and/or an appeal.

On March 6, 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 19, 2024, the court issued an order denying Acella's motion. The parties have been unable to reach a settlement to date. Fact discovery is now closed and expert discovery is currently ongoing. The trial-ready date is currently set for no earlier than August 3, 2026. ANI disputes any liability in this matter and intends to defend this lawsuit vigorously.

***Patent Litigation***

On November 21, 2023, a complaint was filed against Novitium and certain other defendants in the case of Harmony Biosciences, LLC, Bioprojet Societe Civile de Recherche and Bioprojet Pharma SAS (collectively, the "Plaintiffs") v. AET Pharma US, Inc., Annora Pharma Private Limited, Novitium Pharma LLC, Zenara Pharma Private Limited and Biophore India Pharmaceuticals Private Limited in the U.S. 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. On January 15, 2026, Plaintiffs and Novitium entered into a Settlement Agreement, and on January 16, 2026, Plaintiffs and Novitium filed a Stipulation and Joint Dismissal of all claims, counterclaims and defenses, which order was entered by the court on January 20, 2026, effectively terminating the case against Novitium.

On December 27, 2024, a complaint was filed against Novitium by Athena Bioscience, LLC ("Athena") in the U.S. 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. On March 7, 2025, Novitium filed its answer, denying all allegations and asserting counterclaims of non-infringement and invalidity. On March 28, 2025, Athena filed its answer to Novitium's answer and counterclaims. On September 4, 2025, Athena and Novitium jointly filed a Stipulation and Order of Dismissal of all claims, counterclaims and defenses, which order was entered by the court on September 8, 2025, effectively terminating the case.

***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. Plaintiffs filed reply briefs in September 2024. Oral arguments were heard on October 10, 2025, and a decision from the court is pending.

ANI and Novitium dispute any liability in this matter.

***State Court Personal Injury Litigation***

*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 currently named in one bellwether case (Bautista), one wave 2 case (Austin), one wave 3 case (Rodarte), three wave 5 cases, six wave 6 cases, and four wave 7 cases. The court heard arguments for the demurrers on August 22, 2024 and issued its final ruling on August 28, 2024, allowing some counts to survive. The surviving counts as to generic defendants include strict liability (manufacturing defect) and general negligence (storage and transport, failure to warn and product containers). Novitium filed its answer to the second amended master complaint on September 6, 2024.

In December 2023, the Keller Postman firm filed a large number of 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. No case including Novitium is expected to go to trial before June 2026.

Novitium disputes 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 former Chairman of the Company's Board of Directors and current Director, Patrick D. Walsh, is an operating partner of Ampersand Capital Partners, an affiliate of the PIPE Investor.

During the quarter ended September 30, 2025, all PIPE Shares were converted to shares of common stock, and as such there were no PIPE Shares outstanding as of December 31, 2025. Refer to Note 13 “Mezzanine and Stockholders' Equity” to the notes to the consolidated financial statements for further information related to the conversion of the PIPE Shares.

***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 Private Limited (“Scitus”), which provides clinical research services to Novitium. Mr. Shanmugam holds interests in certain entities with which the Company conducts business, including 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 each of Esjay Pharma Private Limited and Esjay LLC (together, “Esjay”), which provides research and development services, certain finished goods, and certain consulting services to the Company; and a minority interest in each of SThree Chemicals Pvt Ltd and SThree Chemicals LLC (together, “SThree”), which acquires and supplies API to Novitium.

A summary of payments to related parties is presented below:

| | Years Ended December 31, | | |
|---|---|---|---|
| **(in thousands)** | **2025** | **2024** | **2023** |
| Scitus | $ 4,066 | $ 2,759 | $ 3,646 |
| SS Pharma | — | 1,244 | 8,235 |
| Esjay | 4,566 | 115 | — |
| SThree | 8,268 | 11,428 | — |
| Total Payments | $ 16,900 | $ 15,546 | $ 11,881 |

As of December 31, 2025, the outstanding balances due to Scitus, Esjay, and SThree were $0.5 million, $0.9 million, and $1.3 million, respectively. There was no outstanding balance due to SS Pharma or Nuray at December 31, 2025.

On December 12, 2023, the Company paid $12.5 million of cash consideration to the Company Members of Novitium for the achievement of the "ANDA Filing Earn-Out," as defined in the Novitium Merger Agreement, and as discussed in Note 2 “Revenue Recognition and Related Allowances” in the notes to the consolidated financial statements. The Company paid each of Mr. Shanmugam, Esjay, and Mr. Gassert, through his company Chali Properties LLC, approximately $0.1 million, $6.6 million, and $1.9 million, respectively, for their portion of the cash consideration due to them as part of the Novitium Merger Agreement.

