2023 Annual Report

www.anipharmaceuticals.com

CORPORATE INFORMATION

BOARD OF DIRECTORS

Patrick D. Walsh, Chairman of the Board
Chief Executive Officer, Alcami Corporation

Thomas Haughey, Director
Former 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
Chief Pharmacy Strategy Officer, Capsule

David B. Nash, M.D., Director
Grandon Professor of Health Policy, Jefferson College of Population Health

Antonio R. Pera, Director
Former 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
Former President and Chief Executive Officer of SPI Pharma Inc.

EXECUTIVE OFFICERS

Nikhil Lalwani
President and Chief Executive Officer

Stephen P. Carey
Senior Vice President 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

James G. Marken
Senior Vice President, Operations

Christopher Mutz
Senior Vice President, Head of Rare Disease

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

Thomas Rowland
Senior Vice President, Head of Established Brands

CODE OF ETHICS

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

CORPORATE HEADQUARTERS

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

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, 2024 via webcast through the link:
www.virtualshareholdermeeting.com/ANIP2024

INVESTOR RELATIONS

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

INDEPENDENT AUDITORS

EisnerAmper LLP
One Logan Square
130 North 18th Street, Suite 3000
Philadelphia, PA 19103
Phone: (215) 881-8800

TRANSFER AGENT

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

LEGAL COUNSEL

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

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

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

For the fiscal year ended December 31, 2023

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

For the transition period from _____ to _____.

Commission file number 001-31812

ANI PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
210 Main Street West **Baudette, Minnesota**	**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, 2023 was $824.2 million (based upon the last reported sale price of $53.83 per share on June 30, 2023, on The Nasdaq Global Market).

As of February 22, 2024, 21,068,122 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 2024 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, 2023

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

CAUTIONARY STATEMENT CONCERNING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and certain information incorporated herein by reference contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Such statements include, but are not limited to, statements about future operations, strategies and growth potential, the revenue potential (licensing, royalty and sales) of products we sell, development timelines, expected timeframe for submission of new drug applications, abbreviated new drug applications, or supplemental new drug applications to the U.S. Food and Drug Administration (the "FDA"), pipeline or potential markets for our products, selling and marketing strategies and associated costs to support the sales of Purified Cortrophin® Gel (Repository Corticotropin Injection USP) ("Cortrophin Gel"), impact of accounting principles, litigation expenses, liquidity and capital resources, the impact of the novel coronavirus ("COVID-19") global pandemic on our business, and other statements that are not historical in nature, particularly those that utilize terminology such as "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words, and the use of future dates. Such forward-looking statements are based on the reasonable beliefs of our management as well as assumptions made by and information currently available to our management. Readers should not put undue reliance on these forward-looking statements. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified; therefore, our actual results may differ materially from those described in any forward-looking statements. Factors that might cause such a difference include, but are not limited to, those discussed in our periodic reports filed with the U.S. Securities and Exchange Commission (the "SEC"), including those discussed in the "Risk Factors" section in Part I, Item 1A.of this Annual Report on Form 10-K, and the following factors:

- Cortrophin Gel is our first rare disease pharmaceutical product. To the extent we are not able to continue to achieve commercial success with this product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted;
- our approved products, including Cortrophin Gel, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability;
- acquisitions and investments could disrupt our business and harm our financial position and operating results;
- the limited number of suppliers for our active pharmaceutical ingredients ("API") could result in lengthy delays in production if we need to change suppliers;
- delays or failure in obtaining and maintaining approvals by the FDA of the products we sell;
- changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls;
- acceptance of our products at levels that will allow us to achieve profitability;
- our ability to develop, license or acquire, and commercialize new products;
- the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products;
- our ability to protect our intellectual property rights;
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- the impact of any litigation to which we are, or may become, a party;
- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries;
- our ability to maintain the services of our key executives and other personnel;
- whether we experience difficulties closing a sale transaction with a buyer for the plant and property resulting from the closure of our Oakville, Ontario manufacturing plant; and
- general business and economic conditions, such as inflationary pressures, geopolitical conditions including, but not limited to, the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, conflicts related to the attacks on cargo ships in the Red Sea, and the effects and duration of outbreaks of public health emergencies, such as COVID-19.

NOTE REGARDING TRADEMARKS

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

PART I

Item 1. Business

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. The team is focused on delivering growth by scaling up the Rare Disease business through the successful launch of its lead asset, Cortrophin Gel, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. The Company's three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, and one is located in East Windsor, New Jersey, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. The Company has ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. The Company has fully completed the transition of the products manufactured or packaged in Oakville to one of the three U.S.-based manufacturing sites. On November 6, 2023, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement for the purchase and sale of the Oakville, Ontario manufacturing facility. However, during December 3023, the agreement was mutually terminated. In February 2024, the Company entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of 19.2 million Canadian Dollars, or approximately $14.2 million US Dollars, based on the current exchange rate. The sale is expected to close in March 2024 (see Note 19. Subsequent Events, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

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

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

We have a commercial portfolio of 116 products with a wide variety of indications and a robust portfolio of pipeline products as of December 31, 2023. This portfolio is the result of internal research and development, acquisitions of businesses, acquisitions of Abbreviated New Drug Applications ("ANDAs"), New Drug Applications ("NDAs"), product rights, and entry into agreements to obtain the distribution rights for various products..

Strategy

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

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

Building a successful Rare Disease platform

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

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

During 2021 and 2022, we invested significantly in leadership, expertise and infrastructure in the areas of commercialization of rare disease therapies and developed a launch strategy and commercial plan for this product. During this timeframe, we hired a significant number of new employees and assembled and trained our Rare Disease field force. On January 24, 2022, we announced the commercial launch of Cortrophin Gel in the U.S as our foundational Rare Disease asset. On October 2, 2023, we announced FDA approval and commercial availability of a 1-mLvial of Cortrophin Gel, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares. We continued to invest in our Rare Disease team and support investments in Cortrophin Gel during 2023.

We plan to continue to expand our rare disease business through a combination of organic growth, as described above, and through acquisition. While we continue to 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.

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

We have grown our generics business through a combination of market share gains on existing products and new product launches. We have also successfully acquired numerous ANDAs through business and asset acquisitions. Our most recent business acquisition was Novitium, including its portfolio of commercial and pipeline generic products, manufacturing and development facilities and expert workforce. The Novitium acquisition significantly increased our generic pharmaceutical research and development and manufacturing capabilities. We have begun to increase our focus on niche lower competition opportunities such as injectables, Paragraph IV, and competitive generic therapy ("CGT") designation filings. Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses. During 2022, we completed an asset acquisition of four ANDAs from Oakrum Pharma, including two that were commercial at the time of acquisition. During the second quarter of 2023, we acquired two ANDAs and one pipeline product from the Chapter 7 Trustee for the estates of Akorn Holding Company and certain of its affiliates. During the third quarter of 2023, we acquired an ANDA and registered patents and pending patent applications from Slayback Pharma Limited Liability Company. During the fourth quarter of 2023, we completed two additional asset acquisitions in which we acquired an ANDA from PAI Pharma LLC for one product, and also product rights for a separate product from Alvogen, Inc., which we plan to launch commercially in early 2024.

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

Generic Product Development Considerations

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

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

Competitive Generic Therapy

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

Products

Products

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

Manufacturing, Suppliers, and Raw Materials

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

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

Government Regulation

The pharmaceutical industry in the U.S. is highly regulated by multiple U.S. government agencies, such as the FDA, the DEA, and the Centers for Medicare and Medicaid Services ("CMS"). As a result, we are subject to extensive and complex rules and regulations, which are subject to revision from time to time. While we have experience with these regulations, there can be no assurance that we will be able to fully comply with all applicable regulations.

Branded and Generic Pharmaceutical Products

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

New Drug Application ("NDA")—An NDA is filed when approval is sought to market a newly developed branded product and, in certain instances, for a new dosage form, a new delivery system, or a new indication for an approved drug.

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

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

The Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Act") provides that generic drugs may enter the market after the approval of an ANDA, which requires (1) that bioequivalence to the branded product be demonstrated through clinical studies, and (2) either the expiration, invalidation or circumvention of any patents or the end of any other relevant market exclusivity periods related to the branded drug.

Accordingly, generic products generally provide a safe, effective, and cost-efficient alternative to users of branded products. Growth in the generic pharmaceutical industry has been driven by the increased market acceptance of generic drugs, as well as the number of branded drugs for which patent terms and/or other market exclusivities have expired.

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

In order to obtain FDA approval of NDAs and ANDAs, our manufacturing procedures and operations must conform to FDA requirements and guidelines, generally referred to as "cGMP." The requirements for FDA approval encompass all aspects of the production process, including validation and recordkeeping, the standards around which are continuously changing and evolving. As a result, we must consistently monitor and comply with these changes.

Our facilities, procedures, operations, and testing of products are subject to periodic inspection by the FDA, the DEA, and other authorities. In addition, the FDA conducts pre-approval and post-approval reviews and plant inspections to determine whether our systems and processes are in compliance with cGMP and other FDA regulations. Our suppliers are subject to similar regulations and periodic inspections.

Post-approval Requirements

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

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

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 in nature. Additionally, manufacturers may only promote their product for approved indications outlined by the FDA. Physicians may prescribe drugs or biologics off-label but manufacturers cannot promote such uses unless they have been previously authorized 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.

The Prescription Drug Marketing Act ("PDMA") regulates the distribution of a manufacturer's prescription drug samples and requires a compliance program governing the storage, security, distribution and recordkeeping of samples, as well as monitoring for loss or theft. The Drug Supply Chain Security Act ("DSCSA") requires manufacturers and their trading partners, such as repackagers, wholesale distributors, dispensers, and third-party logistics providers, to implement product tracking and tracing technology at the package level to identify and trace certain prescription drugs as they are distributed in the United States. ANI started manufacturing serialization-compliant products in November 2018. 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."***

Controlled Substances

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

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

Unapproved Products

Three of our products, EEMT, Opium Tincture, and Thyroid Tablets, are marketed without approved NDAs or ANDAs. During the fourth quarter of 2023, we acquired product rights for Hyoscyamine, a product without approved NDAs, which we plan to launch commercially in early 2024. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. We continue to believe that, so long as we comply with applicable manufacturing standards, the FDA will continue to operate on a risk-based approach and will not take action against us. However, we can offer no assurance that the FDA will continue to follow this approach or that it will not take a contrary position with any individual product or group of products. See **"Risk Factors –** ***Three products, which together comprised less than 10% of our total revenue in 2023, are marketed without approved NDAs or ANDAs and we can offer no assurances that the FDA will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected."***

Medicaid/Medicare

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

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

The ACA also made changes to Medicaid law that has negatively impacted our business. Pharmaceutical manufacturers that want their drug products covered by state Medicaid programs must enter into a rebate agreement with CMS and pay rebates to state Medicaid agencies on utilization of their drugs dispensed to Medicaid beneficiaries. The ACA raised the rebate percentages for both generic and branded pharmaceuticals effective January 1, 2010. The basic rebate is currently 13% of the average manufacturer price for sales of Medicaid-reimbursed products marketed under ANDAs. Sales of Medicaid-reimbursed products marketed under NDAs require manufacturers to rebate the greater of 23.1% of the average manufacturer price or the difference between the average manufacturer price and the "best price" (as defined in the Medicaid statute) during a specific period. In addition, there is an additional rebate if the average manufacturer price of the drug is rising faster than inflation. Since passage of ACA in 2010, Medicaid rebates have been capped at average manufacturer price per unit. However, beginning January 1, 2024 pursuant to the American Rescue Plan of 2021 Medicaid rebates will no longer be capped at average manufacturer price. As a result we could end up paying substantially higher Medicaid rebates on certain products. Furthermore, in a Proposed Rule released in May 2023 CMS proposed changing how "best price" is determined. If enacted it would require a manufacturer to aggregate any and all discounts and rebates to best price eligible customers when determining best price rather than considering only discounts and rebates to each best price eligible customer individually. If finalized, we could end up owing additional rebates on Medicaid utilization of our branded products to the states.

Medicare is run by the federal government and is largely focused on the elderly and disabled. The Medicare Modernization Act of 2003 ("MMA") created Medicare Part D to provide voluntary prescription drug coverage for Medicare beneficiaries. The MMA has increased coverage of pharmaceuticals, which has benefited the pharmaceutical industry for both brands and generic drugs. The ACA made some changes to Part D to make it easier for Medicare beneficiaries to obtain drugs, such as reducing coinsurance amounts. The ACA also required pharmaceutical companies to provide discounts to Medicare Part D beneficiaries for the cost of branded prescription drugs. The ACA created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, or BBA, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Under the Medicare Coverage Gap Discount Program, any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a "generic," is subject to the discount requirement. Certain of our products, while marketed as "generics," are sold under approved NDAs and, therefore, are subject to the discount requirement. The Inflation Reduction Act of 2022 ("IRA"), was signed into law by President Biden on August 16, 2022. The IRA brings sweeping changes to Medicare coverage and reimbursement for prescription drugs that could negatively impact us and other pharmaceutical manufacturers. Of note, beginning January 1, 2025 the IRA alters the current structure of the Medicare Part D standard benefit by eliminating the coverage gap. The IRA reduces a beneficiary's out-of-pocket maximum to $2,000 beginning in 2025. The existing coverage gap discount program for pharmaceutical manufacturers will be replaced by a new manufacturer discount program effective in 2025. Under the new program, manufacturers will provide a 10 percent discount off the negotiated price for applicable drugs (branded drugs and biologics manufactured by companies that have Part D discount agreements) after the deductible is satisfied through the catastrophic phase of the benefit. In the catastrophic phase, manufacturers will provide a 20 percent discount off negotiated price. Any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a "generic," is subject to the manufacturer discount requirement. This could increase discounts due on Medicare Part D utilization of our drug products.

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

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

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

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

Patents, Trademarks, and Licenses

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

Distribution Agreements

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

Customers

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

In recent years, the wholesale distributor network for pharmaceutical products has been subject to increasing consolidation, which has increased the concentration of our wholesale customers. In addition, the number of retail market chains and, in particular, the number of independent drug stores and small chains, has decreased as retail consolidation has occurred, also increasing the concentration of our retail customers. As a result of this trend toward consolidation, a smaller number of companies each control a larger share of pharmaceutical distribution channels. For the year ended December 31, 2023, approximately 70% of our net revenues were attributable to four customers. For the years ended December 31, 2022 and 2021, three customers, together accounted for approximately 59% and 68% of our net revenues, respectively. In addition, as noted below, our customers also distribute our products. The loss of any of these customers, including in their role as distributors, could have a material adverse effect on our business.

Due to strategic partnerships between wholesalers and pharmacy chains, we have experienced, and expect to continue to experience, increases in net sales to the wholesalers, with corresponding decreases in net sales to the pharmacy chains.

In the rare disease business there is a limited distribution network and a select group of specialty pharmacies which can dispense product to appropriate patients. We contract and engage with the largest health insurance payers across the appropriate channels and classes of trade.

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

Sales, Marketing, and Distribution

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

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

Competition

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

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

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

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

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

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

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

Principal competitors for the pharmaceutical market in which we do business include, but are not limited to, Amneal Pharmaceuticals, Inc., Apotex Inc., Aurobindo Pharma, Camber Pharmaceuticals Inc., Hikma Pharmaceuticals plc, Lupin Pharmaceuticals, Inc., Mallinckrodt Pharmaceuticals, Rising Pharmaceuticals, Inc., Strides Pharma Inc., Sun Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA, Inc., Viatris Inc., and Zydus Pharmaceuticals USA.

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 2024, we have 642 employees, of which 569 are located in the United States, including Puerto Rico, 1 is located in Canada, and 72 are located in India. As of January 2023, we had 600 employees, of which 496 are located in the United States, including Puerto Rico, 48 located in Canada, and 56 are located in India. We occasionally use a small number of part-time and consultant resources to meet our operational needs and our turnover is in line with similar businesses in our industry and locations.

Our Purpose and Core Values

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

Culture, Engagement, and Diversity, Equity, and Inclusion

We believe that attracting, retaining, and promoting engagement for talented employees is critical to the success of our business, and we take pride in our values, culture, and communities. We are committed to creating a diverse, equitable, and inclusive work environment within all levels of the business. As of the end of 2023, approximately 41% of our workforce identified as female and approximately 59% identified as male. In the same period, approximately 45% of our workforce identified as a person of color or indigenous person, with approximately 55% identifying as white.

Furthermore, we do not tolerate discrimination or harassment on the basis of gender, race, or ethnicity, 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 25% of our employees participated in a benefits satisfaction survey in 2023). We offer ongoing training and career development to all employees, both through curriculum developed internally, and through external resources (e.g. LinkedIn Learning). Together, we own our culture and participate in ongoing open dialogue as we strive for continued growth.

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

Total Rewards

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

Health and Safety Management and Training

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

Environmental Stewardship and Sustainability

ANI is committed to Serving Patients, Improving Lives, both directly 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. We continue to increase our efforts and have formed an Environmental, Social, and Governance ("ESG") Steering Committee to oversee cross-functional initiatives. The ESG Steering Committee reports to our Board of Directors through our Nominating and Governance Committee and is committed to providing progress updates at least twice per year.

Available Information

We file annual, quarterly and current reports, proxy statements and other information required by the Securities Exchange Act of 1934, as amended (the "Exchange Act"), with the Securities and Exchange Commission ("SEC"). We make available free of charge on our website (www.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 – Corporate Governance" section are our Corporate Governance Guidelines, Code of Ethics and the charters for the Audit and Finance, Compensation, and Nominating and Corporate Governance Committees. Information on, or accessible through, our website is not a part of, and is not incorporated into, this report or any other SEC filing. Copies of our SEC filings or corporate governance materials are available without charge upon written request to Investor Relations, c/o ANI Pharmaceuticals, Inc., 210 Main Street West, Baudette, Minnesota, 56623.

Item 1A. Risk Factors

Risk Factor Summary

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

- Cortrophin Gel is our first rare disease pharmaceutical product. To the extent we are not able to continue to achieve commercial success with this product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted;
- Our approved products, including Cortrophin Gel, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability;
- Acquisitions and investments could disrupt our business and harm our financial position and operating results;
- The limited number of suppliers for our 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 third parties, which we cannot control and could result in us being unable to market and distribute products;

- We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business;
- The continuing trend toward consolidation of customer groups that could result in declines in the sales volume and prices of our products, and increased fees charged by customers;
- Pharmaceutical product quality standards are steadily increasing on all products, and if we cannot meet these standards, we may be required to discontinue marketing and/or recall products from the market;
- Federal and state false claims litigation brought against us by private individuals and the government could result in civil and criminal penalties, damages, fines and other related actions;
- The use of legal, regulatory, and legislative strategies by competitors could result in increased costs to develop and market our products, delay new product introductions and reduce profit potential;
- Third-party payer actions may prevent us from effectively marketing our products or cause us to decrease pricing;
- Continuing studies of our products could produce results that could have a negative impact on our business;
- Healthcare reform legislation could have a material adverse effect on our business, financial position, and operating results;
- Barriers in achieving anticipated revenue growth and profitability could have a material adverse effect on our business, financial position, and operating results;
- We may not achieve the anticipated benefits from our acquisition of Novitium Pharma LLC ("Novitium");
- The obligations and liabilities of Novitium, some of which may be unanticipated or unknown, may be greater than we have anticipated, which may diminish the value of Novitium to us;
- Public health outbreaks, epidemics, or pandemics (such as COVID-19) have adversely affected and may in the future adversely affect our business;
- The Food and Drug Administration ("FDA") does not provide guidance on safety labeling for products that are marketed without approved New Drug Applications ("NDAs") or Abbreviated New Drug Applications ("ANDAs"), which could increase our potential liability with respect to failure-to-warn claims for these products;
- Four of our products are marketed without approved NDAs or ANDAs and we can offer no assurances that the FDA will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected;
- If the Drug Enforcement Administration ("DEA") does not approve supply of the API we need to manufacture our controlled substances, we may be unable to manufacture controlled substances, which would eliminate our revenue on these products;
- Our Medicaid rebate accruals have increased and continue to increase due to our acquisitions and subsequent sales of branded products and authorized generics of branded products;
- Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions;
- We face vigorous competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of our products;
- We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products;
- Production at any or all of our three current manufacturing facilities could be interrupted, which could cause us to fail to deliver product on a timely basis;
- We rely on third parties to assist with our clinical studies. 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;
- Inability to protect our intellectual property in the U.S. and foreign countries could negatively affect sales of our branded products;
- With the exception of patents on a limited number of products we do not own or license any material patents associated with the majority of our products, and our ability to protect and control unpatented trade secrets, know-how, and other technological innovation is limited;

- Our success is largely dependent upon certain key employees, including members of our senior management, the loss of whom could adversely affect our operations;
- We rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology could harm our ability to operate the business effectively;
- We are involved in and may become involved in legal proceedings from time to time, which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources;
- We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums;
- Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods;
- Making interest and principal payments under our Credit Agreement with Truist requires a significant amount of cash;
- We previously identified material weaknesses in our internal control over financial reporting, and the failure to maintain an effective system of internal controls and procedures may cause investors to lose confidence in our financial reporting;
- Our Credit Facility contains restrictive and financial covenants and if are not in compliance with these covenants, our outstanding indebtedness under this facility could be accelerated and the lenders could terminate their commitments under the facility;
- 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;
- 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; and
- Our operations, including those resulting from our acquisition of Novitium and its international operations, will subject us to political and economic risks, increase our exposure to potential liability under anti-corruption, trade protection, tax, and other laws and regulations.

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

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

On October 29, 2021, we received approval from the FDA for our Cortrophin Gel product for the treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis ("MS") and rheumatoid arthritis ("RA"), in addition to excess urinary protein due to nephrotic syndrome. We have devoted significant time and money over the past eight years to the development of this product since we acquired the rights to the product in 2016. We have invested and continue to invest significantly in the commercialization of this product in the U.S, including building out a sales force and developing a patient support program, with a full-scale launch in January 2022. In October 2023, we announced FDA approval and commercial availability of a 1-mLvial of Cortrophin Gel, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares. The ability for us to generate significant net product revenues from our Cortrophin Gel products will depend upon our ability to successfully sell the product and numerous other factors, including:

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

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

We are continuing to develop our marketing and sales organization to support Cortrophin Gel and have limited experience in marketing prescription rare disease drug products. If we are unable to continue to develop marketing and sales capabilities for Cortrophin Gel, our business will suffer.

