2022 Annual Report

www.anipharmaceuticals.com

CORPORATE INFORMATION

BOARD OF DIRECTORS

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

Robert E. Brown, Jr., Director
President, MVP Management Company

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

Nikhil Lalwani, Director
President and Chief Executive Officer

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

Antonio R. Pera, Director
Former President, Par Pharmaceutical

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

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 and Product Development

Christopher Mutz
Senior Vice President, Head of Rare Disease

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

www.anipharmaceuticals.com

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 23, 2023 via webcast through the link: www.virtualshareholdermeeting.com/ANIP2023.

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

(Mark one)

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

For the fiscal year ended December 31, 2022

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

For the transition period from _____ to _____.

Commission file number 001-31812

ANI PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**58-2301143**
(State or other jurisdiction of incorporation or organization)	(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, 2022 was $372.9 million (based upon the last reported sale price of $29.67 per share on June 30, 2022, on The Nasdaq Global Market).

As of March 2, 2023, 17,493,224 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 2023 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, 2022

TABLE OF CONTENTS

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:

- risks that we may face with respect to importing raw materials and delays in delivery of raw materials and other ingredients and supplies necessary for the manufacture of our products from both domestic and overseas sources due to supply chain disruptions or for any other reason;
- delays or failure in obtaining and maintaining approvals by the FDA of the products we sell;
- changes in policy or actions that may be taken by the FDA and other regulatory agencies, including drug recalls;
- the ability of our manufacturing partners to meet our product demands and timelines;
- our dependence on single source suppliers of ingredients due to the time and cost to validate a second source of supply;
- acceptance of our products at levels that will allow us to achieve profitability;
- our ability to develop, license or acquire, and commercialize new products;
- the level of competition we face and the legal, regulatory and/or legislative strategies employed by our competitors to prevent or delay competition from generic alternatives to branded products;
- our ability to protect our intellectual property rights;
- the impact of legislative or regulatory reform on the pricing for pharmaceutical products;
- the impact of any litigation to which we are, or may become, a party;
- our ability, and that of our suppliers, development partners, and manufacturing partners, to comply with laws, regulations and standards that govern or affect the pharmaceutical and biotechnology industries;

- our ability to maintain the services of our key executives and other personnel;
- whether we experience disruptions to our operations resulting from the anticipated closure of our Oakville, Ontario manufacturing plant, including the transition of certain products manufactured there to our other facilities which remains ongoing, or have difficulties finding a buyer for the plant and property; and
- general business and economic conditions, such as inflationary pressures, geopolitical conditions including the conflict between Russia and the Ukraine, 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. Our team is focused on delivering growth by building a successful Purified Cortrophin Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our manufacturing capabilities. Our four current pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, one is located in East Windsor, New Jersey, and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. On June 2, 2022, we announced that we intend to cease operations at our Oakville, Ontario, Canada manufacturing plant by first quarter 2023. This action is part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. We have transitioned the majority of products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites and are on track to cease operations by the end of the first quarter 2023. We are seeking to find potential buyers for the Oakville site.

Through research and development, acquisitions of businesses, acquisitions of Abbreviated New Drug Applications ("ANDAs"), New Drug Applications ("NDAs"), product rights, and entry into agreements to obtain the distribution rights for various products, we have a commercial portfolio of 111 products with a wide variety of indications and a robust portfolio of pipeline products as of December 31, 2022. Refer to our website at www.anipharmaceuticals.com for information on our products, including indications/treatments.

On November 19, 2021, we completed the acquisition of Novitium. With operations in East Windsor, New Jersey, and Chennai, India, Novitium is a pharmaceutical company that specializes in development, manufacturing, and distribution of niche generic products. Founded in 2016, Novitium has since developed a growing commercial product portfolio spanning a diverse range of dosage forms and therapeutic categories.

Unless otherwise required by the context, references in this Annual Report on Form 10-K to the "Company," "we," "us," and "our" refer to ANI Pharmaceuticals, Inc., a Delaware corporation formed in April 2001. Our principal executive offices are located at 210 Main Street West, Baudette, Minnesota, 56623, our telephone number is (218) 634-3500, and our website address is www.anipharmaceuticals.com.

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 active pharmaceutical ingredient ("API"), a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin gel fill/finish contract manufacturer. During the second quarter of 2021, we submitted a Supplemental New Drug Application ("sNDA") to the FDA.

On October 29, 2021, the FDA approved the Company's sNDA for Purified Cortrophin Gel (Repository Corticotropin Injection USP) for the treatment of certain chronic autoimmune disorders, including acute exacerbations of

multiple sclerosis ("MS") and rheumatoid arthritis ("RA"), in addition to excess urinary protein due to nephrotic syndrome. Cortrophin Gel is an adrenocorticotropic hormone ("ACTH"), also known as purified corticotropin.

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

We plan to continue to invest behind Cortrophin Gel and our Rare Disease platform in 2023 and beyond.

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 designation filings. Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses. On July 21, 2022, we completed an asset acquisition of four ANDAs from Oakrum Pharma, including two that were commercial at the time of acquisition.

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, all of which influence the level of competition upon product launch. These criteria include:

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

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

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

- ***Profit Potential.*** We research the availability and cost of active pharmaceutical ingredients in determining which products to develop or acquire. In determining the potential profit of a product, we forecast our

anticipated market share, pricing, including the expected price erosion caused by competition from other generic manufacturers, and the estimated cost to manufacture the products.

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

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

In addition to laboratories that support the requirements of raw material, finished product, and stability testing, we have a 1,000-square foot pilot laboratory offering liquid, suspension and solid dose development capabilities. This pilot laboratory offers a full range of analytical capabilities, including method development, validation and de-formulation, and is licensed by the Drug Enforcement Administration ("DEA"). Finally, a separate development suite located within our high-potency manufacturing facility offers additional capabilities for product development.

We also lease a 968-square foot industrial space in Chennai, India where we perform research and development activities.

Products and Markets

Products

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

Markets

In determining which products to pursue for development, we target products that are complex to manufacture and therefore have higher barriers to entry. These factors provide opportunities for growth, utilizing our competitive strengths at the same time that they decrease the number of potential competitors in the markets for these products. These markets currently include controlled substances, oncology products, hormones and steroids, injectables, and complex formulations, including extended release and combination products.

Controlled Substances

Schedule II controlled substances are drugs considered to have a high abuse risk but that also have safe and accepted medical uses. In addition to our Schedule II products currently on the market, our pipeline includes ANDAs in this market. One of our manufacturing facilities in Baudette, Minnesota and our manufacturing facility in East Windsor, New Jersey is licensed by the DEA for the manufacture of Schedule II controlled substances.

Oncology Products

Due to the capabilities of our containment facility and our expertise in manufacturing segregation, we are focused on developing and manufacturing niche oncology products (anti-cancer). In particular, we are targeting products subject to priority review by the FDA, more specifically those with no blocking patents and no generic competition. We currently have a variety of oncology products on the market.

Hormone and Steroid Drugs

The market for hormone and steroid drugs includes hormone therapy to alleviate menopausal symptoms in women, contraceptives, testosterone replacement therapies for men, and therapies for treating hormone-sensitive cancers.

Hormone Therapy ("HT") has been a long-accepted medical treatment for alleviating the symptoms of menopause. Initially, HT consisted of estrogen only but has evolved to include combination therapies of estrogen, progesterone, and androgens. We target niche products in the HT and steroid product market for several reasons, including:

- Hormone and steroid products are a core competency based on our manufacturing and product development teams' long history of manufacturing these types of products; and
- The aging "baby boomer" population, of which women represent a majority, is expected to support continued growth in the HT market.

Injectables

Our burgeoning injectable portfolio contains injectable ANDA products encompassing several key therapeutic areas. Cortrophin Gel is our first branded injectable product. We work with world-class manufacturing partners to support these efforts.

Complex Formulations

We have a range of complex formulation products currently on the market and a pipeline that includes various extended-release products and combination products.

Competitive Generic Therapy

The FDA Reauthorization Act of 2017, or ("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.