On February 22, 2024, the Company paid $12.5 million of cash consideration to the Company Members of Novitium for the achievement of the "Gross Profit Earn-Out," as defined in the Novitium Merger Agreement, and as discussed in Note 2 “Revenue Recognition and Related Allowances” in the notes to the consolidated financial statements. The Company paid each of Mr. Shanmugam, Esjay, and Mr. Gassert, through his company Chali Properties LLC, approximately $0.1 million, $6.6 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, the operating results of which 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 for which 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 CODM resulting in changes to the Company's identification of significant segment expenses. Therefore, the Company has recast 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, manufacture 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 ILUVIEN (there were no sales of YUTIQ during the third and fourth quarters of 2025). In addition, the Brands reporting unit includes a portfolio of approximately 20 branded products that are principally sold in highly genericized markets.

- **Generics and Other** – Consists of operations related to the development, manufacture, 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, 2025, this reporting segment was comprised of over 120 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, as well as 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, 2025 | | | |
|---|---|---|---|---|
| **(in thousands)** | **Generics and Other** | **Rare Disease and Brands** | **Corporate and Unallocated** | **Total** |
| Net Revenues | $ 399,433 | $ 483,933 | $ — | $ 883,366 |
| Cost of sales (excluding depreciation and amortization) | (201,955) | (139,355) | — | (341,310) |
| Research and Development expense | (36,815) | (14,849) | — | (51,664) |
| Selling, general, and administrative expense | (5,675) | (188,489) | (123,581) | (317,745) |
| Depreciation and amortization | — | — | (91,417) | (91,417) |
| Contingent consideration fair value adjustment | — | — | 31,012 | 31,012 |
| Loss on disposal of assets | — | — | (382) | (382) |
| Intangible asset impairment charge | — | — | (767) | (767) |
| Operating Income (Loss) | $ 154,988 | $ 141,240 | $ (185,135) | $ 111,093 |
| | | | | |
| Unrealized gain on investment in equity securities | $ — | $ — | $ 2,824 | $ 2,824 |
| Interest expense, net | — | — | (20,060) | (20,060) |
| Other income, net | — | — | 1,934 | 1,934 |
| Income (Loss) Before Income Tax Expense | $ 154,988 | $ 141,240 | $ (200,437) | $ 95,791 |

| | Year Ended December 31, 2024 | | | |
|---|---|---|---|---|
| (in thousands) | 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 expense | (30,519) | (14,062) | — | (44,581) |
| Selling, general, and administrative expense | (5,120) | (125,972) | (118,544) | (249,636) |
| Depreciation and amortization | — | — | (67,731) | (67,731) |
| Contingent consideration fair value adjustment | — | — | 619 | 619 |
| Gain on disposal of assets | — | — | 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 Income Tax Benefit | $ 116,024 | $ 72,469 | $ (210,705) | $ (22,212) |

| | Year Ended December 31, 2023 | | | |
|---|---|---|---|---|
| (in thousands) | 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 expense | (28,197) | (6,089) | — | (34,286) |
| Selling, general, and administrative expense | (2,451) | (73,466) | (85,780) | (161,697) |
| Depreciation and amortization | — | — | (59,791) | (59,791) |
| Contingent consideration 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 Income Tax Expense | $ 105,927 | $ 89,173 | $ (175,228) | $ 19,872 |

**Geographic Information**

The following depicts the Company's total revenue according to geographic location. The Company 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 years ended December 31, 2025 and 2024 in the table below. The majority of the assets of the Company are located in the U.S. The Company also maintains operations in India, Ireland, Portugal, Germany, and the United Kingdom.

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

| (in thousands) | Years Ended December 31, | | |
|---|---|---|---|
| **Location of Operations** | **2025** | **2024** | **2023** |
| United States | $ 852,443 | $ 604,989 | $ 486,251 |
| International | 30,923 | 9,387 | 565 |
| Total Revenue | $ 883,366 | $ 614,376 | $ 486,816 |

The following table depicts the Company's property, plant and equipment, net according to geographic location during the year ended:

| (in thousands) | December 31, 2025 | December 31, 2024 |
|---|---|---|
| United States | $ 59,548 | $ 54,730 |
| International | 2,928 | 2,133 |
| Total property and equipment, net | $ 62,476 | $ 56,863 |

**20. SUBSEQUENT EVENTS**

*U.S. Tariff Update*

On February 20, 2026, the United States Supreme Court issued a ruling striking down certain tariffs previously imposed under the International Emergency Economic Powers Act ("IEEPA"). The ultimate availability, timing, and amount of any potential refunds of such tariffs remain highly uncertain and are subject to further legal, regulatory, and administrative developments. Following the Supreme Court's decision, the U.S. presidential administration announced its intention to invoke other laws to collect tariffs and announced new tariffs on imports from all countries, in addition to any existing non-IEEPA tariffs. There remains substantial uncertainty regarding the duration of existing and newly announced tariffs, potential changes or pauses to such tariffs, tariff levels, and whether further additional tariffs or other retaliatory actions may be imposed, modified, or suspended, and the impacts of such actions on the Company. The Company continues to monitor and evaluate these developments and assess their potential impact on its business, financial condition, and results of operations.

**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, 2025. 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, 2025. 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, 2025, our internal control over financial reporting is effective.