We first established our rare disease sales, marketing or distribution capabilities in 2021 and have limited institutional experience in marketing rare disease products. We intend to continue to develop an in-house marketing organization and sales force, which will require significant expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel.

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.

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

Our ability to manufacture and distribute products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the U.S. During the year ended December 31, 2023, no single vendor represented at least 10% of inventory purchases. During the year ended December 31, 2022, we purchased approximately 19% of our inventory from one supplier. During the year ended December 31, 2021, no single vendor represented at least 10% of inventory 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, and operating results. Virtually all of our generic contracts for the supply of pharmaceutical products to customers contain "failure to supply" clauses. Under these clauses, if we are unable to supply the requested quantity of product within a certain period after receipt of a customer's purchase order, the customer is entitled to procure a substitute product elsewhere and we must reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product. Therefore, our ability to source sufficient quantities of API for manufacturing is critical. We source the raw materials for our products from both domestic and international suppliers. Generally, we qualify only a single source of API for use in each product due to the cost and time required to validate and qualify a second source of supply. Any change in one of our API suppliers must usually be approved through a Prior Approval Supplement ("PAS") by the FDA. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we carefully select suppliers, based on various factors including quality, reliability of supply, and long-term financial stability. Certain of the 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.

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

We have acquired, and may continue to acquire, a variety of products that we seek to commercialize. Some of these products, including injectables, softgel capsules, and Purified Cortrophin Gel, are products that we cannot currently manufacture in our facilities. As a result, we may seek partners to contract manufacture the products on our behalf, and we rely on third parties to manufacture and/or package many of our products. Like our company, these firms must comply with cGMPs and other federal, state, and local laws and regulations regarding pharmaceutical manufacturing. Noncompliance by those firms may result in warning letters, fines, product recalls, and partial or total suspension of production and distribution. If we are unable to find qualified contract manufacturers or if a contract manufacturer 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 delays or difficulties with third-party manufacturers could adversely affect the marketing and distribution of these products, or future products, which could have a material adverse effect on our business, financial position, and operating results.

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

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

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

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

Any of these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows.

We are subject to certain privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements, as well as any breach of unsecured identifiable personal information protected by law, could subject us to significant costs, fines, penalties (civil and criminal), and civil litigation which may have a material adverse effect on our business, financial condition or results of operations.

As regulatory focus on privacy issues continues to increase, and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. In addition, the interpretation and application of consumer, health-related, and data protection laws are often uncertain, contradictory, and in flux, which complicates compliance efforts.

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

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

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

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

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

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

Our branded products may become subject to increased generic competition.

Many of our branded products have not been patent-protected for several years and no longer have market exclusivity. As a result, they face competition from lower priced generic products which may reduce and limit the sales of our mature brand products. Additionally, increased focus by the FDA on approval of generic products may accelerate this trend. If generic products are substituted for these branded products, our revenue from these products will decrease, which could have an 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 Medicaid rebate accruals have increased significantly due to our acquisitions and subsequent sales of branded products and authorized generics of branded products. We accrue for these rebates at the time of sale based on our estimates of the amount of our product that will be prescribed to Medicaid beneficiaries. The resulting accruals are significant, and as Medicaid utilization trends change, we may need to change our estimates accordingly. We cannot guarantee that actual results will not differ from our estimates. In addition, the Patient Protection and Affordable Care Act ("PPACA") included a significant expansion of state Medicaid programs. As more individuals become eligible for coverage under these programs, Medicaid utilization of our products could increase, resulting in a corresponding increase in our rebate payments. Increases in Medicaid rebate payments could decrease our revenues from product sales, which in turn could adversely affect our business, financial position, and operating results.

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

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

We have entered into distribution agreements under which we market products under ANDAs and NDAs owned by third parties. Any changes to these agreements could have a material adverse effect on our business, financial position, and operating results.

We have entered into several distribution agreements to market and distribute products under our own label that are sold under ANDAs and NDAs owned by third parties, over which we have no control. Generally, the responsibility for maintaining the ANDAs and NDAs lies with these third parties. If any regulatory issues were to arise with the underlying ANDA or NDA for one of these products, we could be required to discontinue sales of the product, which could have an adverse effect on our business, financial position, and operating results.

We face vigorous competition from other pharmaceutical manufacturers that may adversely impact commercial acceptance and pricing of our products. If we are unable to successfully compete, such competition could have a material adverse effect on our business, financial position, and operating results.

The generic pharmaceutical industry is highly competitive. We face intense competition from U.S. and foreign manufacturers, many of whom are significantly larger than us and operate in lower cost geographies. Our competitors may be able to develop products and processes competitive with or superior to ours for many reasons, including but not limited to the possibility that they may have:

- greater financial resources;
- proprietary processes or delivery systems;
- larger research and development and marketing staffs;
- larger production capabilities;
- more products;
- access to lower cost wages; or
- more experience in developing new drugs.

Any of our significant competitors, due to one or more of these and other factors, could have a material adverse effect on our business, financial position, and operating results.

Our approved products may not achieve commercialization at levels of market acceptance that allow us to achieve profitability, which could have a material adverse effect on our business, financial position, and operating results.

We seek to develop, license, or acquire products that we can commercialize at levels of market acceptance that would allow us to recoup our costs, grow market share, and achieve profitability. Even if we are able to obtain regulatory approvals for our pharmaceutical products, if we fail to predict accurately demand for such products, 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:

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

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

We have entered into several collaborative arrangements that may not result in marketable products.

We have entered into several collaborative arrangements to develop generic products for us to market in the U.S. We can offer no assurances that these arrangements will result in additional approved products, or that we will be able to market the products at a profit. In addition, any expenses related to clinical trials, or additional studies required by the FDA, that we may incur in connection with these collaborative arrangements may negatively affect our business, financial position, and operating results. Specifically:

- clinical trials could be more costly than we anticipate;
- formulation development could take longer and be more costly than we expect;
- we may be required to obtain specialized equipment in order to manufacture products on a commercial scale; and
- we may be subject to milestone payments to collaborative partners, the timing of which we may be unable to predict.

Any of these events could have a material adverse effect on our business, financial position, and operating results.

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

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

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

Our internal manufacturing operations are currently based in three facilities. We have transitioned the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites, and we are seeking to find potential buyers for the Oakville site. While these three remaining 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 our contracts for the supply of generic products to our customers contain "failure to supply" clauses which require us to reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product in the event we failed to deliver the requested quantity within a specified period of time. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements and can be far in excess of the revenue that we would otherwise have received on the sale of our own product. Therefore, our ability to produce and ship a sufficient quantity of product on a consistent basis is critical. Failure to deliver products could have a material adverse effect on our business, financial position, and operating results.

We rely on third parties to assist with our clinical studies. 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 studies 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 studies. 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 studies. We are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical studies 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 studies, to assure that data and reported results are accurate and that the clinical study 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 studies 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 studies 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 studies. 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.

With the exception of patents or patent applications related to Veregen, baclofen, and hydrochlorothiazide products, we do not own or license any material patents associated with our products, and our ability to protect and control unpatented trade secrets, know-how, and other technological innovation is limited.

Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. Except for licenses for patent technology for Veregen, and ownership of patents and patent applications relating to our baclofen and hydrochlorothiazide products, we do not own or license any material patents associated with our products and therefore do not enjoy the same level of intellectual property protection with respect to such products as would a pharmaceutical manufacturer that markets a patented product. We have limited ability to protect and control trade secrets, know-how, and other technological innovation, all of which are unpatented. Others independently may develop similar or better proprietary information and techniques and disclose them publicly. In addition, others may gain access to our trade secrets, and we may not be able to protect our rights to our unpatented trade secrets. In addition, confidentiality agreements and other measures may not provide protection for our trade secrets in the event of unauthorized use or disclosure of such information. Failure to protect and control such trade secrets, know-how and innovation could harm the value of our trade secrets, know-how and other technological innovation, which could have a material adverse effect on our business, financial position, and operating results.

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

We own the trademark names for most of our branded products, including, Apexicon, Cortenema, Purified Cortrophin Gel, Cortrophin-Zinc, Inderal LA, Inderal XL, InnoPran XL, Lithobid, Reglan, Vancocin, and Veregen. We license the trademark names for Atacand, Atacand HCT, Arimidex, Casodex, Oxistat, and Pandel. 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.

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

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

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

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

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

We are currently involved in and in the future may become involved in legal proceedings in the ordinary course of our business, as a party or non-party witness, with both private parties and certain government agencies. We may incur substantial time and expenses participating in these types of lawsuits and investigations, which could also divert management's attention from ongoing business concerns and normal operations. In addition, these matters and any other substantial litigation may result in verdicts against us or government enforcement actions, which may include significant monetary awards, and preventing the manufacture, marketing and sale of our products. Any dispute resolved unfavorably, could have a material adverse effect on our business, financial position, and operating results. For a description of legal proceedings which are currently pending, see Note 15. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

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.

Currency fluctuations and changes in exchange rates could have a material adverse effect on our business, financial position, and operating results.

A portion of our transactions are denominated in a foreign currency, the Indian rupee. Because we engage in certain transactions in a foreign currency, we are subject to the effects of exchange rate fluctuations. If the U.S. dollar depreciates against the Indian rupee, the expenses we recognize from Indian-denominated transactions made by our Indian subsidiary could be translated at an unfavorable rate, leading to foreign exchange losses. Foreign exchange gains or losses as a result of exchange rate fluctuations in any given period could harm our operating results and negatively impact our financial position and results of operations.

We may not achieve the anticipated benefits from our acquisition of Novitium, which could have a material adverse effect on our business, financial position, and operating results.

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

We may not realize the potential benefits from the Acquisition that we or the market expects. Risks associated with the Acquisition include:

- failure to effectively manage our expanded operations, which were materially increased by the Acquisition;
- diversion of management's attention, the disruption or interruption of, or the loss of momentum in, the businesses of ANI and Novitium or inconsistencies in standards, controls, procedures, and policies, any of which could adversely affect our ability to maintain relationships with customers, partners, and employees or our ability to achieve the anticipated benefits of the acquisition;
- loss of key employees; and
- failure to maintain relationships with third parties, including Novitium's and our pre-existing customers, which relationships may be affected by customer preferences or public attitudes about the Acquisition. Any adverse changes in these relationships could adversely affect our business, financial condition, and results of operations.

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

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

Risks Related to our Industry

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

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

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

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

Consolidation and the formation of strategic partnerships among and between wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies, each controlling a larger share of pharmaceutical distribution channels. For example, our net revenues are concentrated among four customers representing 31%, 13%, 13%, and 12% of net revenues, respectively, during the year ended December 31, 2023. As of December 31, 2023, accounts receivable from these four customers was approximately 81% of our accounts receivable, net. Drug wholesalers and retail pharmacy chains, which represent an essential part of the distribution chain for generic pharmaceutical products, have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in declines in our sales volumes if a customer is consolidated into another company that purchases products from a competitor. In addition, the consolidation of drug wholesalers and retail pharmacy chains could result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business and enabling those groups to charge us increased fees. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to extract price discounts on our products. The result of these developments or the loss of our relationship with one or more of these wholesalers, may have a material adverse effect on our business, financial position, and operating results.

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

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

Three products, which together comprised less than 10% of our total revenue in 2023, are marketed without approved NDAs or Abbreviated New Drug Applications ("ANDAs") and we can offer no assurances that the U.S. Food and Drug Administration ("FDA") will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected.

Three products, Esterified Estrogen with Methyltestosterone ("EEMT"), Opium Tincture, and Thyroid Tablets are marketed without approved NDAs or ANDAs.

The Company obtained the rights to Hyoscyamine, a product without approved NDAs or ANDAs, on of December 27, 2023. During 2023 the Company recorded only contract manufacturing revenues for Hyoscyamine (see further discussion in Note 15. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K). We plan to launch Hyoscyamine commercially in early 2024.

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

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

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

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

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

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

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

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

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

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

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

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

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

Pharmaceutical products approved prior to the implementation of new or revised quality standards, including those produced or sold by us, may not meet these standards, which could require us to discontinue marketing and/or recall such products from the market, either of which could adversely affect our business, financial position, and operating results. In addition, results of periodic testing we conduct on our products may indicate the presence of substances at levels greater than those deemed acceptable under FDA or other standards, which could potentially require a recall of the product. For example, during the fourth quarter of 2019, testing of the API used in our ranitidine drug product, as well as testing of the drug product itself, indicated a level of a nitrosamine impurity called N-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 15. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

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

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

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

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

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

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

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

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

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

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

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

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

The U.S. government has enacted the Federal Drug Supply Chain Security Act ("DSCSA") that requires development of an electronic pedigree to track and trace each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10-year period. All prescription pharmaceutical products distributed in the U.S. must be serialized with unique product identifiers. ANI started manufacturing serialization-compliant products in November 2018. The DSCSA establishes national traceability standards requiring drugs to be labeled and tracked at the bottle level, preempts state drug pedigree requirements, and requires all supply-chain stakeholders to participate in an electronic, interoperable prescription drug traceability system by November 2023. In August 2023, however, the FDA established a one-year stabilization period to allow trading partners to implement, troubleshoot and mature their electronic interoperable systems. The FDA expects trading partners to use this stabilization period, which expires on November 27, 2024, to build and validate interoperable systems and processes, manage products and data, and ensure continuity of the supply chain and product availability to patients. Additionally, certain of our largest customer are requiring earlier compliance with the DSCSA, despite the stabilization period enacted by the FDA. 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. In addition, if we are unable to comply with DSCSA as of the required dates, we could face penalties or be unable to sell our products.

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

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

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

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

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

Continuing studies of our products could produce negative results, which could require us to implement risk management programs, or discontinue product marketing. In addition, ongoing post-approval drug safety surveillance of our products could result in the submission of adverse event reports to the FDA.

Studies of the proper utilization, safety, and efficacy of pharmaceutical products are being conducted by the industry, government agencies, and others on a continuous basis. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety, and efficacy of current and previously marketed products, including those that we produce. In addition, we are required by the FDA to submit reports of adverse events involving the use of our products. In some cases, studies and safety surveillance programs have resulted, and in the future may result, in the 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.

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

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

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

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

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

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

Inflationary pressures are currently being experienced and may continue to exist in the U.S. and key worldwide markets. The rate of inflation may significantly increase input costs for our products and, given the competitive nature of the generic and rare disease markets in which we compete, we 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, and India. Significant judgment is required in determining our international provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. In addition, we have potential tax exposures resulting from the varying application of statutes, regulations, and interpretations, which include exposures on intercompany terms of cross-border arrangements between our U.S. operations and our Indian subsidiary in relation to various aspects of our business, including research and development services, tech transfers, and contract manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions; such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and which could have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations.

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

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

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

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

The Foreign Corrupt Practices Act and other anti-corruption laws and regulations ("Anti-Corruption Laws") prohibit corrupt payments by our employees, vendors, or agents. From time to time, we receive inquiries from authorities in the U.S. and elsewhere about our business activities outside of the U.S. and our compliance with Anti-Corruption Laws. While we devote substantial resources to our compliance programs and have implemented policies, training, and internal controls designed to reduce the risk of corrupt payments, our employees, vendors or agents may violate our policies and with the acquisition of Novitium, 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 Indian foreign tax regulations. 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 Novitium's operations (including those of its Indian subsidiary Novitium Labs Private Limited) 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 operates, including India, the risks could have a material adverse effect on our business, results of operations, or financial condition.

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

We are subject to complex transfer pricing and other tax regulations in the United States and India 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 2023 did not result in an impairment charge related to goodwill, there can be no assurances that our goodwill will not be impaired in the future.

Our material definite-lived intangible assets consist of ANDAs for previously marketed generic products, NDAs and product rights for our branded products, product rights related to certain generic products, and a non-compete agreement. These assets are being amortized over their useful lives of seven to 10 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. No impairment losses were recognized in the year ended December 31, 2023.

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

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

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

We previously identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, any of which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

As of December 31, 2022, we identified material weaknesses related to ineffective control environment at our Novitium subsidiary, subsequent to the acquisition of Novitium in November 2021, and information technology general controls ("ITGCs") in the areas of user access over certain information technology systems that support our financial reporting processes. These material weaknesses continued into 2023 and were fully remediated as of December 31, 2023. For a detailed summary of these material weaknesses, including our remediation steps, please refer to Item 9A. - Controls and Procedures. As of December 31, 2023 management has concluded that the Company's internal control over financial reporting was effective.

If we are unable to maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process, and report financial information accurately and to prepare financial statements within required time periods could be adversely affected, which could subject us to litigation, investigations, or penalties; negatively affect our liquidity, our access to capital markets, perceptions of our creditworthiness, our ability to complete acquisitions, our ability to maintain compliance with covenants under our debt instruments or derivative arrangements regarding the timely filing of periodic reports, or investor confidence in our financial reporting, any of which may divert management resources or cause our stock price to decline. Further, remediation of a material weakness does not provide assurance that our remediation or other controls will continue to operate properly or remain adequate.

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

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

Risks Related to our Debt

Making interest and principal payments under our Credit Facility consisting of $300.0 million term loan and a $40.0 million revolving credit facility, requires a significant amount of cash.

In connection with the completion of the Novitium acquisition, we entered into a $300.0 million term loan and a $40.0 million revolving credit facility. The Credit Facility, which is secured by all our assets and the assets of our subsidiaries, was used to finance the cash consideration of the acquisition of Novitium and terminate and repay our previous senior credit facilities. In order to service the debt we incur under this facility, 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 sufficient to service our debt. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional debt or equity financing on terms that may not be favorable to us or available to us at all. Our ability to refinance any such debt will depend on the capital markets and our financial condition at that time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default under our current or future indebtedness. Any event of default or inability to otherwise satisfy our obligations could have a material adverse effect on our future operating results and financial condition.

Our 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 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 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 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 Credit Agreement, 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.

Changes in the method of determining London Interbank Offered Rate ("LIBOR"), or the replacement of LIBOR with an alternative reference rate, such as SOFR, may adversely affect interest expense related to outstanding debt.

In July 2023, we amended our Credit Agreement to transition from LIBOR to SOFR due to the cessation of LIBOR pursuant to the terms of Amendment No.1 to the Credit Agreement. SOFR will be applied to the Credit Facility for the interest period (as defined in the Credit Agreement) beginning on August 1, 2023 and will replace all LIBOR terms. We have no other material financing agreements that use LIBOR as an interest index. There is no guarantee that the transition from LIBOR to SOFR will not result in financial market disruptions, significant increases in benchmark rates, or borrowing costs to borrowers. While we will continue to use SOFR, certain factors may impact SOFR, including factors causing SOFR to cease to exist, new methods of calculating SOFR to be established, or the use of alternative reference rates. These consequences are not entirely predictable and could have an adverse impact on our financing costs and our results of operations. As such, the future of SOFR at this time remains uncertain.

Risks Related to our Common Stock

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

Our current principal stockholders, directors, and executive officers beneficially own approximately 13% of our outstanding capital stock entitled to vote as of December 31, 2023. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions, or other extraordinary transactions. They may also have interests that differ from stockholders generally and may vote in a way with which other stockholders disagree and which may be adverse to their interests. This concentration of ownership may have the effect of delaying, preventing, or deterring a change of control of ANI, could deprive stockholders of an opportunity to receive a premium for their common stock as part of a sale of ANI, and might ultimately affect the market price of our common stock.

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

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

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

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

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

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

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

General Risk Factors

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

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP") requires us to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the period. There are inherent uncertainties involved in estimates, judgments and assumptions, and any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position, and operating results.

In the consolidated financial statements included in the periodic reports filed with the SEC, estimates, judgments, and assumptions are used for, but not limited to, revenue recognition, allowance for credit losses, accruals for chargebacks, rebates, returns and other allowances, allowance for inventory obsolescence, stock-based compensation, valuation of financial instruments and intangible assets, allowances for contingencies and litigation, deferred tax assets and liabilities, deferred tax valuation allowance, contingent consideration, and the depreciable lives of fixed and intangible assets. Actual results could differ from those estimates. Estimates, judgments, and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses, and income. Any such changes could have a material adverse effect on our business, financial position, and operating results.

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

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

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

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk management and strategy

We maintain a comprehensive process for identifying, assessing and managing material risks arising from cybersecurity threats, and have integrated these into our overall risk management processes. Our senior leadership team, along with representatives from our information technology, legal, human resources and finance departments, are responsible for developing the Company's overall risk management program and are also responsible for executing our cybersecurity policies.

We are establishing a formal written information security policy and incident response policy which outlines the methods for assessing, identifying, and managing risks related to the Company. We've developed a robust cybersecurity program which includes multiple security layers. We understand the importance of a strong cybersecurity framework and have hired external security consultants to assess, audit, and monitor its security controls and events. We also ensure that third-party service providers have the ability to implement and maintain appropriate security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company. In addition, we maintain a cybersecurity insurance policy. Our business strategy, results of operations and financial condition have not been materially affected by risks from cybersecurity threats.

Governance

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

Item 2. Properties

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

We ceased operations at our subsidiary, ANI Pharmaceuticals Canada, Inc., a wholly owned subsidiary of the Company located in Oakville, Ontario, Canada as of March 31, 2023. This action is part of ongoing initiatives to capture operational synergies following our acquisition of Novitium. We have fully completed the transition of the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites. On November 6, 2023, ANI Pharmaceuticals Canada Inc., entered into an agreement for the sale of the Oakville, Ontario manufacturing facility. On December 22, 2023, the agreement was terminated by mutual agreement. In February 2024, the Company entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of 19.2 million Canadian Dollars, or approximately $14.2 million US Dollars, based on the current exchange rate. The sale is expected to close in March 2024 (see Note 19. Subsequent Events, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

We lease spaces for warehouse and packaging activities in East Windsor, New Jersey, and for research and development activities in Chennai, India. In September 2022, we entered into a lease for office space in Princeton, New Jersey, which includes certain employees in our corporate, legal, human resources, business functions, and rare disease operations. The leases will expire between 2025 and 2028. During 2023, we have expanded our East Windsor, New Jersey facility to accommodate additional laboratory, product development, and employee office space.

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 15. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K.

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 22, 2024, there were approximately 264 shareholders of record of our common stock, which does not include stockholders that beneficially own shares held in a "nominee" or in "street" name, and six holders of record of Class C stock.

Dividends

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. Our shares of Series A convertible preferred stock (the "PIPE Shares"), accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and will also participate, on a pro-rata basis, in any dividends that may be declared with respect to our common stock. To date, we have paid all preferred stock dividends in cash. We currently intend to retain all remaining available funds and any future earnings to fund the development and growth of our business.

Recent Sales of Unregistered Securities

None.