Contract Manufacturing

We manufacture pharmaceutical products for several branded and generic companies, who outsource production in order to:

- Free-up internal resources to focus on sales and marketing as well as research and development;
- Employ internal capacity to manufacture higher volume or more critical products; and
- Utilize our specialized equipment and expertise.

We currently anticipate that revenues from contract manufacturing arrangements will begin to decline as we focus our efforts on Rare Disease and leveraging our generic R&D and manufacturing platform for ANI labeled products.

In conjunction with our acquisitions of WellSpring and Novitium, we acquired WellSpring's and Novitium's pharmaceutical manufacturing facilities. As a result of these transactions, we perform contract manufacturing in our Baudette, Minnesota and East Windsor, New Jersey facilities. On June 2, 2022, we announced that we intend to cease operations at our Oakville, Ontario, Canada manufacturing plant by first quarter 2023. This action is part of ongoing initiatives to capture operational synergies following our acquisition of Novitium in November 2021. We have

transitioned the majority of products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites and are on track to cease operations by the end of the first quarter 2023.

Manufacturing, Suppliers, and Raw Materials

We require a supply of quality raw materials, including active pharmaceutical ingredients ("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. and Canada is highly regulated by multiple U.S. and Canadian government agencies, such as the FDA, the DEA, the Centers for Medicare and Medicaid Services ("CMS"), and Health Canada. 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 any product they approve. A REMS is designed to ensure that a drug's benefits outweigh its risks, and may include 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.

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.

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

Two of our products, EEMT and Opium Tincture, are marketed without approved NDAs or ANDAs. The FDA's policy with respect to the continued marketing of unapproved products appears in the FDA's September 2011 Compliance Policy Guide Sec. 440.100 titled "Marketed New Drugs without Approved NDAs or ANDAs." Under this policy, the FDA has stated that it will follow a risk-based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case-by-case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. We continue to believe that, so long as we comply with applicable manufacturing standards, the FDA will continue to operate on a risk-based approach and will not take action against us. However, we can offer no assurance that the FDA will continue to follow this approach or that it will not take a contrary position with any individual product or group of products. See **"Risk Factors –** ***Two of our products, which together comprised less than 10% of our total revenue in 2022, 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. Federal and/or state governments may continue to enact measures aimed at reducing the cost of drugs to the Medicaid program.

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 the amount of reimbursement for pharmaceuticals, a trend that we believe will continue to benefit the generic pharmaceutical industry. 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. Our Candesartan Hydrochlorothiazide, Fenofibrate, Fluvoxamine, Hydrocortisone Enema, Lithium Carbonate ER, Mesalamine, Propranolol ER, Terbutaline, and Vancomycin products, while marketed as "generics," are sold under approved NDAs and, therefore, are subject to the discount requirement.

Since its enactment, there have been judicial, administrative, executive and Congressional legislative challenges to certain aspects of the ACA. For example, the ACA is currently subject to a broad legal challenge in California vs. Azar before the U.S. Supreme Court. Additionally, in November 2020, the U.S. Supreme Court heard argument in Texas v. Azar, which challenges the constitutionality of the ACA. Pending resolution of the litigation, all of the ACA, except for the individual mandate to buy health insurance remains in effect. Were the Supreme Court to invalidate the ACA, that could have far-reaching consequences of an uncertain nature for our industry. There are a number of additional bills pending in Congress and healthcare reform proposals at the state level that would affect drug pricing in the Medicare and Medicaid programs. This changing federal landscape has both positive and negative impacts on the U.S. healthcare industry with much remaining uncertain as to how various provisions of federal law, and potential modification or repeal of these laws, will ultimately affect the industry.

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.

There has also been recent heightened federal governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, a recent Presidential administration released a "Blueprint", or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products

paid by consumers. For example, the Inflation Reduction Act of 2022 imposes a requirement on manufacturers to negotiate drug prices with Medicare, beginning in 2026, with negotiated prices subject to a cap. The negotiation provision focuses on single-source drugs and biologics that represent the highest Medicare expenditure, while orphan drugs and certain other drugs are exempt. Also, certain drugs with price increases that outpace inflation will become subject to additional rebates. Under Medicare Part B, the rebate will first be due with respect to Q1 2023, and applies to single-source drugs and biologicals, including biosimilars. Under Medicare Part D, the rebate will first be due with respect to the period from October 1, 2022, to September 30, 2023, and applies to brand drugs and generics that are the sole drug on the market. The law's expansion of inflation-based rebates in the Medicare Part B and D space, and changes to the coverage gap discount program, will further complicate pricing strategies, particularly as to the launch of new products.

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. 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 will 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 own or 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 formerly received royalties from a license for patent rights initially owned by Cell Genesys, Inc., which merged with BioSante in 2009. The royalties were received as a result of sales and milestones related to the Yescarta® product. These royalties ceased after a final payment in 2021. See Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K for further information.

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 products are sold by three major retail pharmacy chains: CVS, Rite Aid, and Walgreens. Our customers include five major national wholesalers: AmerisourceBergen, Cardinal Health, McKesson, Smith Drug Company, and Morris Dickson. In addition, our customers include national mail order houses, including CVS Caremark, Humana, and ExpressScripts, 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, 2022, approximately 59% of our net revenues were attributable to three wholesalers: AmerisourceBergen Corporation, 26%, McKesson Corporation, 18%, and Cardinal Health, Inc., 15%. For the years ended December 31, 2021 and 2020, McKesson Corporation, Cardinal Health, Inc., and AmerisourceBergen Corporation, together accounted for approximately 68% and 74% 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 a strategic partnership between Amerisource Bergen and Walgreens, Amerisource Bergen handles product distribution for Walgreens. Similarly, Cardinal Health and CVS established a partnership in which Cardinal performs some product distribution for CVS. McKesson also entered into a strategic alliance with both Wal-Mart and Rite Aid. As a result of these 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 are in the process of contracting with 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 five major wholesalers in the United States: AmerisourceBergen, Cardinal, McKesson, Smith Drug Company, and Morris Dickson.

- ***Retail Market Chains.*** We conduct business with three major retail chains in the United States: CVS, Rite Aid, and Walgreens.

- ***Distributors and Mail Order Pharmacies.*** We have contracts with several major distributors and mail order pharmacies in the United States, including Anda, CVS Caremark, Humana, 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 Amneal Pharmaceuticals, Inc., Alvogen, Inc., Apotex Inc., Glenmark Pharmaceuticals Ltd, Hikma Pharmaceuticals plc, Mallinckrodt Pharmaceuticals, Par Pharmaceutical, Inc., Padagis LLC., Rising Pharmaceuticals, Inc., Sun Pharmaceutical Industries Ltd., and Teva Pharmaceuticals USA, Inc., and Viatris Inc.

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 2023, we have 600 employees, of which 496 are located in the United States, including Puerto Rico, 48 are 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. We are committed to creating a diverse and inclusive work environment within all levels of the business.

Attracting and retaining talented employees is critical to the success of our business, especially at our manufacturing operations in Baudette, Minnesota, which is located in a sparsely populated area of Northern Minnesota, with a population of approximately 1,100. As a result, it can be challenging to find sufficiently qualified personnel in all functional areas. To address this, we support remote working arrangements for a number of employees in several functions throughout the business, including at the executive level. In September 2023, we opened a corporate office in Princeton, NJ which houses certain employees in our corporate, legal, and business functions. Additionally, our compensation plans are designed to be competitive within the pharmaceuticals industry as well as competitive with local employers for jobs of a cross-industry nature. Our approach provides ANI with the resources to recognize and reward employee performance, productivity, and quality commitment. Our total compensation program includes competitive base salaries, comprehensive benefits, and employee equity programs.

Our U.S. and India facilities are committed to the safety and health of our employees, patient-customers, and the general public. It is critical within our mission to ensure we keep our employees and customers safe while accomplishing our business goals. We accomplish these initiatives through the following:

Health and Safety Management and Training

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

ANI is committed to minimizing waste and emissions, promoting reuse and recycling and conserving resources, where feasible, to reduce our environmental footprint on our environment.