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. The effectiveness of the Company's internal control over financial reporting as of December 31, 2025 has been audited by EisnerAmper LLP, an independent registered public accounting firm, as stated in their attestation report, included herein.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2025, 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, 2025, none of our directors or officers (as defined in Rule 16a-1(f) of the Exchange Act) entered into, adopted, modified (as to the amount, price or timing of trades), or terminated (i) contracts, instructions or written plans for the purchase or sale of our securities that are intended to satisfy the conditions specified in 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).

**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.anipharmaceuticals.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 2026 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 2026 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 2026 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 2026 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 2026 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 2026 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 2026 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, Iselin, New Jersey, 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 2026 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, 2025 and 2024, the related consolidated statements of operations, statements of other comprehensive income (loss), changes in stockholders' equity, and cash flows for each of the years ended December 31, 2025, 2024, and 2023, 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 146.

**ANI PHARMACEUTICALS, INC.**

**EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K**
**FOR THE YEAR ENDED DECEMBER 31, 2025**

| Exhibit No. | Exhibit | Method of Filing |
|---|---|---|
| 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 | Certificate of Amendment to the Restated Certificate of Incorporation of ANI Pharmaceuticals, Inc., dated May 22, 2025 | Incorporated by reference to Exhibit 3.1 to ANI's Current Report on Form 8-K filed on May 22, 2025 (File No. 001-31812) |
| 3.3 | 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) |
| 4.1 | Description of Securities | Filed herewith |
| 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) |
| 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) |

| Exhibit No. | Exhibit | Method of Filing |
|---|---|---|
| 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 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) |
| 10.7* | Amendment No. 1 to Employment Agreement between Stephen P. Carey and ANI Pharmaceuticals, Inc., dated October 27, 2025 | Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2025 (File No. 001-31812) |
| 10.8* | Amendment No. 1 to Employment Agreement between Meredith Cook and ANI Pharmaceuticals, Inc., dated October 27, 2025 | Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2025 (File No. 001-31812) |
| 10.9* | Amendment No. 1 to Employment Agreement between Ori Gutwerg and ANI Pharmaceuticals, Inc., dated October 27, 2025 | Incorporated by reference to Exhibit 10.5 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2025 (File No. 001-31812) |
| 10.10* | Amendment No. 1 to Employment Agreement between Nikhil Lalwani and ANI Pharmaceuticals, Inc., dated October 27, 2025 | Incorporated by reference to Exhibit 10.6 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2025 (File No. 001-31812) |
| 10.11* | Amendment No. 1 to Employment Agreement between Christopher Mutz and ANI Pharmaceuticals, Inc., dated October 27, 2025 | Incorporated by reference to Exhibit 10.7 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2025 (File No. 001-31812) |
| 10.12* | Amendment No. 1 to Employment Agreement between Muthusamy Shanmugam and ANI Pharmaceuticals, Inc., dated October 27, 2025 | Incorporated by reference to Exhibit 10.8 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2025 (File No. 001-31812) |
| 10.13 | 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) |
| 10.14 | 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) |
| 10.15* | Amended and Restated ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan | Incorporated by reference to Exhibit 10.1 to ANI's Form S-8 filed on July 11, 2025 (File No. 001-31812) |
| 10.16* | Amended and Restated 2022 Stock Incentive Plan | Incorporated by reference to Exhibit 10.1 to ANI's Form S-8 filed on July 11, 2025 (File No. 001-31812) |

| Exhibit No. | Exhibit | Method of Filing |
|---|---|---|
| 10.17* | 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) |
| 10.18* | 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) |
| 10.19* | 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) |
| 10.20 | 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) |
| 10.21 | 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) |
| 10.22† | 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) |
| 10.23 | 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) |
| 10.24 | 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 | Incorporated by reference to Exhibit 19.1 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (File No. 001-31812) |
| 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, 2025, 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, 2025 formatted in inline XBRL (included in Exhibit 101) | Filed herewith |

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(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 27, 2026

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

Date: February 27, 2026

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 |
|---|---|---|
| /s/ Nikhil Lalwani<br>Nikhil Lalwani | Director, President, and Chief Executive Officer (principal executive officer) | February 27, 2026 |
| /s/ Stephen P. Carey<br>Stephen P. Carey | Senior Vice President, Finance and Chief Financial Officer (principal financial and accounting officer) | February 27, 2026 |
| /s/ Muthusamy Shanmugam<br>Muthusamy Shanmugam | Director, Head of Research and Development and Chief Operating Officer of New Jersey Operations | February 27, 2026 |
| /s/ Thomas J. Haughey<br>Thomas J. Haughey | Director and Chairman of the Board of Directors | February 27, 2026 |
| /s/ Matthew J. Leonard<br>Matthew J. Leonard | Director | February 27, 2026 |
| /s/ Antonio Pera<br>Antonio Pera | Director | February 27, 2026 |
| /s/ Renee Tannenbaum<br>Renee Tannenbaum | Director | February 27, 2026 |
| /s/ Jeanne Thoma<br>Jeanne Thoma | Director | February 27, 2026 |
| /s/ Patrick D. Walsh<br>Patrick D. Walsh | Director | February 27, 2026 |

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