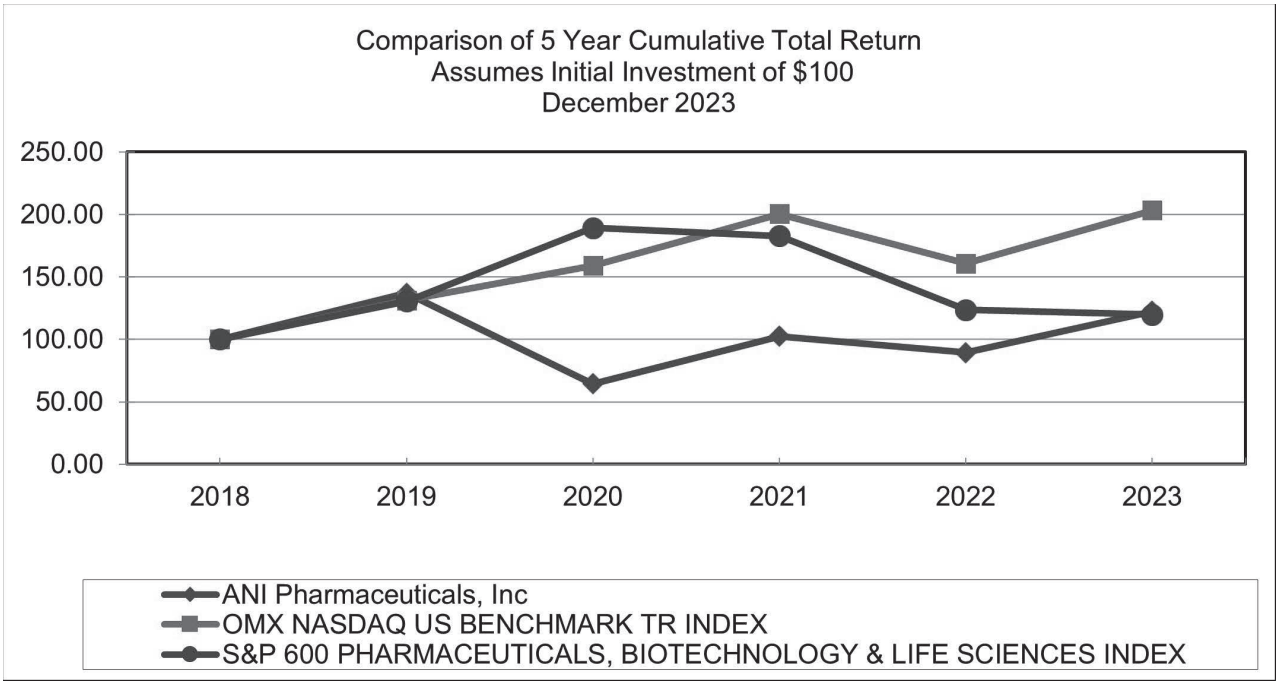
Issuer Purchases of Equity Securities

Period	Total Number of Shares Purchased[1]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or approximate dollar value) of Shares that may yet be Purchased Under the Plans or Programs
October 1 - October 31, 2023	—	$ —	—	$ —
November 1 - November 30, 2023	2,528	$ 52.30	—	$ —
December 1 - December 31, 2023	1,865	$ 52.91	—	$ —
Total	4,393	$ 52.56	—	

[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, 2018, with dividends being reinvested. The stock price performance in the graph below is not necessarily indicative of future price performance.



Item 6. Reserved

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

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

This section of this Form 10-K generally discusses 2023 and 2022 items and year-to-year comparisons between 2023 and 2022. Discussions of 2021 items and year-to-year comparisons between 2022 and 2021 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, 2022, filed with the SEC on March 9, 2023.

Executive Overview

ANI Pharmaceuticals, Inc. and its consolidated subsidiaries (together, "ANI," the "Company," "we," "us," or "our") is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by scaling up our Rare Disease business through the successful launch of our lead asset, Cortrophin Gel, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. We own and operate three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, and one is located in East Windsor, New Jersey, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. We ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. We have fully completed the transition of the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites.

On November 6, 2023, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement with a potential buyer for the sale of the Oakville, Ontario manufacturing facility, however, the agreement was subsequently terminated in December 2023 by mutual agreement. In February 2024, the Company entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of 19.2 million Canadian Dollars, or approximately $14.2 million US Dollars, based on the current exchange rate. The sale is expected to close in March 2024 (see Note 19. Subsequent Events, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

Strategy

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

Building a successful Rare Disease platform

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

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

During 2021 and 2022, we invested significantly in leadership, expertise and infrastructure in the areas of commercialization of rare disease therapies and developed a launch strategy and commercial plan for this product. During this timeframe, we hired a significant number of new employees and assembled and trained our Rare Disease field force. On January 24, 2022, we announced the commercial launch of Cortrophin Gel in the U.S as our foundational Rare Disease asset. On October 2, 2023, we announced FDA approval and commercial availability of a 1-mLvial of Cortrophin Gel, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares. As a result of the build out of our Rare Disease team, our expenditures in support of these efforts were significantly higher in 2022 as compared to the prior year, and we continued to invest behind Cortrophin Gel and our Rare Disease platform in 2023.

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

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

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

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

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

Generic Product Development Considerations

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

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

Fiscal 2023 Developments

Election of Directors

On August 21, 2023, the Board of Directors of ANI (the "Board"), appointed Matthew Leonard to serve on the Board as a director with a term expiring at the Company's 2024 annual meeting of stockholders. Mr. Leonard serves as a member of the Audit and Finance Committee and member of the Nominating and Corporate Governance Committee. On August 22, 2023, Dr. David B. Nash, M.D. informed the Board of his decision not to seek reelection as a director on the Board at the Company's 2024 Annual Meeting of Stockholders (the "2024 Annual Meeting"). Dr. Nash will continue to serve for the remainder of his term as a director until the 2024 Annual Meeting. Dr. Nash has served as a member of the Company's Board since May 2018 and has served as Chair of the Nominating and Corporate Governance Committee and as a Member of the Audit and Finance Committee.

Public Offering

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

Restructuring Update

We ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following our acquisition of Novitium in November 2021. We have fully completed the transition of the products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites. On November 6, 2023, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement with a potential buyer for the sale of the Oakville, Ontario manufacturing facility, however, the agreement was subsequently terminated in December 2023 by mutual agreement. In February 2024, the Company entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of 19.2 million Canadian Dollars, or approximately $14.2 million US Dollars, based on the current exchange rate. The sale is expected to close in March 2024 (see Note 19. Subsequent Events, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K).

Products Launches

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

General

Impacts to our 2023 and 2022 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)	**2023**	**2022**
Net Revenues	$ 486,816	$ 316,385
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	181,513	138,785
Research and development	34,286	22,318
Selling, general, and administrative	161,697	124,044
Depreciation and amortization	59,791	56,972
Contingent consideration fair value adjustment	1,426	3,758
Restructuring activities	1,132	5,679
Intangible asset impairment charge	—	112
Operating Income (Loss)	46,971	(35,283)
Interest expense, net	(26,940)	(28,052)
Other (expense) income, net	(159)	670
Income (Loss) Before Expense (Benefit) for Income Taxes	19,872	(62,665)
Income tax expense (benefit)	1,093	(14,769)
Net Income (Loss)	$ 18,779	$ (47,896)

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,	
	2023	2022
Net Revenues	100.0 %	100.0 %
Operating Expenses		
Cost of sales (excluding depreciation and amortization)	37.3 %	43.9 %
Research and development	7.0 %	7.1 %
Selling, general, and administrative	33.2 %	39.2 %
Depreciation and amortization	12.3 %	18.0 %
Contingent consideration fair value adjustment	0.3 %	1.2 %
Restructuring activities	0.2 %	1.8 %
Intangible asset impairment charge	— %	0.0%
Operating Income (Loss)	9.6 %	(11.2)%
Interest expense, net	(5.5)%	(8.9)%
Other (expense) income, net	0.0%	0.2 %
Income (Loss) Before Expense (Benefit) for Income Taxes	4.1 %	(19.9)%
Income tax expense (benefit)	0.2 %	(4.7)%
Net Income (Loss)	3.9 %	(15.2)%

Results of Operations for the Years Ended December 31, 2023 and 2022

Net Revenues

	Year Ended December 31,			
(in thousands)	2023	2022	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 269,449	$ 210,121	$ 59,328	28.2 %
Established brand pharmaceutical products, royalties, and other pharmaceutical services	105,250	64,578	40,672	63.0 %
Generics, established brands, and other segment total net revenues	$ 374,699	$ 274,699	$ 100,000	36.4 %
Rare Disease Segment				
Rare disease pharmaceutical products	112,117	41,686	$ 70,431	169.0 %
Total net revenues	$ 486,816	$ 316,385	$ 170,431	53.9 %

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

Net revenues for the year ended December 31, 2023 were $486.8 million compared to $316.4 million for the same period in 2022, an increase of $170.4 million, or 53.9%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $269.4 million during the year ended December 31, 2023, an increase of 28.2% compared to $210.1 million for the same period in 2022, driven by increased volumes on the base business, increased volumes from the inclusion of 2022 launches in 2023 and 2023 new product launches. From a product perspective, the increase was principally driven by revenues from year over year increases in products such as Acebutolol, Colestipol, Digoxin, Famotidine, Fluoxetine, Levocarnitine, Mixed Amphetamine Salts Extended Release, Misoprostol, Nitrofurantoin, Pyrazinamide, Thyroid, Tolterodine, Tranexamic Acid, Trimethorpim, and various other products tempered by a decrease in revenues of Cholestyramine, Fenofibrate, Mesalamine, Nicardipine, Oxybutynin Chloride, Paliperidone Extended Release, and Prazosin, among others.
- Net revenues for branded pharmaceutical products, royalties, and other pharmaceutical services were $105.3 million during the year ended December 31, 2023, an increase of 63.0% compared to $64.6 million for the same period in 2022, driven by a net increase in volume.
- Net revenues of rare disease pharmaceutical products, which consists entirely of sales of Purified Cortrophin Gel, were $112.1 million during the year ended December 31, 2023, which represents an increase of $70.4 million from $41.7 million for the same period in 2022. This increase was driven by increased volume in this second year of launch (product was launched in late January 2022).

In addition to the above, within our Generic, established brand, and other segment in the current year period, we were successful in supplying incremental volume in markets that were experiencing supply chain disruptions for competing products. Generally, when opportunities for volume and revenue upside related to our products arise in the marketplace, there is no assurance as to how long these favorable market conditions may persist.

Cost of Sales (Excluding Depreciation and Amortization)

	Year Ended December 31,			
(in thousands)	2023	2022	Change	% Change
Cost of sales (excluding depreciation and amortization)	181,513	138,785	$ 42,728	30.8 %

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

For the year ended December 31, 2023, cost of sales increased to $181.5 million from $138.8 million for the same period in 2022, an increase of $42.7 million or 30.8%. The increase is primarily due to a significant increase in sales volumes of generic and rare disease pharmaceutical products and a net increase in sales of products that bear a royalty payable, including Purified Cortrophin Gel. During the year ended December 31, 2022, we recognized $5.3 million in cost of sales representing the excess of fair value over cost for inventory acquired in acquisitions and subsequently sold during the year ended December 31, 2022. There are no comparable expenses in the year ended December 31, 2023.

Cost of sales, as a percentage of net revenues, decreased from 42.2% to 37.3% for the year ended December 31, 2023, compared to the same period in 2022. The decrease was primarily due to the non-recurrence of $5.3 million expense recognized in the year ended December 31, 2022, related to the excess of fair value over cost for inventory acquired in a business combination, as well as the increased sales of Established brand pharmaceutical products, royalties, and other pharmaceutical services products and Cortrophin Gel coupled with increased generic volumes with a mix shift in higher margin products.

During the year ended December 31, 2023, no single vendor represented at least 10% of inventory purchases. During the year ended December 31, 2022, we purchased 19% of our inventory from one supplier.

Other Operating Expenses

(in thousands)	Year Ended December 31, 2023	2022	Change	% Change
Research and development	$ 34,286	$ 22,318	$ 11,968	53.6 %
Selling, general, and administrative	161,697	124,044	37,653	30.4 %
Depreciation and amortization	59,791	56,972	2,819	4.9 %
Contingent consideration fair value adjustment	1,426	3,758	(2,332)	(62.1)%
Restructuring activities	1,132	5,679	(4,547)	(80.1)%
Intangible asset impairment charge	—	112	(112)	(100.0)%
Total other operating expenses	$ 258,332	$ 212,883	$ 45,449	21.3 %

For the year ended December 31, 2023, other operating expenses increased to $258.3 million from $212.9 million for the same period in 2022, an increase of $45.4 million, or 21.3%, primarily as a result of the following factors:

- Research and development expenses increased from $22.3 million to $34.3 million, an increase of 53.6%, primarily due to expenses related to a 505(b)(2) filing for one product of approximately $1.6 million, expenses related to ANDA filings, and a higher level of activity associated with ongoing and new projects in the year ended December 31, 2023.

- Selling, general, and administrative expenses increased from $124.0 million to $161.7 million, an increase of 30.4%, due to increased employment related costs, Rare Disease sales and marketing costs, legal expenses, as well as an overall increase in activities required to support the growth of our business.

- Depreciation and amortization expense was $59.8 million for the year ended December 31, 2023, compared to $57.0 million for the same period in 2022, an increase of $2.8 million. The increase is primarily due to an increase in amortization expense related to intangible assets acquired during 2023, and amortization of IPR&D which commenced during the year ended December 31, 2023.

- We recognized a loss of $1.4 million and loss of $3.8 million in the year ended December 31, 2023 and 2022, respectively, for the contingent consideration fair value adjustment. The change in the fair value adjustment is primarily related to changes in the anticipated cash flows, specifically extending the timeframe over which cash flows will be generated by the products, offset by the passage of time (i.e., moving closer to the anticipated payment date of the consideration), an increase to the probability of payment for the product development-based milestone payments, and by fluctuations in the discount rates utilized throughout the year.

- We recognized restructuring activities of $1.1 million of expense in the year ended December 31, 2023, in relation to the closure of our Oakville, Ontario, Canada facility. Costs included severance and other employee benefits costs of $0.2 million, and $0.7 million of accelerated depreciation costs. We recognized restructuring activities of $5.7 million of expense in the year ended December 31, 2022, in relation to the closure of our Oakville, Ontario, Canada facility. Costs included $2.1 million in termination benefits, $3.1 million in fixed asset impairments and accelerated depreciation, and $0.4 million of other costs.

- We recognized an impairment charge of $0.1 million in the year ended December 31, 2022, in relation to an ANDA asset. No impairment charges were recognized in the year ended December 31, 2023.

Other Expense, net

(in thousands)	Year Ended December 31, 2023	2022	Change	% Change
Interest expense, net	(26,940)	(28,052)	$ 1,112	(4.0)%
Other (expense) income, net	(159)	670	(829)	(123.7)%
Total other expense, net	$ (27,099)	$ (27,382)	$ 283	(1.0)%

For the year ended December 31, 2023, we recognized total other expense, net of $27.1 million versus total other expense of $27.4 million for the same period in 2022, a decrease of $0.3 million. Interest expense, net for the year ended December 31, 2023 and 2022 consisted primarily of interest expense on borrowings under our Term Facility, amortization of deferred debt issuance costs, dividend income earned on our money market funds, the effects of the interest rate swap, and interest earned on cash balances. The decrease in interest expense is due to dividend income earned on our money market funds, income from our interest rate swap, and increased interest income earned on higher cash balances, offset by an increased borrowing rate on the Term Facility and an increase in amortization of finance fees. For the year ended December 31, 2023, there was $0.6 million of interest capitalized into construction in progress, compared to less than $0.1 million of interest capitalized for the year ended December 31, 2022, representing an offset to interest expense.

Income Tax Expense (Benefit)

	Year Ended December 31,			
(in thousands)	2023	2022	Change	% Change
Income tax expense (benefit)	$ 1,093	$ (14,769)	$ 15,862	(107.4)%

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 14. 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, 2023, we recognized an income tax expense of approximately $1.1 million. The Company's effective tax rate was 5.5% after discrete items for the year ended December 31, 2023. The effective tax rate differed from the federal statutory rate of 21% primarily due to the recognition of the U.S. federal research and development credit, permanent differences, and stock based compensation.

For the year ended December 31, 2022, we recognized an income tax benefit of $(14.8) million, an effective benefit rate of 23.6% of consolidated pre-tax losses reported in the period, as well as the net effects of certain discrete items occurring in 2022 which impact our income tax provision in the period in which they occur. There were no material discrete items occurring during the year ended December 31, 2022.

Liquidity and Capital Resources

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

(in thousands)	December 31, 2023	December 31, 2022
Cash and cash equivalents	$ 221,121	$ 48,228
Current restricted cash	—	5,006
Accounts receivable, net	162,079	165,438
Inventories	111,196	105,355
Prepaid income taxes	—	3,827
Assets held for sale	8,020	8,020
Prepaid expenses and other current assets	17,400	8,387
Total current assets	$ 519,816	$ 344,261
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	36,683	29,305
Accrued royalties	16,276	9,307
Accrued compensation and related expenses	23,786	10,312
Accrued government rebates	12,168	10,872
Income taxes payable	8,164	—
Returned goods reserve	29,678	33,399
Current contingent consideration	12,266	—
Accrued expenses and other	5,606	5,394
Total current liabilities	$ 145,477	$ 99,439

As of December 31, 2023, we had $221.1 million in unrestricted cash and cash equivalents. On December 31, 2022, we had $48.2 million in unrestricted cash and cash equivalents. In 2023 and 2022, we invested in leadership, expertise, and infrastructure in the areas of commercialization of rare disease therapies, and in 2022 began to commercialize our Cortrophin Gel product.

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

Our working capital ratio, defined as total current assets divided by total current liabilities, is 3.6 as of December 31, 2023. We believe that our financial resources, consisting of net current working capital of approximately $374.3 million, anticipated future operating revenue and corresponding collections from customers, and our Credit Facility, under which $40.0 million remains available for borrowing as of December 31, 2023, will be sufficient to enable us to meet our working capital requirements and debt obligations for at least the next 12 months. If our assumptions underlying estimated revenue and expenses are wrong, or if our cash requirements change materially as a result of shifts in our business or strategy, we could require additional financing. If we are not able to continue to be profitable in future years or are not able to continue to generate cash from operations as anticipated and additional capital is needed to support operations, we may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations, or accept financing terms that are not as attractive as desired.

Consolidation among wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. Our net revenues were concentrated among four customers representing 31%, 13%, 13%, and 12% of net revenues during the year ended December 31, 2023. As of December 31, 2023 accounts receivable from these four customers totaled approximately 81% of accounts receivable, net. Our net revenues were concentrated among three customers representing 26%, 18%, and 15% of net revenues during the year ended December 31, 2022. 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 23% and 13% of our net revenues in 2023 and 2022, respectively. We pay to Merck Sharpe & Dohme B.V. ("Merck") quarterly contingent consideration in the form of a perpetual, tiered royalty expressed as a percentage of Cortrophin Gel net sales. During the initial two years of commercialization (2022 and 2023) this royalty approximated 10% of net sales. We currently anticipate the blended Merck royalty rate to be in the upper teens in 2024. In the case of significant revenue growth beyond 2024, we anticipate the blended rate may reach the low 20 percent range.

Sources and Uses of Cash

Debt Financing

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

The Credit Facility permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the SOFR Rate (or alternate benchmark rate as defined in the Credit Agreement) in the case of SOFR loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the SOFR Rate (as defined in the Credit Facility) in the case of loans under the Revolving Facility. Amendment No. 1 also includes the addition of a credit spread adjustment of 0.11448% for an interest period of one-month duration, 0.26161% for a three-month duration, and 0.42826% for a six-month duration, in addition to SOFR and the applicable margin, as noted above. There were no other changes or modifications to the Credit Agreement.

The Credit Facility has a subjective acceleration clause in case of a material adverse effect. The Term Facility includes a repayment schedule, pursuant to which $750 thousand of the loan will be paid in quarterly installments during the 12 months ending December 31, 2024. As of December 31, 2023, $3.0 million of principal of the loan was recorded as current borrowings, net of deferred financing costs, in the consolidated balance sheet. As of December 31, 2023, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

Equity Financing

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

Uses of Cash

Our primary cash requirements are to fund operations, including Purified Cortrophin Gel commercialization efforts, 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.

On November 19, 2021, we completed our previously announced acquisition of all of the interests of Novitium pursuant to the terms of the Agreement and Plan of Merger (the "Merger Agreement"), dated as of March 8, 2021, for cash consideration, 2,466,654 restricted shares of our common stock valued at $91.2 million based on our closing stock price of $43.54 on the date of closing and discounted for lack of marketability due to restrictions on shares, and up to $46.5 million in additional contingent consideration. Additionally, we agreed to pay certain debts of Novitium in the amount of $8.5 million, which we deemed to be paid in consummation of the transaction closing, and not assumed liabilities, and thus were included as additional cash consideration. This acquisition was accounted for as a business combination. The contingent consideration is based on the achievement of certain milestones, including milestones on gross profit of Novitium portfolio products over a 24-month period, regulatory filings completed during this 24-month period, and a percentage of net profits on certain products that are launched in the future. As of the closing of the acquisition, the contingent consideration had a fair value of $30.8 million. Refer to Note 10 for changes in contingent consideration and changes in fair value. Total consideration including cash, restricted shares and contingent consideration was valued at $206.5 million.

In connection with entry into the Credit Facility, on November 19, 2021, we terminated our existing Amended and Restated Credit Agreement, dated as of December 27, 2018 (the "Prior Credit Agreement"), among the Company, as borrower, and Citizens Bank with other lenders. In connection with the termination of the Prior Credit Agreement, on November 19, 2021, we used borrowings under the Credit Facility to prepay the full amount of indebtedness under the Prior Credit Agreement, and to pay related accrued and unpaid interest, legal fees, and expenses. We made a reacquisition payment of $200.1 million, representing the remaining principal balance on the debt of $200.1 million plus certain legal fees.