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:

- 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;
- The uncertain impact that novel coronavirus ("COVID-19") will have on our business and results of operations, including the emergence of variants of the virus;
- 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;
- Cortrophin Gel is our first rare disease pharmaceutical product. To the extent we are not able to achieve commercial success with this product, including gaining market share, our business, financial condition, and results of operations will be negatively impacted;
- The limited number of suppliers for our active pharmaceutical ingredients ("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;
- 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;
- 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.
- Acquisitions and investments could disrupt our business and harm our 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;
- 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;
- Our approved products, including Cortrophin Gel, may not achieve commercialization at levels of market acceptance that allow us to achieve profitability;
- 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 four 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;
- We have very limited staffing and are dependent upon key employees, 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 identified material weaknesses in our internal control over financial reporting. If we do not effectively remediate these material weaknesses or if we otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud;
- 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; and
- Our international operations, including those resulting from our acquisition of Novitium and the global nature of its 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

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.

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 arrangements with third parties in which we sell products under ANDAs or NDAs owned or licenses 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.

Cortrophin Gel is our first rare disease pharmaceutical product. To the extent our 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 five 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. The ability for us to generate significant net product revenues from Cortrophin Gel 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 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 no experience in marketing prescription rare disease drug products. If we are unable to successfully establish marketing and sales capabilities for Cortrophin Gel, our business will suffer.

We have only recently established rare disease sales, marketing or distribution capabilities and have no 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.

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, 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. During the year ended December 31, 2020, we purchased approximately 10% of our inventory from one supplier. Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect our ability to manufacture and distribute our products and could result in legal liabilities that could materially affect our ability to realize profits or otherwise harm our business, financial, and operating results. 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. In addition, the COVID-19 pandemic and associated workforce factors has disrupted certain supply chains and generally led to longer lead times for the procurement of goods that are essential to the manufacture of our products.

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.

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.

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.

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 manufacturing operations are currently based in four facilities. We have transitioned the majority of products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites, and we are seeking to find potential buyers for the Oakville site. 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 a license of patent technology for Veregen 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 a license for patent technology for Veregen 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.

We have very limited staffing and are dependent upon key employees, 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 a relatively small management team and staff. 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. The population in northern Minnesota, where two of our four 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 13. 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 of 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 Canadian dollar and 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 Canadian dollar and the Indian rupee, the expenses we recognize from Canadian-denominated and Indian-denominated transactions made by our Canadian and Indian subsidiaries 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.

Risks Related to our Industry

The COVID-19 pandemic is ongoing and its impact on the global economy and our operations remains uncertain. A continuation of the pandemic could have a material adverse impact on our business, results of operations and financial condition and on the market price of our common stock.

On March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States and Canada, imposed unprecedented restrictions on travel, and there were business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID-19. While restrictions and impacts eased in 2021, significant uncertainty remains as to the continued potential impact of the COVID-19 pandemic on our operations and on the global economy as a whole.

Demand for the products we sell was negatively impacted by COVID-19 during the years ended December 31, 2021 and 2020, as fewer patients visited physicians for conditions treated by our products, fewer elective surgeries occurred and visits to pharmacies declined due to government orders and closures of or restrictions placed on visits to medical offices and facilities. Additionally, we have experienced disruptions to our supply chain, including increased lead times on the procurement of materials. While most government orders, closures and restrictions have now lapsed, this situation could continue or worsen depending on the duration and severity of the COVID-19 pandemic, the level of success in implementing mitigation measures, such as vaccines, the continued emergence of new variants of COVID-19, the length of time it takes for normal economic and operating conditions to resume, the impact of the pandemic on inflation, additional governmental actions that may be taken, and numerous other uncertainties.

It is currently not possible to predict how long the pandemic will continue, whether new government restrictions will be reinstituted, the effectiveness of mitigation efforts such as vaccines, the emergence of new variants of the virus, and the related impact on economic activity, including inflation. A disruption in the financial markets and volatility, as seen in 2020, 2021, and 2022, could have an adverse effect on our ability to access capital, our pharmaceutical supply chain, our business, results of operations and financial condition, and the market price of our common stock.

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

Consolidation and the formation of strategic partnerships among and between wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies, each controlling a larger share of pharmaceutical distribution channels. For example, our net revenues are concentrated among three customers representing 26%, 18%, and 15% of net revenues, respectively, during the year ended December 31, 2022. As of December 31, 2022, accounts receivable from these three customers was approximately 82% 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.

Two of our products, which together comprised less than 10% of our total revenue in 2022, 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.

Two of our products, Esterified Estrogen with Methyltestosterone ("EEMT") and Opium Tincture, are marketed without approved NDAs or ANDAs.

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

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

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

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

Imported API are subject to inspection by the FDA and the FDA can refuse to permit the importation of API for use in products that are marketed without approved NDAs or ANDAs. We are dependent on imported API to make certain of our products. If the FDA detained or refused to allow the importation of such API, 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 and Opium Tincture.

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 and Opium Tincture. 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.

Pharmaceutical product quality standards are steadily increasing and all products, including those already approved, may need to meet current standards or enhanced standards in the future. 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.

Steadily increasing quality standards are applicable to pharmaceutical products still under development and those already approved and on the market. These standards result from product quality initiatives implemented by the 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. 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 will 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 13. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

Another example of evolving standards occurred in December of 2021, when the FDA issued an information request to manufacturers of propranolol products, including Inderal LA (Propranolol ER) currently being marketed 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. Pfizer, Inc. and its affiliates ("Pfizer"), our contract manufacturer for both our Inderal LA brand product and our authorized generic product, Propranolol ER, initiated that evaluation and shared its analysis and test results with the Company in February 2022. Pfizer also manufactures and markets Inderal LA in Canada. On March 1, 2022, Pfizer announced that it was recalling all lots and strengths (60 mg, 80 mg, 120 mg, and 160 mg) of Inderal LA in the Canadian market after engagement with Health Canada. We are currently undertaking our own review and analysis of the nitrosamine impurity at issue, working with testing and toxicology experts, and are in active communication with the FDA on the appropriate acceptable daily intake for NNP and the appropriate approach for the product in the U.S. The FDA has not provided public notification for a final NNP acceptable intake. After briefly halting and then resuming further sales of the product to our trade customers, there has been no recall in the United States of Inderal LA and Propranolol ER, and the necessity for any recall has not been determined.

The discussion above illustrates the potential risk of a recall of a product due to enhanced standards, at the initiation of the Company and/or the FDA. The loss of sales of this product would have an adverse effect on our results of operations, as revenues from Inderal LA and Propranolol ER are anticipated to contribute approximately 4% of our forecasted total 2023 ex-Cortrophin Net Revenues. In addition, Pfizer's decision to withdraw the product in Canada creates uncertainties as to the future supply of our product from Pfizer which could have an adverse effect on our operating results if we are unable to supply the product pursuant to existing contracts with 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 final requirement for tracking the products will commence on November 27, 2023. 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 Canada and India. Our Canadian operations are subject to regulation by Health Canada and other federal, provincial, and local regulatory authorities. Health Canada regulates the testing, manufacture, labeling, marketing, and sale of pharmaceutical products manufactured and distributed in Canada. Our operations in Canada and 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 globally (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 rapidly developing 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 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, 2023. 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.

Significant developments that may adversely affect pricing in the United States include proposed drug pricing and Medicare reforms by Congress and regulatory changes to Medicare Part B (physician administered drugs) and Medicare Part D (prescription drug benefit) could financially impact us. On November 19, 2021, the U.S. House of Representatives passed the Build Back Better Act, which includes several provisions aimed at lowering prescription drug costs and reducing spending by the federal government and private payers by, among other things, allowing the U.S. federal government to negotiate prices for certain high-cost drugs covered under Medicare, imposing rebates on manufacturers of single-source drugs and biologics covered by Medicare Part B and nearly all drugs covered under Part D, if drug prices increase faster than the rate of inflation, based on the Consumer Price Index for All Urban Consumers ("CPI-U"). Build Back Better would also re-structure the Part D benefit and replace the existing Coverage Gap Discount Program with another manufacturer-imposed rebate or discount program, which could result in additional rebates to Medicare Part D plans in order to obtain Medicare Part D coverage. These concepts were included in the Inflation Reduction Act, which was signed into law on August 16, 2022. We are actively evaluating how this legislation will impact our business and operations.