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)	**2023**	**2022**
Operating Activities	$ 118,959	$ (31,203)
Investing Activities	$ (18,511)	$ (15,738)
Financing Activities	$ 67,439	$ (5,126)

Net Cash Provided by (Used in) Operations

Net cash provided by operating activities was $119.0 million for the year ended December 31, 2023, compared to $31.2 million used in operating activities during the same period in 2022, a change of $150.2 million. The increase was driven by net income in the current year period due to increased sales and gross profit and the non-recurrence of significant utilization of cash during the initial launch period of Cortrophin Gel in 2022, as well as other net changes in our assets and liabilities.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2023 was $18.5 million, principally due to $8.9 million of capital expenditures and consideration paid for asset acquisitions of ANDAs and other product rights from Akorn Holding Company, Slayback Pharma Limited Liability Company, and Alvogen, Inc. totaling $9.6 million. Net cash used in investing activities for the year ended December 31, 2022 was $15.7 million, principally due to $8.9 million of capital expenditures and the consideration paid for asset acquisitions of intangible assets totaling $7.6 million, partially offset by $0.8 million of proceeds from the sale of long-lived assets during the period.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities was $67.4 million for the year ended December 31, 2023, principally due to $80.6 million in net proceeds from the May 2023 public offering and $9.0 million from proceeds from stock option exercises and ESPP purchases. This is offset by cash used in financing activities related to $12.5 million to Company Members of Novitium, $3.0 million maturity payments on the Term Facility, $5.0 million of treasury stock purchased in

relation to restricted stock vests, and $1.6 million convertible preferred stock dividends paid. Net cash used in financing activities for the year ended December 31, 2022 was $5.1 million, principally due to the $3.0 million maturity payments on the Term Facility, $2.0 million of treasury stock purchased in relation to restricted stock vests, and $1.6 million convertible preferred stock dividends paid.

Contractual Obligations

We believe our available cash and cash equivalents along with our ability to generate operating cash flow and continued access to debt markets are sufficient to fund existing and planned cash requirements. Our contractual obligations and commitments as of December 31, 2023 are comprised of principal payments on debt, interest payments on debt, operating leases, purchase obligations, dividends, and contingent consideration.

Our largest contractual obligation relates to our principal payments on our interest payments on our debt. As of December 31, 2023, the principal amount of our Term Facility was $294.0 million. The interest rate on our Term Facility is currently 1-month SOFR plus 6.00% per annum, plus a credit spread adjustment of 0.11448% for an interest period of one-month duration, subject to a 0.75% floor. The interest rate under the Term Facility as of December 31, 2023 is 11.46%. See Note 5, Indebtedness, 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. We also have an interest rate swap used to manage changes in SOFR-based interest rates underlying a portion of the borrowing under the Term Facility. Under the swap agreement, ANI pays the counterparty a fixed rate of 2.26% and receives variable 1-month SOFR, subject to a 0.75% floor, on the outstanding notional value. As of December 31, 2023, the notional value of the interest rate swap was $139.4 million. See Note 6, 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.

Our operating leases are for facilities 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 15, Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for additional discussion and timing of payments related to these operating lease obligations.

Our convertible preferred stock (“PIPE Shares”) accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind. Dividends are payable until the preferred stock is converted, either at the option of the PIPE investor, at any time, or the option of ANI, beginning two years after the November 19, 2021 issuance provided ANI’s stock price reaches a certain level. See Note 11, 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.

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 Agreement and Plan of Merger, dated as of March 8, 2021, on December 12, 2023, the Company paid $12.5 million of cash consideration to the Company Members, defined as the holders of Novitium ownership interests in the Agreement and Plan of Merger, of Novitium for the achievement of the "ANDA Filing Earn-Out," as defined in the Agreement. On February 22, 2024, the Company paid $12.5 million to Novitium related to the achievement of the milestone, see Note 2 and Note 10, 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 our contingent consideration.

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

Critical Accounting Estimates

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

apparent from other sources. Actual results could differ from those estimates. Due to the estimation processes involved, the following summarized accounting policies and their application are considered to be critical to understanding our business operations, financial condition, and operating results.

Revenue Recognition

Revenues are primarily derived from sales of generic, rare disease, and established brand 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.

Our 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, our 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, we could be exposed to losses or gains that could be material, as changes to chargeback estimates could cause an increase or decrease in revenue recognized during the year and increase or decrease accounts receivable. If there were a 1% change in the chargeback estimates throughout the year, our net revenues would be affected by $5.9 million for the year ended December 31, 2023.

Government Rebates

If actual results were not consistent with our estimates as related to government rebates, we 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 $2.4 million for the year ended December 31, 2023.

Returns

If actual results were not consistent with our estimates, we 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 $1.8 million for the year ended December 31, 2023.

Administrative Fees and Other Rebates

If actual results were not consistent with our estimates, we 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 $5.6 million for the year ended December 31, 2023.

Prompt Payment Discounts

If customers do not take 100% of available discounts as we estimate, we could need to re-adjust our methodology for calculating the prompt payment discount reserve. If there were a 10% decrease in the prompt payment discounts estimates throughout the year, our net revenues would increase by $2.3 million for the year ended December 31, 2023.

Impairment of Goodwill and Intangible Assets

Goodwill

We allocate goodwill to reporting units based on the reporting unit expected to benefit from the business combination. We evaluate our 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, 2023 was $28.2 million. As part of the Novitium acquisition on November 19, 2021, we acquired goodwill of $24.6 million. We believe 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

We review our 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. We evaluate 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. Our 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 our 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.

Contingent Consideration

The fair value of our contingent consideration was $24.0 million and $35.1 million at December 31, 2023 and 2022, 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 charges of $1.4 million and $3.8 million during the years ended December 31, 2023 and 2022, respectively.

Stock-Based Compensation

Stock-based compensation cost for stock options is determined at the grant date using an option pricing model and stock-based compensation cost for restricted stock is based on the closing market price of the stock at the grant date. The value of the award is recognized as expense on a straight-line basis over the employee's requisite service period. Awards may also be issued in the form of Performance Stock Units ("PSUs") to certain employees of the Company. PSUs represent the right to receive an amount of cash, a number of shares of common stock or a combination of both, contingent upon the achievement of specified performance and market objectives during a specified performance period. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized straight-line over the vesting term.

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

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

	Years Ended December 31,		
(in thousands)	2023	2022	2021
Selling, general, and administrative	$ 19,036	$ 13,316	$ 9,905
Research and development	910	751	564
Cost of sales	706	532	20
	$ 20,652	$ 14,599	$ 10,489

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

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

Changes in estimates could affect compensation expense within individual periods. If there were to be a 10% change in our stock-based compensation expense for the year, our Income (Loss) Before Expense (Benefit) for Income Taxes would be affected by $2.1 million for the year ended December 31, 2023.

Income Taxes

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

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact to the consolidated financial statements. We are subject to taxation in various U.S. jurisdictions, Canada, and India and remain subject to examination by taxing jurisdictions for the years 1998 and all subsequent periods due to the availability of net operating loss carryforwards. To the extent we are 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.

We consider 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 we believe 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.

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

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

The Term Facility matures on the six-year anniversary of November 19, 2021 (the “Closing Date”) and the Revolving Facility matures on the five-year anniversary of the Closing Date.

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

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

Amendment No. 1

In July 2023, the Company amended its Credit Agreement to transition from LIBOR to SOFR due to the cessation of LIBOR pursuant to the terms of Amendment No.1 to the Credit Agreement ("Amendment No. 1"). SOFR will be applied to the Credit Facility for the interest period (as defined in the Credit Agreement) beginning on August 1, 2023 and will replace all LIBOR terms. Amendment No. 1 also includes the addition of a credit spread adjustment of 0.11448% for an interest period of one-month duration, 0.26161% for a three-month duration, and 0.42826% for a six-month duration, in addition to SOFR and the applicable margin, as noted above. There were no other changes or modifications to the Credit Agreement. The Company has applied the optional expedients in ASC 848, Reference Rate Reform, and elected to treat the change in the benchmark interest rate to SOFR as a continuation of the existing Credit Agreement and account for the change prospectively.

In April 2020, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under term facilities related to our Prior Credit Agreement. The interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Facility with Truist Bank, the interest rate swap with a notional value of $168.6 million at origin on November 19, 2021 was novated and is now with Truist Bank and is used to manage changes in LIBOR-based interest rates underlying a portion of the borrowing under the Term Facility. The notional value of the swap was $139.4 million and $151.5 million at December 31, 2023 and 2022, respectively. We are exposed to interest rate risk on the unhedged portion of our Term Facility and if interest rates increased or decreased by 1%, interest expense would have increased or decreased by approximately $1.6 million. If our Revolving Facility were fully drawn and interest rates increased or decreased by 1%, interest expense would have increased or decreased by approximately $0.4 million. The interest rate swap provides an effective fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

We are exposed to risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the year ended December 31, 2023 by approximately $2.2 million.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Indian rupee-denominated transactions from our Indian subsidiary from the Indian-rupee to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the year ended December 31, 2023.

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, 2023 and 2022, 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, 2023 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, 2023 and 2022, and the consolidated results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2023, 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, 2023, 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 29, 2024 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 Matter

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was 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 matter 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 matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Evaluation of Certain Assumptions impacting the Chargeback Accrual

As described in Note 2 to the consolidated financial statements, the Company records certain variable consideration including discounts, which are estimated at the time of sale generally using the expected value method. Amounts accrued for chargebacks as of December 31, 2023, are approximately $84.2 million and are evaluated on a quarterly basis. Management's estimate of chargebacks is based on the inventory levels in the distribution channel as provided by wholesalers, as well as the actual average selling price for each product which is impacted by changes in customer mix, changes in negotiated terms with customers, changes in the volume of off-contract purchases, and changes in the wholesaler acquisition cost, in order to estimate the expected provision.

The principal consideration for our determination that performing procedures relating to the chargeback reserve is a critical audit matter is that there was a significant judgment required by management with respect to measure uncertainty, as the calculation of the chargeback reserve includes assumptions such as average selling price, purchasing trends of distributors and historical product sales used to predict future sales. This in turn led to a high degree of auditor judgment, subjectivity and effort in applying the procedures related to those assumption.

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 reserve, including management's control over the assumptions used to estimate the corresponding accruals. We recalculated the chargeback accrual for a selection of products, based on a combination of Company internal data, historical accrual by recalculating the accrual using our independent assumptions. We evaluated the Company's ability to accurately estimate 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 reserve 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
Philadelphia, Pennsylvania
February 29, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Internal Control over Financial Reporting

We have audited ANI Pharmaceuticals, Inc. and Subsidiaries (the "Company") internal control over financial reporting as of December 31, 2023 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 December 31, 2023, 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, 2023 and 2022, 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, 2023 and the related notes and our report dated February 29, 2024 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
Philadelphia, Pennsylvania
February 29, 2024

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

	December 31, 2023	December 31, 2022
Assets		
Current Assets		
Cash and cash equivalents	$ 221,121	$ 48,228
Current restricted cash	—	5,006
Accounts receivable, net of $97,262 and $161,052 of adjustments for chargebacks and other allowances at December 31, 2023 and 2022, respectively	162,079	165,438
Inventories	111,196	105,355
Prepaid income taxes	—	3,827
Assets held for sale	8,020	8,020
Prepaid expenses and other current assets	17,400	8,387
Total Current Assets	519,816	344,261
Non-current Assets		
Property and equipment, net	44,593	43,246
Deferred tax assets, net of deferred tax liabilities and valuation allowance	90,711	81,363
Intangible assets, net	209,009	251,635
Goodwill	28,221	28,221
Derivatives and other non-current assets	12,072	11,361
Total Assets	$ 904,422	$ 760,087
Liabilities, Mezzanine Equity, and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	36,683	29,305
Accrued royalties	16,276	9,307
Accrued compensation and related expenses	23,786	10,312
Accrued government rebates	12,168	10,872
Income taxes payable	8,164	—
Returned goods reserve	29,678	33,399
Current contingent consideration	12,266	—
Accrued expenses and other	5,606	5,394
Total Current Liabilities	145,477	99,439
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	284,819	285,669
Non-current contingent consideration, net of current	11,718	35,058
Other non-current liabilities	4,809	1,381
Total Liabilities	$ 446,823	$ 421,547
Commitments and Contingencies (Note 15)		
Mezzanine Equity		
Convertible Preferred Stock, Series A, $0.0001 par value, 1,666,667 shares authorized; 25,000 shares issued and outstanding at December 31, 2023 and 2022	24,850	24,850
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 20,730,896 shares issued and 20,466,953 outstanding at December 31, 2023; 17,643,497 shares issued and 17,494,466 shares outstanding at December 31, 2022	2	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at December 31, 2023 and 2022 respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2023 and 2022, respectively	—	—
Treasury stock, 263,943 shares of common stock, at cost, at December 31, 2023 and 149,031 shares of common stock, at cost, at December 31, 2022	(10,081)	(5,094)
Additional paid-in capital	514,103	403,901
Accumulated deficit	(80,132)	(97,286)
Accumulated other comprehensive income, net of tax	8,857	12,168
Total Stockholders' Equity	432,749	313,690
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 904,422	$ 760,087

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,		
	2023	**2022**	**2021**
Net Revenues	$ 486,816	$ 316,385	$ 216,136
Operating Expenses			
Cost of sales (excluding depreciation and amortization)	181,513	138,785	100,610
Research and development	34,286	22,318	11,369
Selling, general, and administrative	161,697	124,044	84,294
Depreciation and amortization	59,791	56,972	47,252
Contingent consideration fair value adjustment	1,426	3,758	500
Legal settlement expense	—	—	8,750
Purified Cortrophin Gel pre-launch charges	—	—	780
Restructuring activities	1,132	5,679	—
Intangible asset impairment charge	—	112	2,374
Total Operating Expenses	439,845	351,668	255,929
Operating Income (Loss)	46,971	(35,283)	(39,793)
Other Expense, net			
Interest expense, net	(26,940)	(28,052)	(11,922)
Other (expense) income, net	(159)	670	(4,343)
Income (Loss) Before Expense (Benefit) for Income Taxes	19,872	(62,665)	(56,058)
Income tax expense (benefit)	1,093	(14,769)	(13,455)
Net Income (Loss)	$ 18,779	$ (47,896)	$ (42,603)
Dividends on Series A Convertible Preferred Stock	$ (1,625)	$ (1,625)	$ (190)
Net Income (Loss) Available to Common Shareholders	$ 17,154	$ (49,521)	$ (42,793)
Basic and Diluted Income (Loss) Per Share:			
Basic Income (Loss) Per Share	$ 0.86	$ (3.05)	$ (3.40)
Diluted Income (Loss) Per Share	$ 0.85	$ (3.05)	$ (3.40)
Basic Weighted-Average Shares Outstanding	18,001	16,260	12,596
Diluted Weighted-Average Shares Outstanding	18,194	16,260	12,596

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,		
	2023	**2022**	**2021**
Net income (loss)	$ 18,779	$ (47,896)	$ (42,603)
Other comprehensive (loss) income, net of tax:			
Foreign currency translation adjustment	44	(112)	12
(Loss) gain on interest rate swap	(3,355)	15,335	8,370
Total other comprehensive (loss) income, net of tax	(3,311)	15,223	8,382
Total comprehensive income (loss), net of tax	$ 15,468	$ (32,673)	$ (34,221)

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, 2023, 2022, and 2021
(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, 2020	$ —	—	$ 1	12,430	$ —	$ 214,354	76	$ (2,246)	$ (11,437)	$ (4,972)	$ 195,700
Stock-based Compensation Expense	—	—	—	—	—	10,489	—	—	—	—	10,489
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	28	(889)	—	—	(889)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	56	—	2,069	—	—	—	—	2,069
Issuance of Restricted Stock Awards	—	—	—	541	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(81)	—	(1)	(21)	—	—	—	(1)
Issuance of Common Stock for Novitium Acquisition	—	—	—	2,467	—	91,199	—	—	—		91,199
Issuance of Common Stock in Public Offering	—	—	—	1,500	—	69,734	—	—	—	—	69,734
Dividends on Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(190)	(190)
Issuance of Series A Convertible Preferred Stock from Mezzanine Equity	24,850	25	—	—	—	—	—	—	—	—	24,850
Other comprehensive income	—	—	—	—	—	—	—	—	8,382	—	8,382
Net Loss	—	—	—	—	—	—	—	—	—	(42,603)	(42,603)
Balance, December 31, 2021	$ 24,850	25	$ 1	16,913	$ —	$ 387,844	83	$ (3,135)	$ (3,055)	$ (47,765)	$ 358,740
Stock-based Compensation Expense	—	—	—	—	—	14,599	—	—	—	—	14,599
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	66	(1,959)	—	—	(1,959)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	52	—	1,458	—	—	—	—	1,458
Issuance of Restricted Stock Awards	—	—	—	748	—	—	—	—	—	—	—
Restricted Stock Awards Forfeitures	—	—	—	(69)	—	—	—	—	—	—	—
Dividends on Convertible Preferred Stock	—	—	—	—	—	—	—	—	—	(1,625)	(1,625)
Other comprehensive income	—	—	—	—	—	—	—	—	15,223	—	15,223
Net Loss	—	—	—	—	—	—	—	—	—	(47,896)	(47,896)
Balance, December 31, 2022	$ 24,850	25	$ 1	17,644	$ —	$ 403,901	149	$ (5,094)	$ 12,168	$ (97,286)	$ 338,540
Stock-based Compensation Expense	—	—	—	—	—	20,652	—	—	—	—	20,652
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	115	(4,987)	—	—	(4,987)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	227	—	8,996	—	—	—	—	8,996
Issuance of Restricted Stock Awards	—	—	—	674	—	—	—	—	—	—	—
Issuance of Performance Stock Units	—	—	—	85	—	—	—	—	—	—	—

Restricted Stock Awards and Performance Stock Units 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

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,		
	2023	2022	2021
Cash Flows From Operating Activities			
Net income (loss)	$ 18,779	$ (47,896)	$ (42,603)
Adjustments to reconcile net income (loss) to net cash and cash equivalents provided by (used in) operating activities:			
Stock-based compensation	20,652	14,599	10,489
Deferred taxes	(11,740)	(15,253)	(16,754)
Depreciation and amortization	59,791	59,653	47,252
Acquired in-process research and development ("IPR&D")	—	1,151	—
Non-cash operating lease expense	1,269	—	—
Non-cash interest	3,922	3,961	2,512
Contingent consideration fair value adjustment	1,426	4,058	500
Loss on extinguishment of debt	—	—	1,458
Asset impairment charges	—	574	2,374
Gain on sale of ANDAs	—	(750)	(1,822)
Changes in operating assets and liabilities, net of acquisition (2021):			
Accounts receivable, net	3,359	(36,912)	(5,548)
Inventories	(5,841)	(23,626)	3,224
Prepaid expenses and other current assets	(9,015)	(798)	127
Accounts payable	7,552	5,038	10,166
Accrued royalties	6,969	3,082	(267)
Current income taxes payable, net	11,991	(160)	(7,573)
Accrued government rebates	1,296	5,380	(3,078)
Returned goods reserve	(3,722)	(2,399)	6,503
Accrued expenses, accrued compensation, and other	12,271	(905)	(3,638)
Net Cash and Cash Equivalents Provided by (Used in) Operating Activities	118,959	(31,203)	3,322
Cash Flows From Investing Activities			
Acquisition of Novitium Pharma LLC, net of cash acquired	—	(33)	(84,494)
Acquisition of product rights, IPR&D, and other related assets	(9,643)	(7,579)	(21,081)
Acquisition of property and equipment, net	(8,868)	(8,876)	(2,557)
Proceeds from the sale of long-lived assets	—	750	2,649
Net Cash and Cash Equivalents Used in Investing Activities	(18,511)	(15,738)	(105,483)
Cash Flows From Financing Activities			
Proceeds from public offering, net of transaction expenses	80,555	—	69,584
Payments on contingent consideration	(12,500)	—	—
Payments on Term Loan and Delayed Draw Term Loan agreements	—	—	(10,862)
Payments on borrowings under credit agreements	(3,000)	(3,000)	—
Borrowings under Prior Revolver agreement	—	—	24,000
Repayment of Prior Credit Facility	—	—	(200,148)
Borrowings under the Credit Facility, net of issuance costs	—	—	286,032
Proceeds from issuance of convertible preferred stock	—	—	25,000
Series A convertible preferred stock dividends paid	(1,625)	(1,625)	(190)
Proceeds from stock option exercises and ESPP purchases	8,996	1,458	2,069
Treasury stock purchases for restricted stock vests	(4,987)	(1,959)	(890)
Net Cash and Cash Equivalents Provided by (Used in) Financing Activities	67,439	(5,126)	194,595
Net Change in Cash and Cash Equivalents	167,887	(52,067)	92,434
Cash and cash equivalents, beginning of year	53,234	105,301	12,867
Cash and cash equivalents, end of year	$ 221,121	$ 53,234	$ 105,301

	Year Ended December 31,		
	2023	2022	2021
Reconciliation of cash, cash equivalents, and restricted cash, beginning of year			
Cash and cash equivalents	48,228	100,300	7,864
Restricted cash	5,006	5,001	5,003
Cash, cash equivalents, and restricted cash, beginning of year	$ 53,234	$ 105,301	$ 12,867
Reconciliation of cash, cash equivalents, and restricted cash, end of year			
Cash and cash equivalents	221,121	48,228	100,300
Restricted cash	—	5,006	5,001
Cash, cash equivalents, and restricted cash, end of year	$ 221,121	$ 53,234	$ 105,301
Supplemental disclosure for cash flow information:			
Cash paid for interest, net of amounts capitalized	$ 31,431	$ 21,477	$ 9,705
Cash paid for income taxes	$ 1,228	$ 288	$ 10,371
Right-of-use assets obtained in exchange for lease obligations	$ 4,715	$ —	$ —
Supplemental non-cash investing and financing activities:			
Fair value of contingent consideration in a business combination	$ —	$ —	$ 30,500
Fair value of equity issued as consideration in a business combination	$ —	$ —	$ 91,199
Acquisition of product rights included in accounts payable	$ —	$ 1,000	$ —
Property and equipment purchased and included in accounts payable	$ 328	$ 452	$ 152

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 (together, "ANI," the "Company," "we," "us," or "our") is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceuticals, including for diseases with high unmet medical need. The team is focused on delivering growth by scaling up the Rare Disease business through the successful launch of its lead asset, Cortrophin Gel, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our North American manufacturing capabilities. The Company owns and operates three pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, and one is located in East Windsor, New Jersey, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. The Company has ceased operations at the Oakville, Ontario, manufacturing facility as of March 31, 2023. This action was part of ongoing initiatives to capture operational synergies following the acquisition of Novitium Pharma LLC ("Novitium") in November 2021. The Company has fully completed the transition of the products manufactured or packaged at Oakville to one of the three U.S.-based manufacturing sites. On November 6, 2023, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement for the sale of the Oakville, Ontario manufacturing facility, however, the agreement was subsequently terminated in December 2023 by mutual agreement. In February 2024, the Company entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of 19.2 million Canadian Dollars, or approximately $14.2 million US Dollars, based on the current exchange rate. The sale is expected to close in March 2024 (Note 19).

Basis of Presentation

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

Principles of Consolidation

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

Foreign Currency

The Company has ceased operations at our subsidiary in Oakville, Ontario, Canada as of March 31, 2023. The Company currently has a subsidiary located in India. The Canada-based subsidiary conducted its transactions in U.S. dollars and Canadian dollars, but its functional currency was the U.S. dollar. The Indian-based subsidiary generally conducts its transactions in Indian rupees, which is also its functional currency. The results of any non-U.S. dollar transactions and balances are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. The gain or loss on transactions denominated in foreign currencies and the translation impact of local currencies to U.S. dollars was immaterial for the years ended December 31, 2023, 2022, and 2021. 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, intercompany, and fixed assets, which are translated using historical rates. Net revenues and expense accounts are translated using an average exchange rate over the period ended on the balance sheet date. Adjustments resulting from the translation of the financial statements of the Company's foreign subsidiaries into U.S. dollars are accumulated as a separate component of shareholders' equity within accumulated other comprehensive income (loss), net of tax.

Use of Estimates

The preparation of the Company's financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. 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 potential adjustments, income tax expense or benefit, deferred taxes and valuation allowance, stock-based compensation, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, including contingent consideration in acquisitions, fair value of long-lived assets, determination of right-of-use assets and lease liabilities, allowance for credit losses, and the depreciable lives of long-lived assets. The Company bases its estimates on historical experience and other market-specific or other relevant assumptions that it believes to be reasonable under the circumstances. Actual results could differ from such estimates. Because of the uncertainties inherent in such estimates, actual results may differ from those estimates.

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, we record involuntary employee- related exit and disposal costs when there is a substantive plan for employee severance and related payments are probable and estimable. For one-time termination benefits, including those with a service requirement, expense is recorded when the employees are entitled to receive such benefits and the amount can be reasonably estimated. Expense related to one-time termination benefits with a service requirement is recorded over time, as the service is completed. Contract termination fees and penalties, and other exit and disposal costs are generally recorded as incurred. Restructuring activities are recognized as an operating expense in 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 we satisfy a performance obligation.

The Company derives its revenues primarily from sales of generic, rare disease, and established brand pharmaceutical products, royalties, and other pharmaceutical services. Revenue is recognized when obligations under the terms of contracts with customers are satisfied, which generally occurs when control of the products sold is transferred to the customer. Generally, the Company does not incur incremental costs to obtain contracts that would otherwise not have been incurred. The Company has not identified any agreements or arrangement that would qualify as a significant financing component.

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

Revenue from Distribution Agreements

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

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 maturities of less than three months, and money market accounts with 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. All interest bearing and non-interest bearing accounts 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.

Restricted cash at December 31, 2022, represented $5.0 million of funds held in a bank account owned by the Company to be used to pay for future milestones related to the purchase of the rights, title, and interest in the NDA for Inderal LA, as well as certain documentation, trademark rights, and finished goods from Cranford Pharmaceuticals, LLC in April 2016. This amount was was released from restricted cash during the first quarter of the year ended December 31, 2023.

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 credits losses are based on historical credit loss experience, review of the current aging or status of accounts receivable and current and forward-looking views from an economic and industry perspective. Receivables are written off when it is determined that amounts are uncollectible. The allowance for credit losses was immaterial as of December 31, 2023 and 2022.

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, 2023, 2022, and 2021.

Assets Held-for-Sale

The Company classifies assets held-for-sale if all held-for-sale criteria is met pursuant to ASC 360-10, *Property, Plant and Equipment*. Criteria include management commitment to sell the disposal group in its present condition and the sale being deemed probable of being completed within one year. Assets classified as held-for-sale are not depreciated and are measured at the lower of their carrying amount or fair value less cost to sell. The Company assesses the fair value of a disposal group, less any costs to sell, each reporting period it remains classified as held-for-sale and reports any subsequent changes as an adjustment to the carrying value of the disposal group, as long as the new carrying value does not exceed the initial carrying value of the disposal group. The Company determined that the Oakville, Ontario, Canada property met the held-for-sale criteria. As of December 31, 2023 and 2022, approximately $8.0 million of assets held for sale were recorded on the consolidated balance sheets. See Note 4 to the consolidated financial statements for additional information.

Leases

Operating lease right-of-use ("ROU") assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Rent expense is recognized on a straight-line basis over the lease term. Leases with an initial term of twelve months or less are not recorded on the consolidated balance sheet, and the Company does not separate lease and non-lease components of contracts. There are no material residual guarantees associated with any of the Company's leases, and there are no significant restrictions or covenants included in the Company's lease agreements. Operating lease ROU assets are included in other non-current assets and operating lease liabilities are included in accrued expenses and other and other non-current liabilities in the consolidated balance sheets. As of December 31, 2023 and 2022, the Company did not have any finance leases.

Intangible Assets

Intangible assets with definite lives are amortized based on their pattern of economic benefit over their estimated useful lives 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 ten 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, 2023, no impairment charges were recognized on intangible assets.. During the year ended December 31, 2022, the Company recognized a full impairment of a definite-lived ANDA asset with a remaining carrying value of $0.1 million. During the year ended December 31, 2021, the Company recognized an impairment charge of $2.4 million related to a definite-lived ANDA intangible asset. No events or circumstances arose in 2023, 2022, or 2021 that indicated that the carrying value of any of the other definite-lived intangible assets may not be recoverable.

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. No events or circumstances arose in 2023 that indicated that the carrying value of any of the indefinite-lived intangible assets may not be recoverable.

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, and Novitium. Goodwill is not amortized, but is subject to periodic review for impairment. The Company is organized in two operating segments, and two reporting units, and has determined that goodwill resides in one reporting unit, Generics, Established Brands, and Other.

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 Generics, Established Brands, and Other reporting unit is greater than its carrying value as of October 31, 2023 and 2022, and therefore no quantitative testing for impairment was required. No impairment loss related to goodwill was recognized in the years ended December 31, 2023, 2022, and 2021.

Collaborative Arrangements

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

Research and Development Expenses

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

Stock-Based Compensation

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

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

The Company also administers an Employee Stock Purchase Plan ("ESPP"). The estimated fair value of stock-based compensation awards are recognized and classified in the expense where the underlying salaries are classified.

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

Income Taxes

The Company uses the asset and liability method of accounting for income taxes. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that are expected to be in effect when the differences are expected to reverse. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in the period that such tax rate changes are enacted. The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized.

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

We use a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not to be sustained upon examination by taxing authorities. We have not identified any uncertain income tax positions that could have a material impact on the consolidated financial statements.

The Company has previously entered into an interest rate swap agreement (Note 6) designated as a cash flow hedge designed to manage exposure to changes in SOFR-interest rate underlying our variable rate debt. Due to the effective nature of the hedge, the initial fair value of the hedge and subsequent changes in the fair value of the hedge are recognized in other comprehensive income (loss) in the consolidated balance sheets. Income taxes are allocated to the hedge component of other comprehensive income (loss) based on appropriate intra-period tax allocations when those effects are deemed material.

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, 2023 for both accounting and tax purposes. The Company has elected hedge accounting for both U.S. GAAP and tax purposes. The Company maintains formal documentation through a periodic memo and accounting analysis that cover what is being hedged, how it is being hedged, hedge effectiveness, the nature of the risk being hedged, among other required analyses. Company policy further includes a quarterly probability analysis covering hedge effectiveness.

Contingent Consideration

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

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, 2023, 2022 due to their short term nature. See Note 10 for additional information regarding fair value.

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

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

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

Recent Accounting Pronouncements Adopted

In March 2020, the FASB issued ASU 2020-04, *Reference Rate Reform (Topic 848): Facilitation of the Effects of Reference Rate Reform on Financial Reporting*. This ASU provides optional expedients and exceptions, that may be elected over time as reference rate reform activities occur, for applying GAAP to contracts, hedging relationships and other transactions that reference the London Interbank Offered Rate ("LIBOR") or another reference rate expected to be discontinued because of reference rate reform. The guidance in this ASU was extended in December 2022 when the FASB issued ASU 2022-06, *Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848*, extending the sunset date under Topic 848 to December 31, 2024 to align the temporary accounting relief guidance with the expected LIBOR cessation.

In August 2023, the Company completed the transition of its debt and derivative instruments from LIBOR to Adjusted Term Secured Overnight Financing Rate ("SOFR") and applied the optional expedients in ASC 848 related to contract modifications and changing critical terms of the Company's hedging relationships. Application of these expedients allowed the Company to preserve presentation of derivatives as qualifying cash flow hedges and to account for the debt modification as a continuation of the existing contract. The adoption of this guidance did not have a material impact on the consolidated financial statements.

2. REVENUE RECOGNITION AND RELATED ALLOWANCES

Revenue Recognition

Revenues are primarily derived from sales of generic, rare disease, and established brand pharmaceutical products, royalties, and other pharmaceutical services. Revenue is recognized when obligations under the terms of contracts with customers are satisfied, which generally occurs when control of the products 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.

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

Products and Services	**Years Ended December 31,**		
(in thousands)	**2023**	**2022**	**2021**
Sales of generic pharmaceutical products	$ 269,449	$ 210,121	$ 143,571
Sales of established brand pharmaceutical products, royalties, and other pharmaceutical services	105,250	64,578	72,565
Sales of rare disease pharmaceutical products	112,117	41,686	—
Total net revenues	$ 486,816	$ 316,385	$ 216,136

Timing of Revenue Recognition	Years Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Performance obligations transferred at a point in time	$ 486,441	$ 313,436	$ 214,826
Performance obligations transferred over time	375	2,949	1,310
Total	$ 486,816	$ 316,385	$ 216,136

In the years ended December 31, 2023 or 2022, the Company did not incur, and therefore did not defer, any material incremental costs to obtain or fulfill contracts. As of December 31, 2023, there were no contract assets recorded which were related to revenue recognized based on percentage of completion but not yet billed.

The Company recognized an increase of $4.1 million of net revenue from performance obligations satisfied in prior periods during the year ended December 31, 2023, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. For the years ended December 31, 2023 and 2022, the Company recognized less than $0.1 million of revenue that was included in deferred revenue as of December 31, 2022 and 2021.

As of December 31, 2023, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $6.3 million, which consists of firm orders for contract manufactured products. We will recognize revenue for these performance obligations as they are satisfied, which is anticipated within six months.

Variable Consideration

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

Chargebacks

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

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

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

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

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

Government Rebates

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

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

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

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

Returns

A returns policy is in place that allows customers to return product within a specified period prior to and subsequent to the expiration date. Generally, product may be returned for a period beginning six months prior to its expiration date to up to one year after its expiration date. Product returns are settled through the issuance of a credit to the customer. The estimate for returns is based upon historical experience with actual returns. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future returns. We continually monitor 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.

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 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, 2023, 2022, and 2021:

	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, 2021 (1)	$ 94,066	$ 5,492	$ 35,831	$ 13,100	$ 4,642
Accruals/Adjustments	642,409	20,657	23,252	42,044	21,302
Credits Taken Against Reserve	(587,913)	(15,277)	(25,684)	(45,702)	(19,456)
Balance at December 31, 2022 (1)	$ 148,562	$ 10,872	$ 33,399	$ 9,442	$ 6,488
Accruals/Adjustments	586,511	23,915	18,360	55,798	22,932
Credits Taken Against Reserve	(650,865)	(22,619)	(22,081)	(53,828)	(24,555)
Balance at December 31, 2023 (1)	$ 84,208	$ 12,168	$ 29,678	$ 11,412	$ 4,865

(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

Customers are primarily wholesale distributors, chain drug stores, group purchasing organizations, and other pharmaceutical companies.

During the year ended December 31, 2023 four customers accounted for 10% or more of net revenues. During the years ended December 31, 2022 and 2021, three customers accounted for 10% or more of net revenues. As of December 31, 2023, accounts receivable from these customers totaled 81% of accounts receivable, net.

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

	Years Ended December 31,		
	2023	2022	2021
Customer 1	31 %	26 %	29 %
Customer 2	13 %	18 %	23 %
Customer 3	13 %	15 %	16 %
Customer 4	12 %	6 %	— %

3. BUSINESS COMBINATION

On November 19, 2021, the Company acquired all of the interests of Novitium pursuant to the terms of the Agreement and Plan of Merger, dated as of March 8, 2021. This acquisition was accounted for as a business combination.

The total consideration consisted of cash of approximately $88.1 million, 2,466,654 restricted shares of common stock valued at $91.2 million, and up to $46.5 million in additional contingent consideration. Additionally, the Company agreed to pay certain debts of Novitium in the amount of $8.5 million. The contingent consideration is based on the achievement of certain milestones, including milestones on gross profit of Novitium portfolio products over a 24-month period, regulatory filings completed during this 24-month period, and a percentage of net profits on certain products that are launched in the future. As of the acquisition date, the contingent consideration had a fair value of $30.8 million. Total consideration including cash, restricted shares and contingent consideration, net of cash acquired of $12.1 million was $206.5 million at the date of purchase.

The fair value of the contingent consideration was $24.0 million and $35.1 million as of December 31, 2023 and 2022, respectively. Refer to Note 10 for changes in contingent consideration and changes in fair value.

The cash consideration was funded in part by borrowings under the credit facility (Note 5) and through issuance of convertible preferred stock shares. Concurrently with the execution of the Merger Agreement, 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 (Note 11).

The acquisition of Novitium was completed due to its proven track record of being a research and development growth engine capable of fueling sustainable growth, to expand the research and development pipeline via niche opportunities, to enhance the contract development and manufacturing organization (“CDMO”) business and U.S. based manufacturing capacity, and to diversify the Company's revenue base.

The net assets were recorded at their estimated fair value. In valuing acquired assets and liabilities, fair value estimates were based primarily on future expected cash flows, market rate assumptions for contractual obligations, and appropriate discount rates. In connection with the acquisition, $46.9 million of indefinite-lived in-process research and development intangible assets, $67.4 million of acquired ANDA intangible assets, $24.9 million of customer relationship intangible assets, and goodwill of $24.6 million was recognized. Goodwill is considered an indefinite-lived asset and relates primarily to intangible assets that do not qualify for separate recognition, such as the assembled workforce and synergies between the entities. Goodwill established as a result of the acquisition is tax deductible in the U.S.

Novitium operations generated $149.9 million and $90.3 million of revenue during the years ended December 31, 2023 and 2022, respectively.

Transaction Costs

In conjunction with the acquisition, approximately $9.4 million in transaction costs were expensed during the year ended 2022 as selling, general, and administrative expense in the consolidated statement of operations.

Restricted Shares

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

Pro Forma Consolidated Financial Information (unaudited)

The following unaudited pro forma consolidated financial information summarizes the results of operations for the periods indicated as if the Novitium acquisition had been completed as of January 1, 2020.

	Year Ended December 31,
(in thousands)	**2021**
Net revenues	$ 272,888
Net loss	$ (31,740)

4. RESTRUCTURING

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

For the year ended December 31, 2023, restructuring activities resulted in expenses of $1.1 million. This included $0.2 million of severance and other employee benefit costs and $0.7 million of asset-related impairment and accelerated depreciation costs, and $0.2 million for other miscellaneous other costs. As of December 31, 2023, $0.1 million of the severance and other employee benefits are unpaid and accrued.

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

There were no restructuring expenses incurred for the year ended December 31, 2021.

These costs are 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, are being accrued over time as they are earned.

In conjunction with the exit of the Canadian facility, the Company has determined that the land and building at the Oakville, Ontario, Canada plant will be sold together and met the criteria to be classified as held for sale as of March 31, 2023. The land and building have a net carrying value of $8.0 million, which is presented as assets held for sale on the accompanying consolidated balance sheets as of December 31, 2023. These assets are part of the Generics, Established Brands, and Other segment.

On November 6, 2023, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement with a potential buyer for the sale of the Oakville, Ontario manufacturing facility, however, the agreement was subsequently terminated in December 2023 by mutual agreement. In February 2024, the Company entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of 19.2 million Canadian Dollars, or approximately $14.2 million US Dollars, based on the current exchange rate. The sale is expected to close in March 2024 (Note 19).

5. INDEBTEDNESS

Credit Facility

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

In July 2023, the Company amended its Credit Agreement to transition from LIBOR to SOFR due to the cessation of LIBOR pursuant to the terms of Amendment No.1 to the Credit Agreement ("Amendment No. 1"). SOFR will be applied to the Credit Facility for the interest period (as defined in the Credit Agreement) beginning on August 1, 2023 and replaced all LIBOR terms.

The Credit Facility permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the SOFR Rate (or alternate benchmark rate as defined in the Credit Agreement) in the case of SOFR loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the SOFR Rate (as defined in the Credit Facility) in the case of loans under the Revolving Facility. Amendment No. 1 also includes the addition of a credit spread adjustment of 0.11448% for an interest period of one-month duration, 0.26161% for a three-month duration, and 0.42826% for a six-month duration, in addition to SOFR and the applicable margin, as noted above. There were no other changes or modifications to the Credit Agreement. The Company has applied the optional expedients in ASC 848, *Reference Rate Reform*, and elected to treat the change in the benchmark interest rate to SOFR as a continuation of the existing Credit Agreement and account for the change prospectively.

The interest rate under the Term Facility was 11.46% at December 31, 2023.

As of December 31, 2023, there was $0 drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

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

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

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

	Current	
(in thousands)	**2023**	**2022**
Current borrowing on debt	$ 3,000	$ 3,000
Deferred financing costs	(2,150)	(2,150)
Current debt, net of deferred financing costs	$ 850	$ 850

	Non-Current	
(in thousands)	**2023**	**2022**
Non-current borrowing on debt	$ 291,000	$ 294,000
Deferred financing costs	(6,181)	(8,331)
Non-current debt, net of deferred financing costs and current component	$ 284,819	$ 285,669

As of December 31, 2023, outstanding principal was $294.0 million on the Term Facility. Of the $0.6 million of unamortized deferred debt issuance costs allocated to the Revolving Facility, $0.4 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 contractual maturity of the Term Facility is as follows for the years ending December 31:

(in thousands)	**Term Facility**
2024	$ 3,000
2025	3,000
2026	3,000
2027	285,000
Total	$ 294,000

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

(in thousands)	**2023**	**2022**	**2021**
Contractual coupon	$ 30,692	$ 26,150	$ 11,129
Amortization of finance fees	2,364	2,363	914
Capitalized interest	(587)	(95)	(98)
	$ 32,469	$ 28,418	$ 11,945

6. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

In April 2020, the Company entered into an interest rate swap with Citizens Bank, N.A. to manage exposure to changes in LIBOR-based interest rates (or alternate benchmark rate as defined in the Credit Agreement) underlying total borrowings under term facilities related to the Prior Credit Agreement. The interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Agreement with Truist Bank, the interest rate swap with a notional value of $168.6 million at origin on November 19, 2021 was novated and Truist Bank became the new counterparty.

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

The interest rate swap provides an effective fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. The notional amount of the interest rate swap was $139.4 million and $151.5 million as of December 31, 2023 and 2022, respectively, and decreased quarterly by approximately $4.0 million until December 2023, after which it remains static until maturity in December 2026. As of December 31, 2023, the fair value of the interest rate swap asset was recorded in other non-current assets in the consolidated balance sheets was $6.2 million. As of December 31, 2023, $8.9 million was recorded in accumulated other comprehensive income (loss) in the consolidated balance sheets.

During the year ended December 31, 2023, the change in fair value of the interest rate swaps was a loss of $3.7 million. During the year ended December 31, 2023, losses on the interest rate swap of $3.4 million were recorded in other comprehensive income (loss), net of tax. 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, 2023 and 2022, $2.6 million and $2.3 million, respectively, of interest expense was recognized in relation to the interest rate swaps. Included in these amounts for the years ended December 31, 2023 and 2022 are reclassifications out of accumulated other comprehensive income (loss) of $2.8 million in expense, related to terminated and de-designated cash flow hedges.

In conjunction with the amendment of the Credit Agreement (Note 5), the Company's derivative positions automatically transitioned to SOFR, the designated fallback terms, as determined by the International Swaps and Derivatives Association on August 1, 2023. Concurrently, the Company updated its hedge documentation to reflect the change of the benchmark index, which changed solely as a result of reference rate reform. Under ASC 848, Reference Rate Reform, hedge accounting may continue without de-designation if certain criteria are met. For cash flow hedges in which the designated hedged risk is LIBOR (or another rate that is expected to be discontinued), the guidance allows an entity to assert that it remains probable that the hedged forecasted transaction will occur. The Company applied the optional expedient within ASC 848 to conclude the updates to the hedge relationship due to reference rate reform did not have a material impact on the Company's consolidated financial statements.

7. INVENTORIES

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

(in thousands)	2023	2022
Raw materials	$ 62,237	$ 67,726
Packaging materials	9,617	7,720
Work-in-progress	3,144	1,889
Finished goods	36,198	28,020
Inventories	$ 111,196	$ 105,355

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, we are dependent upon current vendors to supply reliably the API required for on-going product manufacturing. During the year ended December 31, 2023, no single vendor represented at least 10% of inventory purchases. During the year ended December 31, 2022, the Company purchased approximately 19% of inventory from one supplier. During the year ended December 31, 2021, no single vendor represented at least 10% of inventory purchases.

8. 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)	2023	2022
Land	$ 1,549	$ 1,549
Buildings	17,875	16,659
Machinery, furniture, and equipment	50,412	53,146
Construction in progress	7,692	4,604
	77,528	75,958
Less: accumulated depreciation	(32,935)	(32,712)
Property and equipment, net	$ 44,593	$ 43,246

Depreciation expense for the years ended December 31, 2023, 2022, and 2021 totaled $7.5 million, $7.4 million, and $5.5 million, respectively. During the years ended December 31, 2023, 2022, and 2021 there was $0.6 million, $0.1 million, and $0.1 million, respectively, of interest capitalized into construction in progress, respectively.

9. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of the 2013 merger with BioSante Pharmaceuticals, Inc. ("BioSante"), the Company recorded goodwill of $1.8 million. As a result of the acquisition of WellSpring Pharma Services Inc., the Company recorded goodwill of $1.7 million in 2018. From the acquisition of Novitium in 2021, the Company recorded goodwill of $24.6 million. As of December 31, 2023, the Company had two operating segments, which were also deemed the Company's two reporting units, Generics, Established Brands, and Other reporting unit and the Rare Disease reporting unit. All of the goodwill is recorded in the Generics, Established Brands, and Other reporting unit.reporting unit.