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 markets in which we compete, we may not be able to pass those costs on to our generic customers.

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

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

As a company based in the U.S. with subsidiaries in Canada and India, we are subject to, or potentially subject to, income taxes as well as non-income based taxes in these jurisdictions as well as the U.S. 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 Canadian and Indian subsidiaries 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 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 global 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 the uncertain and changing nature of such tax regulations.

The global 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 global 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 evolving conflict between Russia and the Ukraine;
- 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; and
- the severity and duration of the COVID-19 pandemic and its impacts where we operate globally.

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, Canada, 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 the 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 review of goodwill based on our one reporting unit. 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 2022 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. We recognized an impairment of $0.1 million in the year ended December 31, 2022, in relation to an ANDA asset, and there can be no assurances that our remaining intangible assets will not be impaired in the future.

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 identified material weaknesses in our internal control over financial reporting. If we do not effectively remediate these material weaknesses or if we otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

Management identified material weaknesses in our internal control over financial reporting as of December 31, 2022. See Item 9A, "Controls and Procedures," in this Annual Report on Form 10-K for information regarding the identified material weaknesses and our actions to date to remediate the material weaknesses. If we do not effectively remediate these material weaknesses or if we otherwise fail to maintain effective internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud.

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 new $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, may adversely affect interest expense related to outstanding debt.

Amounts drawn under the New Credit Facility may bear interest rates in relation to LIBOR, depending on our selection. On July 27, 2017, the Financial Conduct Authority ("FCA") in the United Kingdom announced that it would phase out LIBOR as a benchmark by the end of 2021. Subsequently, recent actions taken by the U.K. Financial Conduct Authority, which regulates LIBOR, indicate that the continuation of LIBOR on the current basis cannot and will not be guaranteed after June 30, 2023. Moreover, it is possible that the U.S. LIBOR will be discontinued or modified prior to June 30, 2023. The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U.S. financial institutions, is recommending replacing U.S.-dollar LIBOR with the Secured Overnight Financing Rate ("SOFR"), a new index calculated by short-term repurchase agreements, backed by Treasury securities. At this time, it is not possible to predict the effect any discontinuance, modification, or other reforms to LIBOR, or the establishment of alternative reference rates such as SOFR, or any other reference rate, will have on the Company or its borrowing costs. Our credit agreement allows for a change to an alternate benchmark rate, including SOFR, as defined in the Credit Agreement, but no change has been made yet. In December 2022, the Financial Accounting Standards Board issued ASU 2022-06, which extended the sunset date of the reference rate reform in ASU 848 from December 31, 2022, to December 31, 2024. We have not adopted the guidance and are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

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 28% of our outstanding capital stock entitled to vote as of December 31, 2022. 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 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.

Shares of our common stock are relatively illiquid which may affect the market price of our common stock.

For the twelve months ended December 31, 2022, the average daily trading volume of our common stock on the NASDAQ Global Market was approximately 97,535 shares. Because of our relatively small public float, our common stock may be less liquid than the stock of companies with broader public ownership and trading of a relatively small volume of our common stock may have a greater impact on the market price for our shares than would be the case if our public float were larger.

Item 1B. Unresolved Staff Comments

None.

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 and liquid manufacturing and packaging, warehouse facilities, analytical, stability, and microbiological laboratory space, and employee office and mechanical space. We also 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. This facility is also located in Baudette, Minnesota. We also own a cold storage facility located in Baudette, Minnesota. In addition, we also own a facility in East Windsor, New Jersey, which includes manufacturing, warehousing, laboratory, product development, and employee office space.

In addition, we own a manufacturing facility located in Oakville, Ontario that includes oral solid dose, semi-solids, and non-sterile liquid manufacturing and packaging, warehouse facilities, analytical, stability, and microbiological laboratory space, and employee office and mechanical space. On June 2, 2022, we announced that we intend to cease operations at our Oakville, Ontario, Canada manufacturing plant by the first quarter of 2023. This action is part of ongoing initiatives to capture operational synergies following our acquisition of Novitium in November 2021. We have transitioned the majority of products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites and are on track to cease operations by the end of the first quarter 2023. We are seeking to find potential buyers for the Oakville site, though there can be no assurance as to when or if that will occur or the amount of any net proceeds that may be received.

We lease spaces for warehouse and packaging activities in Baudette, Minnesota, office space in Minnetonka, Minnesota and East Windsor, New Jersey, and for research and development activities in Chennai, India. The leases will

expire between 2025 and 2027. We recently purchased additional warehouse space in Baudette, Minnesota to support our ongoing operations.

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 13. 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 March 2, 2023, there were approximately 232 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. 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.

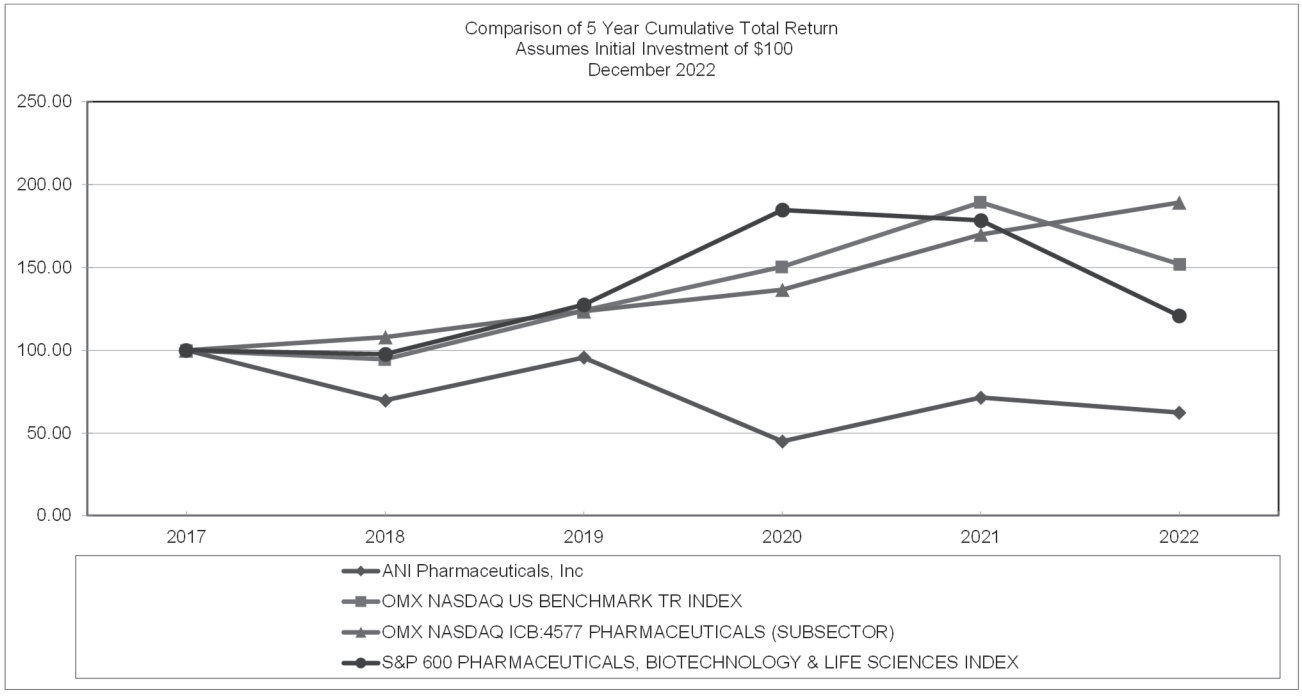
Issuer Purchases of Equity Securities

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, 2022	—	$ —	—	$ —
November 1 - November 30, 2022	2,024	$ 36.60	—	$ —
December 1 - December 31, 2022	1,156	$ 39.24	—	$ —
Total	3,180	$ 37.56	—	

[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, the Nasdaq Pharmaceuticals Index, and the S&P 600 Pharmaceuticals, Biotechnology & Life Sciences Index, assuming the investment of $100.00 on December 31, 2017, 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 2022 and 2021 items and year-to-year comparisons between 2022 and 2021. Discussions of 2020 items and year-to-year comparisons between 2021 and 2020 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, 2021, filed with the SEC on March 15, 2022.