Goodwill is reviewed for impairment at least annually, at October 31st, or more frequently if a triggering event occurs between impairment testing dates. The Company's impairment assessment begins with a qualitative assessment to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying value. Qualitative factors may include, macroeconomic conditions, industry and market considerations, cost factors, and other relevant entity and Company specific events. If, based on the qualitative test, the Company determines that it is "more likely than not" that the fair value of a reporting unit is less than its carrying value, then we evaluate goodwill for impairment by comparing the fair value of the reporting unit to its respective carrying value, including its goodwill. If it is determined that it is "not likely" that the fair value of the reporting unit is less than its carrying value, then no further testing is required.

Based on the qualitative assessments performed by the Company, it was determined that it was more likely than not that the fair value of the Generics, Established Brands, and Other reporting unit was greater than its carrying value as of October 31, 2023, and therefore no impairment charges have been recognized, and no quantitative testing was required.

In addition to the qualitative impairment analysis performed at October 31, 2023, 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, 2023 to December 31, 2023. No impairment loss was recognized during the years ended December 31, 2023, 2022, and 2021, and the balance of goodwill was $28.2 million as of December 31, 2023 and 2022.

Intangible Assets

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

(in thousands)	December 31, 2023			December 31, 2022			Weighted Average Amortization Period(1)
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	
Definite-Lived Intangible Assets:							
Acquired ANDA intangible assets	$ 209,780	$ (100,660)	$ 109,120	$ 195,862	$ (75,606)	$ 120,256	5.2 years
NDAs and product rights	244,871	(184,861)	60,010	242,372	(162,188)	80,184	3.1 years
Marketing and distribution rights	17,157	(14,271)	2,886	17,157	(13,309)	3,848	3.0 years
Non-compete agreement	624	(624)	—	624	(602)	22	- years
Customer relationships	24,900	(7,707)	17,193	24,900	(4,150)	20,750	4.8 years
Total Definite-Lived Intangible Assets	497,332	(308,123)	189,209	480,915	(255,855)	225,060	4.5 years
Indefinite-Lived Intangible Assets:							
In process research and development	19,800	—	19,800	26,575	—	26,575	Indefinite
Total Intangible Assets, net	$ 517,132	$ (308,123)	$ 209,009	$ 507,490	$ (255,855)	$ 251,635	

(1) Weighted average amortization period as of December 31, 2023.

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

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

During 2023, definite-lived intangibles increased approximately $16.4 million, which includes $6.8 million which was reclassified from indefinite-lived IPR&D to acquired ANDA intangible assets upon completion of projects and launch of related products, and the Company added approximately $9.6 million of intangible assets, comprised of $7.1 million of ANDA intangible assets related to asset acquisitions with Slayback Pharma Limited Liability Company and Akorn Holding Company, $2.0 million in product rights related to the transaction with Alvogen, Inc., and other asset acquisitions.

During 2022, approximately $20.3 million was reclassified from indefinite-lived IPR&D to acquired ANDA intangible assets upon completion of projects and launch of related products. The Company added $7.2 million in ANDA intangible assets related to the July 21, 2022 transaction with Oakrum Pharma, LLC (Note 10). These assets will be amortized over a seven-year useful life.

Amortization expense for definite-lived intangible assets was $52.3 million, $49.5 million, and $41.8 million for the years ended December 31, 2023, 2022, and 2021, respectively. Refer to Note 10 for more details on acquired definite-lived and indefinite-lived intangible assets.

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

(in thousands)		
2024	$	50,364
2025		47,128
2026		33,643
2027		24,677
2028		17,895
2029 and thereafter		15,502
Total	$	189,209

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

Indefinite-lived intangible assets are not amortized, and the Company tests for impairment of indefinite-lived intangible assets and definite-lived intangibles when events or circumstances indicate that the carrying value of the assets may not be recoverable, and the Company performs an asset impairment analysis annually, as of October 31, 2023. 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.

Based on the assessments of the aforementioned factors, it was determined that it was more likely than not that the fair value of assets are greater than their carrying amount as of October 31, 2023, and therefore no quantitative testing for impairment was required.

In addition to the qualitative impairment analysis performed at October 31, 2023, there were no events or changes in circumstances that would have reduced the fair value of the indefinite or definite-lived intangible assets below their carrying values from October 31, 2023 to December 31, 2023. No impairment loss was recognized during the year ended December 31, 2023. During the years ended December 31, 2022 and 2021, impairment losses of approximately $0.1 million and $2.4 million, respectively, were recognized in relation to ANDA assets.

10. 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 which 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 funds. The Term Facility bears an interest rate that fluctuates with the changes in SOFR and, because the variable interest rates approximate market borrowing rates available to the Company, the carrying values of these borrowings approximated their fair values at December 31, 2023 and 2022.

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

Money Market Funds

Money market funds are readily convertible into cash and the net asset value of each fund on the last day of the reporting period is used to determine its fair value. Money market funds are included in Cash and cash equivalents within the Consolidated Balance Sheet, and is classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. The Company does not adjust the quoted market price for such financial instruments. The fair value of the money market funds as of December 31, 2023 was approximately $191.8 million.

Interest Rate Swap

The fair value of the interest rate swap is estimated based on the present value of projected future cash flows using the SOFR forward rate curve. The model used to value the interest rate swap includes inputs of readily observable market data, a Level 2 input. As described in detail in Note 5, the fair value of the interest rate swap was a $6.2 million and $8.8 million at December 31, 2023 and 2022, respectively, and was classified as a non-current asset.

Contingent Consideration

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

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

Pursuant to the terms of the Agreement and Plan of Merger, dated as of March 8, 2021, on December 12, 2023, the Company paid $12.5 million of cash consideration to the Company Members, defined as the holders of Novitium ownership interests in the Agreement and Plan of Merger, as the holders of Novitium ownership interests, for the achievement of the "ANDA Filing Earn-Out," as defined in the Agreement (Note 17). Furthermore, on February 22, 2024, the Company paid $12.5 million to Company Members of Novitium upon the achievement of the "Gross Profit Earn-Out," as defined in the Agreement (Note 19).

The fair value of the contingent consideration was approximately $24.0 million and $35.1 million as of December 31, 2023 and 2022, 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:

Payment Type	Valuation Technique	Unobservable Input	Assumptions
Profit-based milestone payments	Probability-weighted discounted cash flow	Discount rate	12%
		Projected fiscal year of payment	2025-2035
Product development-based milestone payments	Probability-weighted discounted cash flow	Discount rate	12.0%
		Probability of payment	100%
		Projected fiscal year of payment	2024

The following table presents the changes in contingent consideration balances classified as Level 3 balances for the years ended December 31, 2023 and 2022:

	Years Ended December 31,	
(in thousands)	**2023**	**2022**
Beginning balance	$ 35,058	$ 31,000
Measurement period adjustment	—	300
Payment of ANDA filing earn-out	(12,500)	—
Change in fair value	1,426	3,758
Ending balance	$ 23,984	$ 35,058

Contingent Value Rights

The contingent value rights ("CVRs"), which were granted coincident with the merger with BioSante expired during June 2023, were considered contingent consideration and were classified as liabilities, and there were no payments made pursuant to the terms of the CVR agreement. The Company determined that the fair value of the CVRs was immaterial as of December 31, 2022, and also determined that the changes in such fair value were immaterial for the years ended December 31, 2022, and 2021.

The following table presents financial assets and liabilities accounted for at fair value on a recurring basis as of December 31, 2023 and December 31, 2022, by level within the fair value hierarchy:

(in thousands) **Description**	**Fair Value at December 31, 2023**	**Level 1**	**Level 2**	**Level 3**
Assets				
Money Market Fund	$ 191,841	$ 191,841	$ —	$ —
Interest rate swap	$ 6,236	$ —	$ 6,236	$ —
Liabilities				
Contingent consideration	$ 23,984	$ —	$ —	$ 23,984

Description	**Fair Value at December 31, 2022**	**Level 1**	**Level 2**	**Level 3**
Assets				
Interest rate swaps	$ 8,759	$ —	$ 8,759	$ —
Liabilities				
Contingent consideration	$ 35,058	$ —	$ —	$ 35,058

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 year ended December 31, 2023, there were no impairment charges recognized related to non-financial assets and liabilities measured at fair value on a non-recurring basis. During the year ended December 31, 2022, the Company recognized an impairment charge of $0.1 million related to a definite-lived ANDA intangible asset. There were no other fair value impairments recognized in the years ended December 31, 2023 and 2022.

Acquired Non-Financial Assets Measured at Fair Value

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

August 14, 2023, the Company acquired one ANDA and registered patents and pending patent applications from Slayback Pharma Limited Liability Company for total consideration of $3.0 million (Note 9). The Company also acquired an NDA which has yet to be filed. The transaction was funded from cash on hand. The transaction was accounted for as an asset acquisition and the transaction costs directly related to the acquisition were capitalized. Intangible assets amounted to $2.8 million as acquired ANDA intangible assets. The payment was allocated to the acquired intangible assets based on relative fair value, which was determined using Level 3 unobservable inputs. The ANDA will be amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2023, and therefore no impairment loss was recognized for the year ended December 31, 2023.

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

On July 21, 2022, we acquired four ANDAs from Oakrum Pharma, LLC for total consideration of $8.0 million plus an immaterial amount for the purchase of finished goods inventory. The transaction was funded from cash on hand. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. The product portfolio included one commercial product, one approved product with a launch completed in September and two filed products, with approval pending. We recognized $7.2 million as acquired ANDA intangible assets and $1.2 million as research and development expense because certain of the generic products have significant remaining work required in order to be commercialized and the products do not have an alternative future use. The payment was allocated to the acquired intangible assets and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. We used the present value of the estimated cash flows related to the products, using a discount rate of 13% to determine the fair value of the acquired intangible assets and in-process research and development. The inventory acquired was immaterial. Contingent liabilities are accrued when they are both estimable and probable. We accrued $0.2 million in contingent payments due to a third party upon the launch of a product completed in September. This was accrued and recorded in the fair value of acquired intangible assets as it was probable at the acquisition date and has been paid in 2022. The ANDAs will be amortized in full over its useful life of seven years and will be tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2023, and therefore no impairment loss was recognized for the year ended December 31, 2023.

In April 2021, we acquired three NDAs and an ANDA and certain related inventories from Sandoz, Inc. for total consideration of $20.7 million. We also incurred and paid $0.4 million in transaction costs directly related to the acquisition. The acquisition was funded via borrowings under our Revolver. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $11.4 million as acquired intangible assets and $9.7 million of inventory at fair value, including $0.6 million of API, $1.0 million of sample inventory, and $8.1 million in finished goods inventory. In order to determine the fair value of the intangible assets, we used the present value of the estimated cash flows related to the product rights using a discount rate of 10%, which are level 3 unobservable inputs. The fair value of the inventory was determined based on the estimated selling price to be generated from the finished goods, less costs to sell, including a reasonable margin, which are level 3 unobservable inputs. The intangible assets are being amortized in full over a useful life of seven years and are tested for impairment when events or circumstances indicate that the carrying value of the asset may not be recoverable. No such triggering events were identified during the period from the date of acquisition to December 31, 2023 and therefore no impairment loss was recognized for the years ended December 31, 2022 and 2023.

11. MEZZANINE AND STOCKHOLDERS' EQUITY

Stockholders' Equity

Authorized shares

The Company is authorized to issue up to 33.3 million shares of common stock with a par value of $0.0001 per share, 0.8 million shares of class C special stock with a par value of $0.0001 per share, and 1.7 million shares of undesignated preferred stock with a par value of $0.0001 per share at December 31, 2023 and 2022.

There were 20.7 million and 20.5 million shares of common stock issued and outstanding as of December 31, 2023, respectively, and 17.6 million and 17.5 million shares of common stock issued and outstanding as of December 31, 2022, 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.

During 2021, the Company issued 1.5 million shares related to a public offering of the Company's common stock and 2.5 million shares as consideration for the acquisition of Novitium.

Class C Special Stock

There were 11 thousand shares of class C special stock issued and outstanding as of December 31, 2023 and 2022. 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

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

The PIPE Shares accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and will also participate, on a pro-rata basis, in any dividends that may be declared with respect to the Company's common stock. The PIPE Shares are convertible into the Company's common shares at the conversion price of $41.47 (i) beginning two years years after their issuance date, at the election of ANI (in which case the PIPE Investor must convert all of the PIPE Shares), if the volume-weighted average price of the Company's common stock for any 20 trading days out of 30 consecutive trading days exceeds 170% of the conversion price, and (ii) at any time after issuance, at the election of the PIPE Investor. As of December 31, 2023, the PIPE shares are currently convertible into a maximum of 602,901 shares of the Company's common stock.

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

There were 25,000 shares of Series A convertible preferred stock outstanding as of December 31, 2023 and 2022.

12. EARNINGS (LOSS) PER SHARE

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

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

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

Earnings (loss) per share for the years ended December 31, 2023, 2022, and 2021 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,		
	2023	2022	2021	2023	2022	2021
Net income (loss) available to common shareholders	$ 17,154	$ (49,521)	$ (42,793)	$ 17,154	$ (49,521)	$ (42,793)
Earnings allocated to participating securities	(1,679)	—	—	(1,663)	—	—
Net income (loss) available to common shareholders	$ 15,475	$ (49,521)	$ (42,793)	$ 15,491	$ (49,521)	$ (42,793)
Basic Weighted-Average Shares Outstanding	18,001	16,260	12,596	18,001	16,260	12,596
Dilutive effect of stock options, ESPP, and performance stock units				193	—	—
Diluted Weighted-Average Shares Outstanding				18,194	16,260	12,596
Earnings (loss) per share	$ 0.86	$ (3.05)	$ (3.40)	$ 0.85	$ (3.05)	$ (3.40)

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, were 2.4 million, 2.6 million, and 1.7 million for the years ended December 31, 2023, 2022, and 2021, respectively. For the years ended December 31, 2022 and 2021, all potentially dilutive shares were anti-dilutive and excluded from the calculation of diluted loss per share because the Company reported a net loss.

13. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, the Company commenced administration of the ANI Pharmaceuticals, Inc. 2016 ESPP. As of December 31, 2023 there are 0.1 million shares of common stock available for issuance under the ESPP. Under the ESPP, participants can purchase shares of common stock at a 15% discount. The Company issued 38 thousand, 29 thousand, and 14 thousand shares in the years ended December 31, 2023, 2022, and 2021, respectively.

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

(in thousands)	Years Ended December 31,		
	2023	2022	2021
Selling, general, and administrative	$ 360	$ 222	$ 87
Cost of sales	60	50	15
Research and development	47	41	21
	$ 467	$ 313	$ 123

Stock Incentive Plan

Equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan (the "2022 Plan"), which was approved by the Company's stockholders at the 2022 Annual Meeting of Stockholders (the "Annual Meeting") held on April 27, 2022. Prior to this approval, the Company granted equity-based incentive awards under the Sixth Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"), which was renamed, amended and restated to the 2022 Plan. The 2022 Plan, among other things, increased the number of shares reserved for issuance thereunder by 1,150,000 shares. As of December 31, 2023, 1.1 million shares of common stock were available for issuance under the 2022 Plan. On May 23, 2023, the Company's stockholders approved an amendment to the 2022 Plan (such amendment, the "2023 Stock Plan Amendment"). Subject to adjustment, the 2023 Stock Plan Amendment increased the number of shares reserved for issuance under the 2022 Plan by 750,000 shares.

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

The cost of equity-based service awards are measured based on the grant-date fair value of the award. The cost is recognized ratably over the period during which an employee is required to provide service in exchange for the award or the requisite service period. Stock-based compensation expense is recognized ratably over the vesting periods of the awards.

The following table summarizes stock-based compensation expense incurred for stock options, restricted stock awards, performance-based restricted stock units, and Inducement Grants and included in the consolidated statements of operations:

(in thousands)	Years Ended December 31,		
	2023	2022	2021
Selling, general, and administrative	$ 18,676	$ 13,094	$ 9,818
Research and development	863	710	543
Cost of sales	646	482	5
	$ 20,185	$ 14,286	$ 10,366

Income tax benefits of approximately $3.3 million, $1.7 million, and $1.0 million were recognized for stock-based compensation-related tax deductions in the 2023, 2022, and 2021 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.

For 2023, 2022, and 2021, the fair value of each option grant was estimated using the Black-Scholes option-pricing model, using the following assumptions:

	Years Ended December 31,		
	2023	**2022**	**2021**
Expected option life (years)	6.25	5.50 - 6.25	5.50 - 6.25
Risk-free interest rate	4.1%	1.71% - 2.83%	0.68% - 1.39%
Expected stock price volatility	49.0%	48.4% - 50.0%	48.2% - 49.5%
Dividend yield	—	—	—

The Company uses the simplified method to estimate the expected option life of options. The risk-free interest rate used is the yield on a U.S. Treasury note as of the grant date with a maturity equal to the estimated life of the option. The calculated estimated volatility rate is based on ANI's historical stock price. The Company has not issued a cash dividend on the common shares in the past nor does the Company have any current plans to do so in the future; therefore, an expected dividend yield of zero was used.

A summary of stock option activity under the 2022 Plan and Inducement Grants during the years ended December 31, 2023, 2022, and 2021 is presented below:

(in thousands, except per share and remaining term data)	Option Shares	Weighted Average Exercise Price	Fair Value	Weighted Average Remaining Term (years)	Aggregate Intrinsic Value
Outstanding December 31, 2020	936	$ 48.44		7.1	$ 372
Granted	168	33.09	$ 15.71		
Exercised	(42)	40.25			552
Forfeited	(19)	59.84			
Expired	(55)	55.59			
Outstanding December 31, 2021	988	$ 45.56		6.6	$ 6,786
Granted	36	34.52	$ 16.82		
Exercised	(23)	30.03			153
Forfeited	(47)	36.91			
Expired	(47)	55.07			
Outstanding 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
Exercisable at December 31, 2023	580	$ 48.75		4.5	$ 5,815

As of December 31, 2023, there was $1.6 million of total unrecognized compensation cost related to non-vested stock options granted under the 2022 Plan and Inducement Grant. The cost is expected to be recognized over a weighted-average period of 1.1 years. During the year ended December 31, 2023, ANI received $8.3 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, 2022, ANI received $0.7 million in cash from the exercise of stock options and recorded a $0.1 million tax provision related to these exercises. During the year ended December 31, 2021, ANI received $1.7 million in cash from the exercise of stock options and recorded a $0.1 million tax provision related to these exercises.

Restricted Stock Awards

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

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

A summary of RSA activity under the Plan during the years ended December 31, 2023, 2022, and 2021 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, 2020	352	$ 48.14	2.7
Granted	541	33.02	
Vested	(125)	48.32	
Forfeited	(61)	48.16	
Unvested at December 31, 2021	707	$ 36.52	2.8
Granted	748	32.76	
Vested	(245)	36.99	
Forfeited	(69)	38.08	
Unvested at December 31, 2022	1,141	$ 33.86	2.6
Granted	674	43.30	
Vested	(383)	34.59	
Forfeited	(81)	38.10	
Unvested at December 31, 2023	1,351	$ 38.11	2.4

As of December 31, 2023, there was $41.5 million of total unrecognized compensation cost related to non-vested RSAs granted under the Plan, which is expected to be recognized over a weighted-average period of 2.4 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. On February 28, 2023, as part of the Company's equity compensation program, PSUs were granted to certain executives. Of these PSUs, 50% were market performance-based restricted stock units (“MPRSUs”), vesting of which is contingent upon the Company meeting certain total shareholder return (“TSR”) levels as compared to a select peer group over the over three years starting January 1, 2023. The MPRSUs are also subject to the recipient’s continued employment or service through December 31, 2025. The MPRSUs cliff vest at the end of the three-year period and have a maximum potential to vest at 200% (85,099 shares) based on TSR performance. The related share-based compensation expense is determined based on the estimated fair value of the underlying shares on the date of grant and is recognized straight-line over the vesting term. The estimated grant date fair value per share of the MPRSUs was $68.65 and was calculated using a Monte Carlo simulation model. These MPRSUs are included at 100% of the estimate number of shares at the end of the three-year performance period and are reflected under “Granted” in the table below.

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

A summary of PSU activity under the Plan during the years ended December 31, 2023 and 2022 is presented below:

(in thousands, except per share and remaining term data)	Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Term (years)
Unvested at December 31, 2022	—	$ —	—
Granted	85	41.84	
Vested	—	—	
Forfeited	(1)	41.84	
Unvested at December 31, 2023	84	$ 41.84	2.0

As of December 31, 2023, there was $2.5 million of total unrecognized compensation cost related to non-vested PSUs granted under the Plan, which is expected to be recognized over a weighted-average period of 2.0 years.

14. INCOME TAXES

On August 6, 2018, ANI Pharmaceuticals Canada Inc. (“ANI Canada”) acquired all the issued and outstanding equity interests of WellSpring in a non-taxable transaction. Following the consummation of the transaction, WellSpring was merged into ANI Canada. For U.S. Federal and state income tax purposes, ANI Canada is not part of ANI’s consolidated group; rather, ANI Canada is subject to income taxes only in Canada and solely based on its stand-alone operations. The foreign current and foreign deferred provisions (benefits) below represent the Company's tax provision (benefit) from the Canadian and Indian taxing jurisdictions.

The Company is required to establish a valuation allowance is required to be established for deferred tax assets if, based on the weight of 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. Projected future taxable income and tax planning strategies in making this assessment.