Executive Overview

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

Strategy

Our objective is to build a sustainable and growing biopharmaceutical company serving patients in need and creating long-term value for our investors. Our growth strategy is driven by the following key 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 active pharmaceutical ingredient ("API"), a supplier of corticotrophin API with whom we have advanced the manufacture of commercial scale batches of API, and a Cortrophin gel fill/finish contract manufacturer. During the second quarter of 2021, we submitted a Supplemental New Drug Application ("sNDA") to the FDA.

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

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

We plan to continue to invest behind Cortrophin Gel and our Rare Disease platform in 2023 and beyond.

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 designation filings. Additionally, we will continue to seek opportunities to enhance our capabilities through strategic partnerships and acquisitions of assets and businesses. On July 21, 2022, we completed an asset acquisition of four ANDAs from Oakrum Pharma, including two that were commercial at the time of acquisition.

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, all of which influence the level of competition upon product launch. These criteria include:

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

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

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

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

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

- ***Competition.*** When determining whether to develop or acquire a product, we research existing and expected competition. We seek to develop products for which we can obtain sufficient market share and may decline to develop a product if we anticipate significant competition. Our specialized manufacturing facilities provide a

means of entering niche markets, such as hormone therapies, in which fewer generic companies are able to compete.

Fiscal 2022 Developments

Restructuring Update

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

Operating Segment Update

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

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

Asset Acquisitions

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

Product Launches

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

Purified Cortrophin Gel Approval and Launch

Purified Cortrophin Gel became available to our customers in late 2021, and we recognized an immaterial amount of revenues during the year ended December 31, 2021. On January 24, 2022, we announced the full-scale U.S. commercial availability and launch of Purified Cortrophin Gel.

COVID-19 Impact

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

COVID-19 pandemic during 2022, including significant lead times for purchases of materials. The pandemic has not impacted our access to capital and has not significantly impacted our use of funds.

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

General

Impacts to our 2022 and 2021 results of operations, including to net revenues, operating expenses, interest and other expense, net, and income taxes are described below. Our results of operations for the year ended December 31, 2022 were impacted by the November 19, 2021 acquisition of Novitium and related activity subsequent to that date. The acquisition provides additional revenues and the incurrence of increased costs, including but not limited to the amortization of intangible assets acquired, other operating costs, and increased interest costs on borrowings used to finance the transaction. During the year ended December 31, 2022, Novitium operations generated $90.3 million in net revenues.

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

	Year Ended December 31,	
(in thousands)	2022	2021
Net revenues	$ 316,385	$ 216,136
Operating expenses		
Cost of sales (exclusive of depreciation and amortization)	138,785	100,610
Research and development	22,318	11,369
Selling, general, and administrative	124,044	84,294
Depreciation and amortization	56,972	47,252
Contingent consideration fair value adjustment	3,758	500
Legal settlement expense	—	8,750
Purified Cortrophin Gel pre-launch charges	—	780
Restructuring activities	5,679	—
Intangible asset impairment charge	112	2,374
Operating loss	(35,283)	(39,793)
Interest expense, net	(28,052)	(11,922)
Other income/(expense), net	670	(4,343)
Loss before benefit for income taxes	(62,665)	(56,058)
Benefit for income taxes	14,769	13,455
Net loss	$ (47,896)	$ (42,603)

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,	
	2022	2021
Net revenues	100.0 %	100.0 %
Operating expenses		
Cost of sales (exclusive of depreciation and amortization)	43.9 %	46.5 %
Research and development	7.1 %	5.3 %
Selling, general, and administrative	39.2 %	39.0 %
Depreciation and amortization	18.0 %	21.9 %
Contingent consideration fair value adjustment	1.2 %	0.2 %
Legal settlement expense	— %	4.0 %
Purified Cortrophin Gel pre-launch charges	— %	0.4 %
Restructuring activities	1.8 %	— %
Intangible asset impairment charge	— %	1.1 %
Operating loss	(11.2)%	(18.4)%
Interest expense, net	(8.9)%	(5.5)%
Other income/(expense), net	0.2 %	(2.0)%
Loss before benefit for income taxes	(19.9)%	(25.9)%
Benefit for income taxes	4.7 %	6.2 %
Net loss	(15.2)%	(19.7)%

Results of Operations for the Years Ended December 31, 2022 and 2021

Net Revenues

	Year Ended December 31,			
(in thousands)	2022	2021	Change	% Change
Generics, Established Brands, and Other Segment				
Generic pharmaceutical products	$ 210,121	$ 143,571	$ 66,550	46.4 %
Established brand pharmaceutical products	39,463	47,561	(8,098)	(17.0)%
Contract manufacturing	16,106	10,042	6,064	60.4 %
Royalty and other	9,009	14,962	(5,953)	(39.8)%
Generics, established brands, and other segment total net revenues	$ 274,699	$ 216,136	$ 58,563	27.1 %
Rare Disease Segment				
Rare disease pharmaceutical products	$ 41,686	$ —	$ 41,686	NM [1]
Total net revenues	$ 316,385	$ 216,136	$ 100,249	46.4 %

We derive substantially all of our revenues from sales of generic, established brand, and rare disease pharmaceutical products, contract manufacturing, royalties on net sales of certain products, and other services, including development services, and laboratory services. Many of our established brand products 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, 2022 were $316.4 million compared to $216.1 million for the same period in 2021, an increase of $100.2 million, or 46.4%, primarily as a result of the following factors:

- Net revenues for generic pharmaceutical products were $210.1 million during the year ended December 31, 2022, an increase of 46.4% compared to $143.6 million for the same period in 2021. From a product perspective, the increase was principally driven by revenues from products acquired in our acquisition of Novitium, which increased $70.1 million, including Prazosin, Famotidine, Oxybutynin Chloride, Dapsone, Prednisone Rifabutin, and various other products. The increase was also due to increased revenues of Nebivolol, which ANI launched in September 2021. Increases were tempered by a decrease in revenues of Penicillamine, EEMT, Propranolol Extended Release, and Bexarotene. The increase in net generic revenues was principally due to the acquisition of Novitium, which drove an increase in volumes, and was tempered by a decrease in average selling prices.

  During the year ended December 31, 2022, generic prescriptions have returned to essentially pre-pandemic levels. During the year ended December 31, 2021, generic prescription levels continued to be suppressed when compared to pre-pandemic levels, most significantly during the three months ended March 31, 2021, and the revenues for many of our generic pharmaceutical products continued to be negatively impacted. Per IQVIA/IMS data, total generic market prescriptions increased sequentially during periods in 2021 and approached pre-pandemic levels near the end of the year.

- Net revenues for branded pharmaceutical products were $39.5 million during the year ended December 31, 2022, a decrease of 17.0% compared to $47.6 million for the same period in 2021. From a product perspective, the net decrease was driven primarily by a decrease in sales of Casodex, InnoPran XL, Inderal XL and Veregen. These decreases were tempered primarily by an increase in sales of Lipofen, Atacand, and Vancocin. The decrease in branded pharmaceutical product revenues for the year ended December 31, 2022 was principally due to lower unit volume sales on key branded products in addition to higher levels of returns and rebates.

  As of the end of the 2021 fiscal year, brand prescription levels returned to pre-pandemic levels.

- Contract manufacturing revenues were $16.1 million during the year ended December 31, 2022, an increase of 60.4% compared to $10.0 million for the same period in 2021, due to an increase in the volume of orders, primarily related to Novitium contract manufacturing revenues in 2022.

- Royalty and other were $9.0 million during the year ended December 31, 2022, a decrease of $6.0 million from $15.0 million for the same period in 2021, primarily due to the one-time recognition of the final royalty of $11.2 million under the Kite Pharma, Inc. license agreement (Yescarta®) pursuant to the Tripartite Agreement in the year ended December 31, 2021. Royalty revenue for the year ended December 31, 2022 includes $5.2 million related to Novitium arrangements.

- Net revenues of rare disease pharmaceutical products, which consists entirely of sales of Purified Cortrophin Gel, were $41.7 million during the year ended December 31, 2022, as the product was launched in late January 2022. There were no sales of rare disease pharmaceutical products during 2021.

Cost of Sales (Excluding Depreciation and Amortization)

	Year Ended December 31,			
(in thousands)	2022	2021	Change	% Change
Cost of sales (excl. depreciation and amortization)	$ 138,785	$ 100,610	$ 38,175	37.9 %

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

For the year ended December 31, 2022, cost of sales increased to $138.8 million from $100.6 million for the same period in 2021, an increase of $38.2 million or 37.9%. The increase is primarily due to increased volumes of generic products, including $34.7 million of costs related to activities of Novitium during the year ended December 31, 2022, compared to $4.0 million in the prior year period, and $5.3 million in costs representing the excess of fair value over cost for inventory acquired in an asset acquisition and a business combination, of which $3.2 million relates to inventory acquired from Novitium. Charges for the excess of fair value over cost for inventory acquired in an asset acquisition were $5.4 million for the comparable period in 2021. Sales of products subject to profit sharing arrangements also accounted for a $3.0 million increase in the current year period.

Cost of sales as a percentage of net revenues, exclusive of the impacts related to excess of fair value over the cost of inventory sold during the period, increased to 42.2% during the year ended December 31, 2022, from 43.1% during the same period in 2021, primarily as a result of increased volumes in a period of declining average selling prices across generic and brand products, $11.2 million in royalty revenue during the comparable 2021 period with no associated cost of goods sold, and higher costs related to sales of products subject to profit sharing arrangements.

During the year ended December 31, 2022, we purchased 19% of our inventory from one supplier. As of December 31, 2022, the amount payable to this supplier was $10.9 million. During the year ended December 31, 2021, no single vendor represented at least 10% of inventory purchases.

Other Operating Expenses

(in thousands)	Year Ended December 31, 2022	2021	Change	% Change
Research and development	$ 22,318	$ 11,369	$ 10,949	96.3 %
Selling, general, and administrative	124,044	84,294	39,750	47.2 %
Depreciation and amortization	56,972	47,252	9,720	20.6 %
Contingent consideration fair value adjustment	3,758	500	3,258	NM (1)
Legal settlement expense	—	8,750	(8,750)	(100.0)%
Purified Cortrophin Gel pre-launch charges	—	780	(780)	(100.0)%
Restructuring activities	5,679	—	5,679	NM (1)
Intangible asset impairment charge	112	2,374	(2,262)	NM (1)
Total other operating expenses	$ 212,883	$ 155,319	$ 57,564	37.1 %

(1) Not meaningful

For the year ended December 31, 2022, other operating expenses increased to $212.9 million from $155.3 million for the same period in 2021, an increase of $57.6 million, or 37.1%, primarily as a result of the following factors:

- Research and development expenses increased from $11.4 million to $22.3 million, an increase of 96.3%, primarily due to expenses related to Novitium activities during the year ended December 31, 2022, in-process research and development charges of $1.2 million recognized in the current year, tempered by a $1.5 million decrease in expense associated with our Cortrophin development efforts due to approval of the launch of the product.

- Selling, general, and administrative expenses increased from $84.3 million to $124.0 million, an increase of 47.2%, primarily due to a $37.6 million increase in sales and marketing expenses related to our launch of Purified Cortrophin Gel, increases related to the addition of Novitium headcount and activities during the year ended December 31, 2022, tempered by a $8.1 million decrease in transaction expenses related to the Novitium acquisition.

- Depreciation and amortization expense was $57.0 million for the year ended December 31, 2022, compared to $47.3 million for the year ended December 31, 2021. The increase is primarily due to the amortization of intangible assets acquired in the Novitium acquisition.

- As described in Note 9, *Fair Value Disclosures*, in the notes to the consolidated financial statements included in Part II, Item 8. of this Annual Report on Form 10-K, we recognized a contingent consideration fair value

adjustment related to the Novitium acquisition of $3.8 million and $0.5 million in the year ended December 31, 2022 and 2021, respectively. The expense is principally due to the passage of time (i.e. moving closer to the ultimate payment date of the consideration, rather than the change in any other variables).

- As described in Note 13, *Commitments and Contingencies*, in the notes to the consolidated financial statements included in Part II, Item 8. of this Annual Report on Form 10-K, we recognized legal settlement expense of $8.8 million in the year ended December 31, 2021, principally related to settlement of the Arbor matter. No legal settlement expenses were recognized in the year ended December 31, 2022.

- As described in Note 14, *Purified Cortrophin Gel Pre-Launch Charges*, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K, we recognized Cortrophin pre-launch charges related to purchases of materials of $0.8 million in the year ended December 31, 2021. No Cortrophin pre-launch charges related to purchases of materials were recognized in the year ended December 31, 2022.

- We recognized restructuring activities of $5.7 million of expense in the year ended December 31, 2022, in relation to the anticipated 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. No restructuring activities were recognized in the year ended December 31, 2021.

- We recognized an impairment of $0.1 million in the year ended December 31, 2022, in relation to an ANDA asset. We recognized an impairment of $2.4 million in the year ended December 31, 2021, in relation to an ANDA asset.

Other Expense, net

	Year Ended December 31,			
(in thousands)	2022	2021	Change	% Change
Interest expense, net	$ (28,052)	$ (11,922)	$ (16,130)	135.3 %
Other income/(expense), net	670	(4,343)	5,013	(115.4)%
Total other expense, net	$ (27,382)	$ (16,265)	$ (11,117)	68.3 %

For the year ended December 31, 2022, we recognized other expense, net of $27.4 million versus other expense, net of $16.3 million for the same period in 2021, an increase of $11.1 million. Interest expense, net for 2022 consisted primarily of interest expense on our Term Facility. Interest expense, net for 2021 consisted primarily of interest expense on our Term Loan, DDTL, and Revolver under our Prior Credit Facility, and interest expense on our new Term Facility subsequent to the termination of our Prior Credit Facility and entry into new Credit Facility on November 19, 2021. The increase in interest expense is due to an increase in the debt outstanding during the year ended December 31, 2022, coupled with an increased borrowing rate on the $300.0 million Term Facility, as compared to the borrowing rate on the Prior Credit Agreement borrowings and an increase in amortization of finance fees. The $5.0 million change in other income/(expense), net is primarily related to the $0.8 million gain on the sale of an ANDA in the year ended December 31, 2022 and the non-recurrence of $4.2 million ticking fee expense related to our Credit Facility that was syndicated on May 24, 2021, a $1.5 million loss on the extinguishment of debt related to our Prior Credit Facility, and $1.8 million in net gains on the sale of ANDAs in the year ended December 31, 2021. For the year ended December 31, 2022 and 2021, there was $0.1 million of interest capitalized into construction in progress.

Benefit for Income Taxes

	Year Ended December 31,			
(in thousands)	2022	2021	Change	% Change
Benefit for income taxes	$ 14,769	$ 13,455	$ 1,314	9.8 %

Our benefit for income taxes consists of current and deferred components, which include changes in our deferred tax assets, our deferred tax liabilities, and our valuation allowance. We measure our deferred tax assets and liabilities using the tax rates that we believe will apply in the years in which the temporary differences are expected to be recovered or paid. See Note 12. 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, 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.

For the year ended December 31, 2021, we recognized an income tax benefit of $13.5 million, an effective benefit rate of 24.0% of consolidated pre-tax losses reported in the period. Our effective tax rate for 2021 was impacted by changes in state tax rates due to our increased presence in certain states, certain non-deductible expenses, and the impact of current period stock-based compensation, among other items.

Liquidity and Capital Resources

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

(in thousands)	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 48,228	$ 100,300
Current restricted cash	5,006	—
Accounts receivable, net	165,438	128,526
Inventories, net	105,355	81,693
Prepaid income taxes	3,827	3,667
Assets held for sale	8,020	—
Prepaid expenses and other current assets	8,387	7,589
Total current assets	$ 344,261	$ 321,775
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	29,305	22,967
Accrued expenses and other	5,394	7,563
Accrued royalties	9,307	6,225
Accrued compensation and related expenses	10,312	8,522
Accrued government rebates	10,872	5,492
Returned goods reserve	33,399	35,831
Deferred revenue	—	87
Total current liabilities	$ 99,439	$ 87,537

On December 31, 2022, we had $48.2 million in unrestricted cash and cash equivalents. On December 31, 2021, we had $100.3 million in unrestricted cash and cash equivalents. In 2022 and 2021, we invested in leadership, expertise, and infrastructure in the areas of commercialization of rare disease therapies and in 2022 commercialized our Cortrophin Gel product.