As of December 31, 2023 and 2022, the consolidated valuation allowance was $0.4 million and $0.4 million, respectively, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

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

(in thousands)	2023	2022	2021
Current income tax provision			
Federal	$ 9,117	$ 152	$ 1,296
State	3,534	249	1,320
Foreign	26	66	691
Total	12,677	467	3,307
Deferred income tax benefit			
Federal	(7,601)	(13,382)	(12,163)
State	(3,946)	(1,722)	(5,122)
Foreign	(29)	(128)	336
Total	(11,576)	(15,232)	(16,949)
Change in valuation allowance	(8)	(4)	187
Total expense (benefit) for income taxes	$ 1,093	$ (14,769)	$ (13,455)

The difference between expected income tax expense (benefit) from applying U.S. Federal statutory tax rates to the pre-tax income (loss) and actual income tax expense (benefit) relates primarily to the effect of the following:

	As of December 31,		
	2023	2022	2021
US Federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes, net of Federal benefit	4.8 %	3.2 %	3.3 %
Foreign taxes	0.0%	0.1 %	(1.0)%
Change in valuation allowance	0.0%	— %	(0.3)%
Stock-based compensation	10.8 %	(1.4)%	(1.7)%
Non-deductible costs	2.1 %	(0.5)%	(0.8)%
Change in state apportionment factors, state and foreign rates	(11.8)%	(0.1)%	5.5 %
Research and experimentation and charitable credits	(19.0)%	1.4 %	0.9 %
Transfer pricing and other	(2.4)%	(0.1)%	(2.9)%
Effective income tax rate	5.5 %	23.6 %	24.0 %

Deferred income taxes reflect the net tax effects of differences between the bases of assets and liabilities for financial reporting and income tax purposes. Deferred income tax assets and liabilities consisted of the following:

	As of December 31,	
(in thousands)	2023	2022
Deferred tax assets:		
Accruals and advances	$ 12,470	$ 9,233
Stock-based compensation	6,013	6,041
Accruals for chargebacks and returns	17,358	15,344
Inventories	4,569	5,292
Intangible assets	40,193	33,431
Net operating loss carryforwards	2,900	5,994
Capitalized research expenditures	11,294	4,708
Other	7,450	11,840
Total deferred tax assets	$ 102,247	$ 91,883
Deferred tax liabilities:		
Depreciation	$ (5,658)	$ (5,776)
Other liabilities	(5,440)	(4,298)
Total deferred tax liabilities	$ (11,098)	$ (10,074)
Valuation allowance	(438)	(446)
Deferred tax assets, net of deferred tax liabilities and valuation allowance	$ 90,711	$ 81,363

As of December 31, 2023, U.S. federal net operating loss carryforwards were approximately $8.0 million, all of which arose as a result of the 2013 merger with BioSante Pharmaceuticals, Inc. Net operating loss carryforwards related to the 2013 merger, if not used, expire in annual increments through 2033 and are limited on an annual basis as prescribed by Section 382 of the U.S. Internal Revenue Code; and the current annual limitation is approximately $0.8 million per year. Additionally, as of December 31, 2023, there were total net operating losses in various states of approximately $13.0 million which begin to expire through 2042, and in Canada of $1.0 million that expire through 2038.

The Company is subject to income taxes in numerous jurisdictions in the U.S., Canada, and India. Significant judgment is required in evaluating the tax positions and determining the provision for income taxes. Liabilities are established for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These liabilities are established when it is believed that certain positions might be challenged despite the belief that our tax return positions are fully supportable. These liabilities are adjusted in light of changing facts and circumstances, such as the outcome of a tax audit. The provision for income taxes includes the impact of changes to the liability that is considered appropriate. There were no material uncertain income tax positions identified as of December 31, 2023 and 2022.

The Company is subject to income tax audits in all jurisdictions for which tax returns are filed. Tax audits by their nature are often complex and can require several years to complete. All of the Company's income tax returns remain subject to examination by tax authorities due to the availability of net operating loss carryforwards.

15. COMMITMENTS AND CONTINGENCIES

Operating Leases

All existing leases as of December 31, 2023 are classified as operating leases. As of December 31, 2023, there are 14 operating leases for facilities and office equipment with remaining terms expiring from 2025 through 2028 and a weighted average remaining lease terms of 3.9 years and 2.6 years, as of December 31, 2023 and 2022, respectively. During April 2023, the Company entered into a lease agreement for additional warehouse space in East Windsor, New Jersey. Additionally, during October 2023, the Company entered into an amendment for the Middleton, Wisconsin location which expanded the Company's square footage and also extended the termination date to December 2028. 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.

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. The weighted average incremental borrowing rates as of December 31, 2023 and 2022 is 8.12% and 3.99%, respectively.

The Company’s lease agreements do not contain any material residual value guarantees or material restrictive covenants. In addition, the Company does not have any finance leases, any sublease arrangements, or any leases where the Company is considered the lessor.

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

(in thousands)	2023	2022	2021
Operating lease costs	$ 2,031	$ 701	$ 240
Variable lease costs	221	236	48
Total lease costs	$ 2,252	$ 937	$ 288

The table below reconciles the fixed component of the undiscounted cash flows for each of the first five years and the total remaining years to the lease liabilities recorded on the Consolidated Balance Sheet as of December 31, 2023:

(in thousands)		
2024	$	1,967
2025		1,610
2026		1,290
2027		1,289
2028		506
Thereafter		—
Total minimum lease payments		6,662
Less: effects of discounting		(990)
Present value of future minimum lease payments		5,672
Less: current lease liability, included in accrued expenses and other		(1,561)
Non-current lease liability, included in other non-current liabilities	$	4,111

Government Regulation

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

Unapproved Products

Three products, Esterified Estrogen with Methyltestosterone (“EEMT”), Opium Tincture, Thyroid Tablets, and are marketed without approved NDAs or ANDAs. During the years ended December 31, 2023, 2022, and 2021, net revenues for Esterified Estrogen with Methyltestosterone (“EEMT”), Opium Tincture and Thyroid Tablets products totaled $22.4 million, $14.2 million, and $16.2 million, respectively. The Company obtained the rights to Hyoscyamine, a product without an approved NDA as of December 27, 2023, which we plan to launch commercially in early 2024 (see further discussion below).

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

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

One group of products that the Company manufactured on behalf of a contract customer, Hyoscyamine, was marketed by that customer without an approved NDA. Contract manufacturing revenues for Hyoscyamine, for the years ended December 31, 2023, 2022, and 2021 were $1.9 million, $2.6 million, and $2.4 million, respectively. On December 27, 2023 the Company purchased the intellectual property and product rights to Hyoscamine from Alvogen, Inc. (Note 10).

Legal proceedings

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

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

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

Furthermore, like many pharmaceutical manufacturers, we are periodically exposed to product liability claims. The prevalence of these claims could limit our coverage under future insurance policies or cause those policies to become more expensive, which could harm our business, financial condition, and operating results. Recent trends in the product liability and director and officer insurance markets is to exclude matters related to certain classes of drugs. Our policies have been subject to such exclusions which place further potential risk of financial loss on us.

Legal fees for litigation-related matters are expensed as incurred and included in the consolidated statements of operations under the selling, general, and administrative expense line item.

Commercial Litigation

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

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

On April 1, 2021, United Therapeutics Corp. and Supernus Pharmaceuticals, Inc. ("UTC/Supernus") filed a complaint in the United States District Court for the District of Delaware against ANI, asserting that ANI's proposed Treprostinil extended release drug product, which is subject to ANI's Abbreviated New Drug Application No. 215667, infringes U.S. Patent Nos. 7,417,070, 7,544,713, 8,252,839, 8,349,892, 8,410,169, 8,747,897, 9,050,311, 9,278,901, 9,393,203, 9,422,223, 9,593,066 and 9,604,901 ("the Asserted Patents"). The complaint sought injunctive relief, attorneys' fee and costs. On May 26, 2022, the parties' respective claims and counterclaims were dismissed pursuant to a confidential settlement agreement.

On October 3, 2022, Azurity filed a complaint in the United States District Court for the District of New Jersey against Novitium, seeking a declaratory judgment that Novitium's manufacture, use, sale, importation and/or offer to sell Bionpharma Inc.'s ("Bionpharma") enalapril maleate oral solution drug product (the "Product") would infringe U.S. Patents Nos. 11,040,023 and 11,141,405 (the "Novitium Action"). The complaint sought injunctive relief, and an award of Azurity's costs and expenses. On October 12, 2022, Bionpharma filed a motion in the New Jersey court to intervene on Novitium's behalf in the litigation and on October 14, 2022, Novitium and Bionpharma jointly moved to transfer venue to the District of Delaware. Transfer was granted on January 20, 2023. On March 27, 2023, the transferred Novitium Action (assigned Delaware Civil Action No. 23-163-MSG) was consolidated with the Delaware Third Wave Suits against Bionpharma (Civil Action Nos. 21-1286-MSG, 21-1455-MSG), which include Azurity's infringement claims against Bionpharma involving the same patents asserted in the Novitium Action, as well as Bionpharma's antitrust claims against Azurity. On August 3, 2023, Azurity filed an amended complaint against Novitium seeking damages for supplying Bionpharma's ANDA product. On November 14, 2023, the court dismissed all of Azurity's claims against Novitium with prejudice and dismissed Novitium as a party from the Delaware Third Wave Suits. Bionpharma has agreed to indemnify Novitium under the terms of its manufacturing and supply agreement for any damages, costs, and expenses relating to actual or alleged infringement of intellectual property rights or sale of the Product by Bionpharma.

On September 29, 2023, Orphalan SA ("Orphalan") filed a complaint in the United States District Court for the District of Delaware against Novitium, asserting that Novitium's proposed triethylenetetramine tetrachloride drug product, which is subject to Novitium's Abbreviated New Drug Application No. 218493, infringes U.S. Patent Nos. 10,988,436 and 11,072,577. The complaint seeks damages, injunctive relief, attorneys' fees and costs. On December 1, 2023, Orphalan voluntarily dismissed the action without prejudice. Novitium disputes any liability in this matter.

On November 21, 2023, Harmony Biosciences, LLC, Bioprojet Societe Civile de Recherche and Bioprojet Pharma SAS filed a compliant in the United States District Court for the District of Delaware against Novitium and certain other defendants named in the complaint, asserting, among other things, that Novitium's proposed pitolisant hydrochloride drug product, which is subject to Novitium's Abbreviated New Drug Application No. 218495, infringes U.S. Patent Nos 8,207,197, 8,354,430 and 8,486,947. The complaint seeks damages, injunctive relief, attorneys' fees and costs. Novitium disputes any liability in this matter.

Ranitidine Related Litigation

State of New Mexico Litigation. In July 2020, ANI and Novitium were served with a complaint brought in the First Judicial Court, County of Santa Fe, State of New Mexico by the Office of the Attorney General of the State of New Mexico against manufacturers and sellers of ranitidine products. The complaint asserted a public nuisance claim and a negligence claim against the generic ranitidine manufacturer defendants, including ANI and Novitium. As damages for the nuisance claim, New Mexico asked that the defendants fund this medical monitoring program. With respect to the nuisance claim, New Mexico asserted that it paid for ranitidine products through state-funded insurance and health-care programs. On April 16, 2021, New Mexico filed an amended complaint in the New Mexico First Judicial District Court in Santa Fe County. It did not name ANI in the amended complaint, effectively voluntarily dismissing ANI from the action. Novitium was named as a defendant in the amended complaint. On September 1, 2023, the court entered an order dismissing Novitium without prejudice.

Federal Court Personal Injury Litigation. In June 2020, ANI was served with a personal injury complaint in the case of *Koepsel v. Boehringer Ingelheim Pharmaceuticals, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-80882-RLR, filed in the United States District Court for Southern District of Florida, in which the plaintiff alleges that he developed kidney cancer in 2018 as a result of taking over the counter medication containing ranitidine. The *Koepsel* action was filed within the existing multi-district litigation concerning ranitidine-containing drugs pending in the Southern District of Florida, *In re Zantac MDL*, 20 MDL 2924 (the "MDL"). A Master Personal Injury Complaint ("MPIC") in that MDL that was filed on June 22, 2020 also named ANI and Novitium as defendants. ANI was dismissed from the *Koepsel* case on August 21, 2020 and was dismissed from the MPIC on September 8, 2020. On December 31, 2020, after ANI was dismissed, the district court dismissed the MPIC claims against generic manufacturer defendants partially with prejudice and partially with leave to replead. The failure to warn and design defect claims were dismissed with prejudice on preemption grounds. An Amended MPIC was filed on February 8, 2021, which did not name ANI but did name Novitium. By opinion dated July 8, 2021, the district court dismissed all claims against the generic manufacturer defendants with prejudice on preemption grounds. In addition, by opinion and order dated December 6, 2022, the district court granted the brand manufacturer defendants' *Daubert* motion to exclude the plaintiffs' expert testimony on general causation for the "designated cancers" that the plaintiffs' leadership team claimed to be caused by ranitidine. The district court also granted the brand manufacturer defendants' motion for summary judgment because the plaintiffs had failed to produce admissible primary evidence of general causation. The plaintiffs have appealed to the Eleventh Circuit Court of Appeals.

ANI and Novitium were named in other individual personal injury complaints filed in the MDL in which plaintiffs allege that they developed cancer after taking prescription and over the counter medication containing ranitidine. ANI was served with complaints in five of those additional cases: *Cooper v. Boehringer Ingelheim Pharmaceuticals, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-81130-RLR (served September 30, 2020), *Lineberry v. Amneal Pharmaceuticals, LLC, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-81079-RLR (served August 20, 2020), *Lovette v. Amneal Pharmaceuticals, LLC, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-81040-RLR (served August 26, 2020), *Hightower v. Pfizer, et al,* MDL No. 20-MD-2924, Case No. 9-20-cv-82214-RLR (served December 16, 2020) and *Bird v. Boehringer Ingelheim Pharmaceuticals, et al.*, MDL No. 20-MD-2924, Case No. 9-20-cv-80837-RLR (served December 30, 2020). Each of the plaintiffs in the five pending cases alleges a cancer diagnosis prior to the time that ANI sold ranitidine, and ANI informally sought dismissal from these cases on that basis. ANI was voluntarily dismissed from the *Cooper*, *Lineberry* and *Lovette* actions on November 20, 2020, from the *Bird* action on March 15, 2021, and from the *Hightower* action on March 29, 2021.

Prior to the district court's July 8, 2021 preemption decision, Novitium had been named in 158 short form complaints filed by claimants in the MDL. Those complaints were effectively dismissed with prejudice with the MPIC on July 8, 2021. Counsel for the plaintiffs have been notified that Novitium did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited period of time, from December 2018 until September 2019 and Novitium's product was voluntarily recalled in October 2019. Out of the 158 short form complaints, approximately 114 plaintiffs either were diagnosed with cancer before Novitium began manufacturing the product, only took over the counter ranitidine, or took ranitidine before Novitium began manufacturing it. Two of those 114 plaintiffs dismissed Novitium from their short form complaints. In light of the Court's dismissal of all claims with prejudice, Novitium has not pursued dismissal of the short form complaints against it at this time. Following the district court's *Daubert* decision, plaintiffs began filing additional short form complaints in the MDL. Novitium currently is named as a defendant in more than 700 short form complaints.

The plaintiffs have taken multiple appeals from decisions issued by the district court in the MDL to the Eleventh Circuit. On September 8, 2023, the Eleventh Circuit remanded a subset of the MDL appeals back to the district court for entry of final judgments pursuant to Rule 58. The defendants filed a motion with the Eleventh Circuit to remand a similarly situated appeal for similar entry of a final judgment. In addition, the defendants are seeking a stay from the Eleventh Circuit of all non-remanded related appeals in order to have all of the related appeals decided together. The district court has entered final judgments and the appeals are now pending before the Eleventh Circuit.

ANI and Novitium dispute any liability in these matters.

State Court Personal Injury Litigation

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

In August 2022, the Keller Postman law firm commenced six multi-plaintiff actions in Illinois state court naming generic ranitidine manufacturers, including ANI and/or Novitium, as defendants. Those cases are: (1) Jodee Gillespie v. Walgreen Co., et. al., Circuit Court of the Third Judicial Circuit, Madison County, Illinois, Case No. 2022LA001007 (naming both Novitium and ANI); (2) John Jackson v. Walgreen Co., et. al., Circuit Court of the Third Judicial Circuit, Madison County, Illinois, Case No. 2022LA001012 (naming Novitium); (3) Ayesha Salahuddin v. Walgreen Co., et. al., Circuit Court of the Twentieth Judicial Circuit, St. Clair County, Illinois, Case No. 22LA0709 (naming Novitium); (4) Lashanda McGruder v. Walgreen Co., et. al., Circuit Court of the Third Judicial Circuit, Madison County, Illinois, Case No. 22LA0710 (naming both Novitium and ANI); (5) Richard Devriendt v. Walgreen Co., et. al., Circuit Court of Cook County, Illinois, Case No. 2022L007429 (naming Novitium); (6) Anthony Stigger v. Walgreen Co., et. al., Circuit Court of Cook County, Illinois, Case No. 2022L007396 (naming both Novitium and ANI). The complaints allege causes of action for failure to warn, design defect, general negligence, loss of consortium and wrongful death. Pursuant to an Order of the Illinois Supreme Court dated October 25, 2022, the pending ranitidine personal injury actions in Illinois have been consolidated in Cook County for coordinated pre-trial proceedings. Plaintiffs filed a master long-form complaint on March 9, 2023 naming Novitium as a defendant. ANI is not named as a defendant. The Keller Postman firm has confirmed that its clients are no longer pursuing claims against ANI. When the court ruled the cases needed to be re-filed as single-plaintiff cases, Novitium was never served. The counts in the master complaint include strict liability for failure to warn/design defects, general negligence, negligent misrepresentation, negligent storage and transport, apparent manufacturer liability, common law fraud, unjust enrichment, civil conspiracy, and breach of express and implied warranties. The complaint further alleges violations of the Illinois Consumer Fraud Act. Pursuant to the court's standing order, the generic defendants filed a motion to dismiss pursuant to IL 2-615 (failure to state a claim on the face of the complaint) on April 13, 2023, claiming preemption by federal law. On August 10, 2023, the court dismissed all claims against the generic defendants, including Novitium, with prejudice on preemption grounds.

California. In August and September 2022, the Keller Postman law firm commenced seven multi-plaintiff actions in California state court, Alameda County, naming generic ranitidine manufacturers, including ANI and/or Novitium, as defendants. Those cases are: (1) Carlos Ascencio v. ANI Pharmaceuticals, et. al., Superior Court of California, County of Alameda, Case. No. 22CV016230 (naming both Novitium and ANI); (2) Andre Lebeau v. Actavis Mid Atlantic, LLC et. al., Superior Court of California, County of Alameda, Case No. 22CV016448 (naming Novitium); (3) Roque Torres v. ANI Pharmaceuticals, Inc., et. al., Superior Court of California, County of Alameda, Case No. 22CV016338 (naming both Novitium and ANI); (4) Deborah Hinds v. ANI Pharmaceuticals, Inc., et. al., Superior Court of California, County of Alameda, Case No. 22CV016123 (naming both Novitium and ANI); (5) Mark Cruz v. ANI Pharmaceuticals, Inc., et. al., Superior Court of California, County of Alameda, Case No. 22CV016338 (naming both Novitium and ANI); (6) Bent Olsen v. ANI Pharmaceuticals, Inc., et. al., Superior Court of California, County of Alameda, Case No. 22CV016402 (naming both Novitium and ANI); (7) John Norman v. Actavis Mid Atlantic, LLC, et. al., Superior Court of California, County of Alameda, Case No. 22CV018334 (naming Novitium). The complaints allege causes of action for failure to warn, design defect, general negligence, loss of consortium and wrongful death. By stipulation and order dated December 28, 2022, the cases were transferred to an existing civil case coordination docket for pretrial proceedings (JCCP) pending in Alameda County. On January 19, 2023, the court ordered that counsel for the plaintiffs must dismiss the individual plaintiffs (other than the first-named plaintiff) from each of the multi-plaintiff complaints and that each of the dismissed plaintiffs must re-file their claims in a single plaintiff complaint. On September 21, 2023, the plaintiff leadership filed a master complaint in the JCCP. The master complaint does not name any generic defendants. However, the short form complaints allow individual plaintiffs to name "other defendants," leaving open the option for individual plaintiffs to name generic manufacturers as defendants. The master complaint alleges strict liability (design defect and failure to warn), negligent failure to warn, and general negligence. In December 2023, the Keller Postman firm filed approximately 200 individual plaintiff short form complaints in the JCCP that name generic defendants. Novitium is named in 28 of the short form complaints which reference the allegations for the master complaint. ANI is not named.

Pennsylvania. In September 2022, two single-plaintiff complaints were filed in Pennsylvania state court, Philadelphia County, naming Novitium as a defendant: (1) William Titus v. Glaxo SmithKline LLC, et. al., Court of Common Pleas, Philadelphia County, Pennsylvania, Case No. 220902548; and (2) Jodi Woodard v. Ajanta Pharma USA, Inc., et. al., Court of Common Pleas, Philadelphia County, Pennsylvania, Case No. 220902329. These complaints allege causes of action for negligence, failure to warn, negligent storage and transportation, breach of express and implied warranties, negligent misrepresentation, and fraud. On February 16, 2023, the Pennsylvania plaintiffs filed a consolidated long-form complaint against the generic defendants, Plaintiffs v. Actavis, et. al. Civil Action No. 1364. The long-form complaint names Novitium as a defendant. The long form complaint asserts causes of action for negligence, failure to warn, negligent storage and transportation, breach of express warranties, breach of implied warranties, negligent misrepresentation, fraud, strict products liability, wrongful death and survivor actions, and loss of consortium. The complaint includes a prayer for punitive damages. The generic defendants filed their preliminary objections to Plaintiffs' consolidated long-form generic complaint on March 20, 2023. The court sustained the generics' objection that plaintiffs' failure to warn/design defect claims were preempted by federal law; therefore, all allegations related to failure to warn/design defects are dismissed. The court also sustained the generics' preliminary objections relating to the counts of strict liability-design defect and breach of implied warranty to the extent Pennsylvania substantive law applies. The court noted the substantive law of another state may not conflict with federal law, and, further, strict liability and breach of implied warranty causes of action of another state may apply in individual cases. This is a determination that can only be made after short form complaints are filed. It is the generics' position that the court's ruling on the preliminary orders effectively dismissed the generics from the case unless and until a non-resident plaintiff names a generic in a short form complaint. Out of an abundance of caution, however, the generics, including Novitium, all filed answers to the long form complaint in June 2023. In January 2024, plaintiffs filed short form complaints naming generic defendants, including Novitium in one complaint, *Titus*.

ANI and Novitium dispute any liability in these matters.

Other Industry Related Matters

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

16. PURIFIED CORTROPHIN GEL PRE-LAUNCH CHARGES

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

Prior to the third quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts were consumed in research and development activities and recognized as research and development expense in the period in which they were incurred. In the third quarter of 2019, the purchase of materials commenced that were intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. The FDA granted approval of the sNDA of this product on October 29, 2021. Prior to FDA approval, under U.S. GAAP, the Company was prohibited from capitalizing these pre-launch purchases of materials as inventory, and accordingly, they were charged to expense in the period in which they were incurred. Subsequent to approval, these purchases are recorded as inventory at net realizable value. During the year ended December 31, 2021, the Company recognized $0.8 million of charges for the purchase of materials. Other charges were incurred directly related to the Cortrophin pre-launch commercialization efforts, including, but not limited to, sales and marketing and consulting expenses. During the year ended December 31, 2021, the Company incurred $14.0 million of these charges, which are included on the consolidated statements of operations as a selling, general, and administrative expense. There were no comparable expenses in 2023 and 2022.

17. RELATED PARTY TRANSACTIONS

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

In connection with the acquisition of Novitium, the Company entered into employment agreements with the two executives and founders of Novitium, Muthusamy Shanmugam, Head of R&D and COO of NJ Operations of ANI, and Chad Gassert, Sr. Vice President, Corporate Development and Strategy of ANI. Both serve as executive officers of the Company and Mr. Shanmugam also serves on the Company's board of directors. Mr. Shanmugam holds a minority interest in Scitus Pharma Services ("Scitus"), which provides clinical research services to Novitium, a majority interest in SS Pharma LLC ("SS Pharma"), which acquires and supplies API to Novitium, a minority interest in Nuray Chemical Private Limited ("Nuray"), which manufactures and supplies API to Novitium, and a majority interest in Esjay Pharma LLC ("Esjay"), which provided research and development and facilities consulting services through September 30, 2022. Mr. Gassert holds a minority interest in Scitus.

A summary of payments to related parties is presented below:

	Years Ended December 31,		
(in thousands)	**2023**	**2022**	**2021 (1)**
Scitus Pharma Services	$ 3,646	$ 2,075	$ —
SS Pharma LLC	8,235	3,669	—
Esjay Pharma LLC	—	101	25
Nuray Chemical Private Limited	—	1,110	365
	$ 11,881	$ 6,955	$ 390

(1) Includes payments during the period from November 19, 2021 to December 31, 2021, subsequent to the acquisition of Novitium.

As of December 31, 2023, the outstanding balances due to Scitus and SS Pharma were $0.7 million and $0.6 million, respectively. There was no outstanding balance due to Nuray or Esjay at December 31, 2023.

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

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

18. SEGMENT REPORTING

An operating segment is defined as a component of an entity that engages in business activities from which it may recognize revenues and incur expense, its operating results are regularly reviewed by the entity’s chief operating decision maker (“CODM”) to make decisions about resources to be allocated to the segment and assess its performance, and its discrete financial information is available. Prior to 2022, based on this definition, the Company was organized as one operating and reporting segment. Prior period segment disclosures have been recast for the new segment presentation. Effective in the first quarter of 2022 and prospectively, in conjunction with the principal completion of the buildout of infrastructure in the areas of commercialization of rare disease therapies and the launch of Cortrophin Gel, it was determined that the Company has two operating segments as follows:

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

The CODM evaluates the performance of the Company as two operating segments based on revenues and EBITDA, exclusive of corporate expenses and other expenses not directly allocated or attributable to an operating segment. These expenses include, but are not limited to, certain management, legal, accounting, human resources, insurance, and information technology expenses.

The Company does not manage assets of the Company by operating segment and 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, including historical information that has been retroactively re-cast to reflect two reporting segments, is as follows:

	Year Ended December 31,		
(in thousands)	**2023**	**2022**	**2021**
Net Revenues			
Generics, Established Brands, and Other	$ 374,699	$ 274,699	$ 216,136
Rare Disease	112,117	41,686	—
Total net revenues	$ 486,816	$ 316,385	$ 216,136
Segment earnings (loss) before interest, taxes, depreciation and amortization ("EBITDA") and reconciliation to income (loss) before income taxes			
Generics, Established Brands, and Other	$ 152,990	$ 78,958	$ 63,418
Rare Disease	12,498	(18,348)	(18,571)
Depreciation and amortization	(59,791)	(56,973)	(47,252)
Corporate and other unallocated expenses[(1)]	(58,726)	(38,920)	(37,388)
Total operating income (loss)	$ 46,971	$ (35,283)	$ (39,793)
Interest expense, net	(26,940)	(28,052)	(11,922)
Other income (expense), net	(159)	670	(4,343)
Income (loss) before expense (benefit) for income taxes	$ 19,872	$ (62,665)	$ (56,058)

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

Geographic Information

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

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

(in thousands)	Years Ended December 31,		
Location of Operations	**2023**	**2022**	**2021**
United States	$ 486,251	$ 312,427	$ 211,893
Canada	565	3,958	4,243
Total Revenue	$ 486,816	$ 316,385	$ 216,136

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

(in thousands)	December 31, 2023	December 31, 2022
United States	$ 43,163	$ 40,343
Canada[(1)]	—	1,856
India	1,430	1,047
Total property and equipment, net	$ 44,593	$ 43,246

[(1)]Amounts as of December 31, 2023 and 2022 exclude the land and building at the Canada facility, which are classified as held for sale as of December 31, 2023 and 2022. These assets have a carrying value of $8.0 million.

19. SUBSEQUENT EVENTS

On February 14, 2024, the Company granted RSA and PSU awards to officers and employees of the Company under the 2022 Plan. The Company granted 525,729 RSAs to employees and officers of the Company. These RSAs vest over four years. The Company granted 73,588 PSUs to employees and officers of the Company (66,433 to officers of the Company). PSU performance will be measured over three years from January 1, 2024 through December 31, 2026 and will cliff-vest contingent upon the achievement of specified performance objectives. PSUs granted to date vest over a three-year performance period. Additionally, on February 15, 2024, the Company granted 13,054 RSAs to new employees of the Company, which will vest over four years.

On February 16, 2024, ANI Pharmaceuticals Canada, Inc. and 1540700 Ontario Limited entered into an agreement of purchase and sale for the Oakville, Ontario manufacturing facility for a purchase price of 19.2 million Canadian Dollars, or approximately $14.2 million US Dollars, based on the current exchange rate. The first and second deposits, each amounting to approximately 1.0 million Canadian Dollars or approximately $0.7 million US Dollars, based on the current exchange rate, were received on February 20, 2024, and February 27, 2024, respectively. The remaining balance of the purchase price, less deposits, will be paid upon closing, which is expected to occur by the end of March 2024. The closing of the transaction is subject to customary termination conditions, including the buyer's right to terminate the agreement if the property is materially damaged prior to the closing.

On February 22, 2024, the Company paid $12.5 million to the Company Members of Novitium for the achievement of the "Gross Profit Earn-Out," as defined in the Novitium acquisition agreement, as discussed in Note 2.

On November 15, 2010, ANI, formerly Biosante, entered into an assignment and technology transfer agreement and stock subscription agreement (collectively the "CG Agreement") with CG Oncology, Inc. formerly, Cold Genesys, Inc. ("CG Oncology"), pursuant to which the Company sold to CG Oncology exclusive, worldwide rights to develop and commercialize BioSante's oncolytic virus technology. The technology includes a replication-competent adenovirus that has completed clinical trials for treatment of superficial bladder cancer. Under the terms of the CG Agreement, the Company received an equity investment in CG Oncology, an upfront cash payment and the right to receive future royalty payments. Historically, this equity investment was recorded at cost and as of December 31, 2023, this equity investment was valued at zero. On January 24, 2024, CG Oncology completed their Initial Public Offering, at an offering price of $19.00 per share. The Company currently holds 219,925 shares of common stock in CG Oncology. As of February 27, 2024 these shares are valued at approximately $10.2 million.

On February 28, 2024, CG Oncology disputed the Company's rights to receive royalties. The dispute is unresolved at this time.

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

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.

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 154-15(e) under the Exchange Act), as of December 31, 2023. Based on this evaluation, our principal executive officer and principal financial officers concluded that our disclosure controls and procedures were effective as of December 31, 2023.

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, 2023. 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, 2023, 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.

As disclosed in Item 9A. Controls and Procedures in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, we identified material weaknesses related to an ineffective control environment at our Novitium subsidiary, and information technology general controls ("ITGCs") in the areas of user access over certain information technology systems that support our financial reporting processes.

As of December 31, 2022, we determined that the designed internal controls were not operating effectively in Novitium related processes including (i) purchase to pay (purchasing, accounts payable, and cash disbursements); (ii) manufacturing and inventory; (iii) human resources/payroll; (iv) financial statement close; and (v) information technology related controls, as well as overall ITGC related to user access which were not operating effectively to adequately restrict user access to our network and financial applications and data, and therefore did not reduce the risk of a material error occurring and going undetected in our financial statements to an acceptable level giving rise to the material weaknesses.

During the fiscal year ended December 31, 2023, we implemented our material weakness remediation plan that included: (i) refining and completing our plan to incorporate procure to pay cycle into the overall company controls; (ii) review and revise control documentation for controls at our Novitium subsidiary; (iii) ensure Novitium processes and controls have adequate resources to properly perform identified controls including hiring of additional resources with the requisite skills to consistently perform control procedures without material exception; (iv) implement one ERP system for the entire company to support the internal control structure; and (v) ensure all personnel are properly trained as to the importance of and specifics over the internal controls for which they are responsible, including consistent, repeatable performance of such controls. We completed our testing of the operating effectiveness of the implemented controls and found them to be effective. As a result, we have concluded the material weaknesses have been remediated as of December 31, 2023. Our independent registered public accounting firm, EisnerAmper LLP, has issued an attestation report on the effectiveness of our internal control over financial reporting, which is included in Item 8. Financial Statements and Supplementary Data of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2023, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Oakville Sale

On November 6, 2023, ANI Pharmaceuticals Canada Inc., a wholly owned subsidiary of the Company, entered into an agreement (the "Agreement") with Mastercom Inc. for the purchase and sale of the Company's Oakville, Ontario former manufacturing facility at a total purchase price of approximately 17.9 million Canadian dollars, or approximately $13.0 million US Dollars based on the current exchange rate, subject to certain market adjustments. On December 22, 2023, the Agreement was terminated by mutual agreement. In February 2024, the Company entered into an agreement for the purchase and sale of the Oakville site, for a purchase price of 19.2 million Canadian Dollars, or approximately $14.2 million US Dollars, based on the current exchange rate. The sale is expected to close in March 2024.

Trading Arrangements

Our directors and officers (as defined in Exchange Act Rule 16a-1(f)) may from time to time enter into plans or other arrangements for the purchase or sale of our shares that are intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or may represent a non-Rule 10b5-1 trading arrangement under the Exchange Act.

On November 27, 2023, Mr. Muthusamy Shanmugam, Head of R&D and COO of NJ Operations, adopted a trading arrangement for the sale of securities of the Company's common stock (a "Rule 10b5-1 Trading Plan") that is intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c). Mr. Shanmugam's Rule 10b5-1 Trading Plan, which has a term from March 4, 2024 through November 29, 2024, provides for the sale of up to 400,000 shares of common stock pursuant to the terms of the plan.

On December 12, 2023, Mr. Chad Gassert, Sr. Vice President, Corporate Development and Strategy, adopted a trading arrangement for the sale of securities of the Company's common stock (a "Rule 10b5-1 Trading Plan") that is intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c). Mr. Gassert's Rule 10b5-1 Trading Plan, which will terminate September 30, 2024, provides for the sale of up to 100,000 shares of common stock pursuant to the terms of the plan.

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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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 2024 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, Philadelphia, Pennsylvania, 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 2024 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, 2023 and 2022, 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, 2023, 2022, and 2021, 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 120.

ANI PHARMACEUTICALS, INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2023

Exhibit No.	Exhibit	Method of Filing
2.1	Amended and Restated Agreement and Plan of Merger, dated as of April 12, 2013, by and among BioSante Pharmaceuticals, Inc., ANI Merger Sub, Inc. and ANIP Acquisition Company (1)	Incorporated by reference to Exhibit 2.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on April 12, 2013 (File No. 001-31812)
2.2	Agreement and Plan of Merger dated March 8, 2021 by and among ANI Pharmaceuticals, Inc., Nile Merger Sub LLC, Novitium Pharma LLC, Esjay LLC, Chali Properties, LLC, Chad Gassert, Muthusamy Shanmugam and Thorappadi Vijayaraj and Shareholder Representative Services LLC as the representative of the Company Members	Incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 9, 2021 (File No. 001-31812)
3.1	Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of July 17, 2013, Certificate of Amendment of the Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc., dated as of June 1, 2012, and Restated Certificate of Incorporation of BioSante Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2013 (File No. 001-31812)
3.2	Second Amended and Restated Bylaws of ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 3.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 6, 2023 (File No. 001-31812)
3.3	Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock of the Company, effective as of November 19, 2021.	Incorporated by reference to Exhibit 3.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 26, 2021 (File No. 001-31812)
4.1	Description of Securities	Incorporated by reference to Exhibit 4.1 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2020 (File No. 001-31812)
4.2	Registration Rights Schedule to the Merger Agreement, effective as of November 19, 2021	Incorporated by reference to Exhibit 4.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 26, 2021 (File No. 001-31812)
10.1*	Employment Agreement, entered into by the Company and James G. Marken	Incorporated by reference to Exhibit 10.4 to ANI's Current Report on Form 8-K filed January 22, 2020 (File No. 001-31812)
10.2*	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)
10.3*	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)

Exhibit No.	Exhibit	Method of Filing
10.4*	Employment Agreement between Muthusamy Shanmugam and the Company, dated as of March 8, 2021 and effective as of November 19, 2021.	Incorporated by reference to Exhibit 10.3 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 26, 2021 (File No. 001-31812)
10.5*	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)
10.6*	Employment Agreement between Ori Gutwerg and the Company, dated January 18, 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)
10.7*	Employment Agreement between Chad Gassert and the Company, dated March 8, 2021.	Incorporated by reference to Exhibit 10.28 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-31812)
10.8*	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)
10.9*	Employment Agreement between Krista Davis and ANI Pharmaceuticals, Inc. dated July 14, 2022.	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2022 (File No. 001-31812)
10.10	Amendment No. 2 to Asset Purchase Agreement, dated as of July 10, 2015, Teva Pharmaceuticals, Inc. and ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2015 (File No. 001-31812)
10.11	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)
10.12	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)
10.13	Asset Purchase Agreement between AstraZeneca AB, AstraZeneca UK Limited, and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.25 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2017 (File No. 001-31812)
10.14	Asset Purchase Agreement between Amerigen Pharmaceuticals LTD. and ANI Pharmaceuticals, Inc.	Incorporated by reference to Exhibit 10.24 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2019 (File No. 001-31812)
10.15	Credit Agreement, dated as of November 19, 2021 by and among the Company, certain of the Company's subsidiaries, as guarantors, Truist Bank, as Administrative Agent and other parties party thereto.	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on November 26, 2021 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.16	Equity Commitment and Investment Agreement, dated as of March 8, 2021, by and between the Company and Ampersand 2020 Limited Partnership	Incorporated by reference to Exhibit 10.2 to ANI's Current Report on Form 8-K as filed with the Securities and Exchange Commission on March 9, 2021 (File No. 001-31812)
10.17	Sublicense Agreement, dated as of October 30, 2009, by and between ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., and Jazz Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.24 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-31812)
10.18	Master Product Development and Collaboration Agreement, dated as of July 11, 2011, by and among ANIP Acquisition Company d/b/a ANI Pharmaceuticals, Inc. and RiconPharma LLC (2)	Incorporated by reference to Exhibit 10.25 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (File No. 001-31812)
10.19	Asset Purchase Agreement between Cranford Pharmaceuticals, LLC and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022 (File No. 001-31812)
10.20	Asset Purchase Agreement between Holmdel Pharmaceuticals, LP and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2022 (File No. 001-31812)
10.21*	ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement on Schedule 14A filed with the Commission on April 14, 2016
10.22*	ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan	Incorporated by reference Appendix A to ANI Pharmaceuticals, Inc.'s definitive proxy statement dated March 25, 2022 filed with the Securities and Exchange Commission on March 25, 2022 (File No. 001-31812).
10.23*	Amendment No. 2023-1 to ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan (including form of Performance Stock Unit Award Agreement)	Incorporated by reference to Exhibit 10.1 to ANI's Form S-8 filed on June 23. 2023 (File No. 001-31812)
10.24*	Amendment No. 2024-2 to ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan	Filed herewith
10.25*	Form of Restricted Stock Grant Agreement	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement for the 2022 Virtual Annual Meeting filed on March 25, 2022 (File No. 001-31812)
10.26*	Form of Stock Option Agreement	Incorporated by reference to Appendix A to ANI's Definitive Proxy Statement for the 2022 Virtual Annual Meeting filed on March 25, 2022 (File No. 001-31812)
10.27*	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)

Exhibit No.	Exhibit	Method of Filing
10.28*	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)
10.29	Amendment No. 1 to the Credit Agreement, dated as of July 3, 2023 by and among the Company, and Truist Bank, as Administrative Agent.	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2023 (File No. 001-31812)
10.30	Underwriting Agreement, dated May 11, 2023, by and between ANI Pharmaceuticals, Inc. and Guggenheim Securities, LLC	Incorporated by reference to Exhibit 1.1 to ANI's Current Report on Form 8-K filed on May 12, 2023 (File No. 001-31812)
10.31	Purchase and Sale Agreement between ANI Pharmaceuticals Canada Inc. and Mastercom Inc.	Filed herewith
10.32	Amendment to Purchase and Sale Agreement between ANI Pharmaceuticals Canada Inc. and Mastercom Inc.	Filed herewith
10.33	Notice of Termination of Purchase and Sale Agreement between ANI Pharmaceuticals Canada Inc. and Mastercom Inc.	Filed herewith
10.34	Form of Indemnification Agreement	Filed herewith
21	List of subsidiaries	Filed herewith
23.1	Consent of EisnerAmper LLP	Filed herewith
31.1	Certification of Chief Executive Officer Pursuant to SEC Rule 13a-14	Filed herewith
31.2	Certification of Chief Financial Officer Pursuant to SEC Rule 13a-14	Filed herewith
32.1	Certification of Chief Executive Officer and Chief Financial Officer Pursuant to Rule 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	Furnished herewith
97.1	ANI Pharmaceuticals, Inc. Amended and Restated Clawback Policy	Filed herewith
101	The following financial information from this annual report on Form 10-K for the fiscal year ended December 31, 2023, 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, 2023 formatted in inline XBRL (included in Exhibit 101)	Filed herewith

(1) All exhibits to this exhibit have been omitted pursuant to Item 601(b)(2) of Regulation S-K. ANI will furnish the omitted exhibits to the SEC upon request by the SEC.
(2) Confidential treatment has been granted with respect to redacted portions of this document or certain information has been omitted from this exhibit in accordance with Regulation S-K Item 601(b)(10)(iv). The Company agrees to furnish supplementally a copy of any omitted information to the Securities and Exchange Commission upon its request.
* Management contract or compensatory plan or arrangement required to be filed as an exhibit to this Annual Report on Form 10-K pursuant to Item 15(a).

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 29, 2024

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

Date: February 29, 2024

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 Nikhil Lalwani	Director, President, and Chief Executive Officer (principal executive officer)	February 29, 2024
/s/ Stephen P. Carey Stephen P. Carey	Senior Vice President, Finance and Chief Financial Officer (principal financial and accounting officer)	February 29, 2024
/s/ Muthusamy Shanmugam Muthusamy Shanmugam	Director, Head of Research and Development and Chief Operating Officer of New Jersey Operations	February 29, 2024
/s/ Patrick D. Walsh Patrick D. Walsh	Director and Chairman of the Board of Directors	February 29, 2024
/s/ Thomas J. Haughey Thomas J. Haughey	Director	February 29, 2024
/s/ David B. Nash, M.D., M.B.A. David B. Nash, M.D., M.B.A.	Director	February 29, 2024
/s/ Matthew J. Leonard Matthew J. Leonard	Director	February 29, 2024
/s/ Jeanne Thoma Jeanne Thoma	Director	February 29, 2024
/s/ Antonio Pera Antonio Pera	Director	February 29, 2024
/s/ Renee Tannenbaum Renee Tannenbaum	Director	February 29, 2024

Company Profile

ANI Pharmaceuticals, Inc. (NASDAQ: ANIP) is a diversified bio-pharmaceutical company serving patients in need by developing, manufacturing, and marketing high quality branded and generic prescription pharmaceutical products, including for diseases with high unmet medical need. Our team is focused on delivering sustainable growth by building a successful Purified Cortrophin® Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our U.S. based manufacturing capabilities. For more information, please visit our website www.anipharmaceuticals.com.

Cautionary Note Regarding Forward Looking Statements

This report, and the documents incorporated by reference herein, may contain forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995. These statements are based on the beliefs and assumptions of management. Although the Company believes that its plans, intentions, and expectations reflected in or suggested by these forward- looking statements are reasonable, the Company cannot assure you that it will achieve or realize these plans, intentions, or expectations. Forward-looking statements are inherently subject to risks, uncertainties, and assumptions. Generally, statements that are not historical facts, including statements about future operations, strategies and growth potential, the revenue potential (licensing, royalty and sales) of products we sell, development timelines, expected timeframe for submission of new drug applications, abbreviated new drug applications, or supplemental new drug applications to the U.S. Food and Drug Administration, pipeline or potential markets for our products, selling and marketing strategies and associated costs to support the sales of Purified Cortrophin® Gel (Repository Corticotropin Injection USP), impact of accounting principles, litigation expenses, liquidity and capital resources, the impact of the novel coronavirus ("COVID-19") global pandemic on our business, are forward-looking statements. In some instances, these statements may be preceded by, followed by or include the words "anticipates," "will," "expects," "plans," "potential," "future," "believes," "intends," "continue," other words of similar meaning, derivations of such words, and the use of future dates.

Forward-looking statements are not guarantees of performance. You should not put undue reliance on these statements which speak only as of the date hereof. You should understand that the following important factors, among others, could affect the Company's future results and could cause those results or other outcomes to differ materially from those expressed or implied in the Company's forward-looking statements: the ability of the Company to grow and manage growth profitably, maintain relationships with customers, compete within its industry and retain its key employees; the possibility that the Company may be adversely impacted by other economic, business, and/or competitive factors; the outcome of any legal proceedings that may be instituted against the Company or others; future exchange and interest rates; and other risks and uncertainties indicated in this report, including those under "Risk Factors" herein, and other filings that have been made or will be made with the SEC.

These and other factors that could cause actual results to differ from those implied by the forward- looking statements in this report are more fully described in the "Risk Factors" section. The risks described in "Risk Factors" are not exhaustive. New risk factors emerge from time to time and it is not possible for us to predict all such risk factors, nor can the Company assess the impact of all such risk factors on its business or the extent to which any factor or combination of factors may cause actual results to differ materially from those contained in any forward-looking statements. All forward-looking statements attributable to the Company or persons acting on its behalf are expressly qualified in their entirety by the foregoing cautionary statements. The Company undertakes no obligations to update or revise publicly any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.