In 2021, we financed the acquisition of Novitium in part with borrowings under the Credit Facility described below under “Sources and Uses of Cash – Debt Financing,” and by a $25.0 million PIPE Investment by Ampersand 2020 Limited Partnership (“Ampersand”).

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 3.5 as of December 31, 2022. Despite a use of cash of $31.2 million by operating activities, we believe that our financial resources, consisting of net current working capital of approximately $244.8 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, 2022, 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 profitable or do not generate cash from operations as anticipated and additional capital is needed to support operations, we may be unable to obtain such financing, or obtain it on favorable terms, in which case we may be required to curtail development of new products, limit expansion of operations, or accept financing terms that are not as attractive as desired.

Consolidation among wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies each controlling a larger share of pharmaceutical distribution channels. Our net revenues were concentrated among three customers representing 26%, 18%, and 15% of net revenues during the year ended December 31, 2022. As of December 31, 2022 accounts receivable from these three customers totaled approximately 82% of accounts receivable, net. Our net revenues were concentrated among three customers representing 29%, 23%, and 16% of net revenues during the year ended December 31, 2021. 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 13% of our net revenues in 2022. None of our products accounted for 10% or more of our net revenues in 2021.

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 Credit Facility is secured by substantially all our assets and the assets of our domestic subsidiaries.

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

The Term Facility matures in November 2027 and the Revolving Facility in November 2026. Each permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the LIBOR Rate (or alternate benchmark rate as defined in the Credit Agreement, which includes a floor of 0.75%) in the case of loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the LIBOR Rate (as defined in the Credit Agreement) in the case of loans under the Revolving Facility. The Credit Facility has a subjective acceleration clause in case of a material adverse effect. The Term Facility includes a repayment schedule, pursuant to which $750 thousand of the loan will be paid in quarterly installments during the 12 months ending December 31, 2023. As of December 31, 2022, $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, 2022, we had not drawn on the Revolving Facility and $40.0 million remained available for borrowing subject to certain conditions.

Equity Financing

Concurrently with the execution of the merger agreement related to the Novitium acquisition, on March 8, 2021, we entered into that certain Equity Commitment and Investment Agreement with Ampersand 2020 Limited Partnership (the "PIPE Investor") pursuant to which, on November 19, 2021, we issued and sold to the PIPE Investor, and the PIPE Investor purchased, 25,000 shares of our Series A Convertible Preferred Stock, for a purchase price of $1,000 per share and an aggregate purchase price of $25.0 million, in a private placement issued in reliance on the exemption from registration provided by Section 4(a)(2) of the Securities Act of 1933, as amended, and/or Regulation D promulgated thereunder.

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

Customer Payments

In addition to the financings in prior years, payments from customers are a significant source of cash in 2022, 2021, and 2020 and were our primary source of cash in 2022 and 2021.

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 9 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.

In the second quarter 2021, we drew $24.0 million under the Revolver of our Prior Credit Agreement, of which $20.7 million was used to fund the acquisition of three NDAs and an ANDA and certain related inventories from Sandoz Inc. In the third quarter 2021, we utilized $8.4 million of cash on hand to settle litigation with Arbor.

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)	2022	2021
Operating Activities	$ (31,203)	$ 3,322
Investing Activities	$ (15,738)	$ (105,483)
Financing Activities	$ (5,126)	$ 194,595

Net Cash (Used in) / Provided by Operating Activities

Net cash used in operating activities was $31.2 million for the year ended December 31, 2022, compared to $3.3 million provided by operating activities during the same period in 2021, a change of $34.5 million. The use of cash was driven by our net loss and changes in working capital, including increases to accounts receivable and inventory of $31.4 million and $26.9 million, respectively, since December 31, 2021, due in part to a number of new product launches during the year ended December 31, 2022.

Net Cash Used in Investing Activities

Net cash used in investing activities for the year ended December 31, 2022 was $15.7 million, principally due to the acquisition of four ANDAs from Oakrum Pharma LLC for $8.0 million consisting of $7.2 million of cash and $0.8 million of other consideration, and $8.9 million of capital expenditures partially offset by $0.8 million proceeds from sale of long-lived assets during the period.

Net Cash (Used in) / Provided by Financing Activities

Net cash used in financing activities was $5.1 million for the year ended December 31, 2022 compared to $194.6 million in cash provided by financing activities for the year ended December 31, 2021, 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 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, 2022 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, 2022, the principal amount of our Term Facility was $297.0 million. The interest rate on our Term Facility is currently 1-month LIBOR plus 6.00%, subject to a 0.75% floor. The interest rate under the Term Facility as of December 31, 2022 is 6.75%. See Note 4, 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 LIBOR-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 LIBOR, subject to a 0.75% floor, on the outstanding notional value. As of December 31, 2022, the notional value of the interest rate swap was $151.5 million. See Note 5, 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 13, 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.

Purchase obligations primarily includes contractual obligation for inventory/material purchase minimums and service agreements. We have a supply agreement with one vendor that includes purchase minimums. Pursuant to this agreement, we will be required to purchase a total of $0.1 million of API from this vendor during the year ended December 31, 2023. Most of our other purchase obligations are related to purchases of information technology services, marketing arrangements, or other service contracts.

Our convertible preferred stock ("PIPE Shares") also 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 10, 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 includes $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. Payments of $25.0 million would be due if gross profit and regulatory milestones are achieved by November 30, 2023, and up to $21.5 million of payments may be made for up to ten years based on a percentage of net profits on products launched in the future. See Note 2, Business Combination, 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

This Management's Discussion and Analysis of Financial Condition and Results of Operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the reporting period. The SEC has defined a company's critical accounting policies as the ones that are most important to the portrayal of the company's financial condition and results of operations, and which require the company to make its most difficult and subjective judgments, often as a result of the need to make estimates of matters that are inherently uncertain. Based on this definition, we have identified the critical accounting policies and judgments addressed below. We also have other key accounting policies, which involve the use of estimates, judgments, and assumptions that are significant to understanding our results.

Our significant accounting policies are discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K. 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

We recognize revenue using the following steps:

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

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

Our revenue recognition accounting methodologies contain uncertainties because they require management to make assumptions and to apply judgment to estimate the amount of discounts, rebates, promotional adjustments, price adjustments, returns, chargebacks, and other potential adjustments, which are accounted for as reductions to revenue. We make these estimates based on historical experience. In addition, for our product development services revenue, we recognize revenue on a percentage of completion basis, which requires judgments related to how much work has been completed on various components our projects.

Revenue from Sales of Generic and Branded Pharmaceutical Products

Product sales consists of sales of our generic and brand pharmaceutical products. Our sole performance obligation in our contracts is to provide pharmaceutical products to customers. Our products are sold at pre-determined standalone selling prices and our performance obligation is considered to be satisfied when control of the product is transferred to the customer. Control is generally transferred to the customer upon delivery of the product to the customer, as our pharmaceutical products are generally sold on an FOB destination basis and because inventory risk and risk of ownership passes to the customer upon delivery. Payment terms for these sales are generally fewer than 100 days. We recognized $249.6 million and $191.1 million of revenue related to sales of generic and branded pharmaceutical products in 2022 and 2021, respectively.

Revenue from Distribution Agreements

From time to time, 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. We have assessed and determined that we control 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, we recognize revenue on a gross basis when control has passed to the customer and we have satisfied our performance obligation. Under these agreements, we pay these 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 our consolidated statements of operations and are accrued in accrued royalties in our consolidated balance sheets until payment has occurred.

Chargebacks

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K, we estimate the amount of

chargebacks based our actual historical experience. A number of factors influence current period chargebacks by impacting the average selling price ("ASP") of products, including customer mix, negotiated terms, volume of off-contract purchases, and wholesale acquisition cost ("WAC").

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 10% change in the chargeback estimates throughout the year, our net revenues would be affected by $64.2 million for the year ended December 31, 2022.

Government Rebates

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K, our estimates for government rebates are based upon several factors. Our estimates for Medicaid rebates are based upon our average manufacturer price, best price, product mix, levels of inventory in the distribution channel that we expect to be subject to Medicaid rebates, and historical experience, which are invoiced in arrears by state Medicaid programs. Our estimates for Medicare rebates are based on historical experience. While such experience has allowed for reasonable estimation in the past, history may not always be an accurate indicator of future rebate experience, and trends in Medicaid and Medicare enrollment and which products are covered by Medicaid and Medicare could change.

If actual results were not consistent with our estimates, 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 $2.1 million for the year ended December 31, 2022.

Returns

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K, our estimate for returns is based upon our 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.

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 $2.3 million for the year ended December 31, 2022.

Administrative Fees and Other Rebates

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K, we accrue for fees and rebates by product by wholesaler, at the time of sale based on contracted rates, ASPs, and on-hand inventory counts obtained from wholesalers.

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 $4.2 million for the year ended December 31, 2022.

Prompt Payment Discounts

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K, we reserve for sales discounts based on invoices outstanding, assuming, based on past experience, that 100% of available discounts will be taken.

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 $2.1 million for the year ended December 31, 2022.

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consist of agreements in which we manufacture a pharmaceutical product on behalf of third party. Our performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The contract manufactured products are sold at pre-determined standalone selling prices and our performance obligations are considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves our dock to be shipped to the customer, as our contract manufacturing products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally fewer than two months. We estimate returns based on historical experience. Historically, we have not had material returns for contract manufactured products. We recognized $16.1 million and $10.0 million of revenue related to sales of contract manufactured products in 2022 and 2021, respectively.

Royalties from Licensing Agreements

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

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

Historically, we recorded royalty income related to Yescarta® on an accrual basis utilizing our best estimate of royalties earned based upon information available in the public domain, our understanding of the various agreements governing the royalty, and other information received from time to time from the relevant parties. Generally, cash was received directly from Cabaret once a year. The agreements governing this royalty were subject to multiple actions in multiple jurisdictions, including litigation between Cabaret and Kite, and separately, ANI and Cabaret. In the first quarter of 2021, we became aware that the litigation between Cabaret and Kite was dismissed. In April 2021, Cabaret and the Company settled all amounts due for amounts actually received by Cabaret or Eshhar for the licensing or use of the patent rights governed by the Kite license agreement. As a result, we recognized $11.2 million as royalties from

licensing agreements in our net revenues during the three month period ended March 31, 2021. In addition, during the three month period ended March 31, 2021, we agreed to reimburse Cabaret $0.4 million, which has been recorded as other expense, net in the accompanying unaudited interim condensed consolidated statement of operations, related to certain legal expenditures incurred. We received final payment from Cabaret in May 2021. Based upon the events that led to the dismissal of the litigation between Cabaret and Kite, we do not expect to receive any future royalty income related to the Kite license agreement. In conjunction with payment of amounts due to us, all outstanding litigation between the Company and Cabaret was dismissed.

Product Development Services Revenue

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

The duration of these technical transfer projects can be up to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a percentage of completion basis, which results in contract assets on our balance sheet. We recognize revenue on a proportional basis, which results in contract assets on our balance sheet. We recognized $2.9 million and $1.3 million of revenue related to product development services in 2022 and 2021, respectively.

Intangible Assets

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K, our definite-lived intangible assets have a carrying value of $225.1 million as of December 31, 2022. These assets include ANDAs, NDAs and product rights, marketing and distribution rights, customer relationships, and a non-compete agreement. These intangible assets were originally recorded at fair value for business combinations and at relative fair value based on the purchase price for asset acquisitions and are stated net of accumulated amortization. During the third quarter of 2022, we added $7.2 million in ANDA intangible assets related to the July 21, 2022 transaction with Oakrum Pharma, LLC. These assets will be amortized over a seven-year useful life.

The ANDAs, NDAs and product rights, marketing and distribution rights, customer relationships, and non-compete agreement are amortized over their remaining estimated useful lives, ranging from seven to 10 years, generally based on the straight-line method unless a pattern reflecting consumption of their economic benefits is readily available. The estimated useful lives directly impact the amount of amortization expense recorded for these assets on a quarterly and annual basis.

We test for impairment of definite-lived intangible assets when events or circumstances indicate that the carrying value of the assets may not be recoverable. Judgment is used in determining when these events and circumstances arise. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss. If the fair value of an intangible asset is determined to be lower than its carrying value, we could be exposed to an impairment charge that could be material.

Our indefinite-lived intangible assets other than goodwill have a carrying value of $26.6 million as of December 31, 2022. These assets include in-process research and development projects (“IPR&D”) acquired in the Novitium acquisition. 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. During the year ended December 31, 2022, $20.3 million was reclassified from IPR&D to ANDA intangible assets upon completion of projects and launch of related products.

We test for impairment of indefinite-lived intangible assets 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. If we determine that the carrying value of the assets may not be

recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss.

If the fair value of an intangible asset is determined to be lower than its carrying value, we could be exposed to an impairment charge that could be material. During the year ended December 31, 2022, we 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, we recognized a full impairment of a definite-lived ANDA asset with a remaining carrying value of $2.4 million.

Goodwill

As discussed in Note 1. Description of Business and Summary of Significant Accounting Policies, in the notes to the consolidated financial statements in Part II, Item 8. of this Annual Report on Form 10-K, our goodwill balance relates to our 2013 merger with BioSante Pharmaceuticals, Inc., the acquisition of WellSpring, and the acquisition of Novitium and represents the excess of the total purchase consideration over the fair value of acquired assets and assumed liabilities, using the purchase method of accounting. Goodwill is not amortized, but is subject to periodic review for impairment. As a result, the amount of goodwill is directly impacted by the estimates of the fair values of the assets acquired and liabilities assumed.

Goodwill is tested for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. We perform our review of goodwill on our one reporting unit. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss.

The carrying value of goodwill at December 31, 2022 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.

Contingent Consideration

The fair value of our contingent consideration was $35.1 million and $31.0 million at December 31, 2022 and 2021, 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 $3.8 million and $0.5 million during the years ended December 31, 2022 and 2021, respectively.

Stock-Based Compensation

Our Amended and Restated 2022 Stock Incentive Plan (the "2022 Plan") includes stock options and restricted stock, which are awarded in exchange for employee and non-employee director services. In July 2016, we commenced administration of our Employee Stock Purchase Plan ("ESPP"). We recognize the estimated fair value of stock-based awards and classify the expense where the underlying salaries are classified.

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

The following table summarizes stock-based compensation expense incurred under the Stock Incentive Plan, Inducement Grant, and 2016 Employee Stock Purchase Plan and included in our consolidated statements of operations:

(in thousands)	Years Ended December 31, 2022	2021	2020
Cost of sales	$ 532	$ 20	$ 137
Research and development	751	564	597
Selling, general, and administrative	13,316	9,905	12,202
	$ 14,599	$ 10,489	$ 12,936

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

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

Changes in estimates could affect compensation expense within individual periods. If there were to be a 10% change in our stock-based compensation expense for the year, our Loss before Benefit for Income Taxes would be affected by $1.5 million for the year ended December 31, 2022.

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 prevail in matters for which a liability has been established, or 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. A favorable tax settlement may reduce our effective income tax rate and would be recognized in the period of resolution.

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

Although 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**.**

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In December 2022, the Financial Accounting Standards Board issued ASU 2022-06, which extended the sunset date of the reference rate reform in ASU 848 from December 31, 2022, to December 31, 2024. We have not adopted the guidance and are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

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

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 Revolving Facility and the Term Facility each permit both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the LIBOR Rate (as defined in the Credit Facility) in the case of Eurodollar Loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the LIBOR Rate (as defined in the Credit Facility) in the case of Eurodollar Loans under the Revolving Facility.

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

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

In April 2020, we entered into an interest rate swap with Citizens Bank, N.A. to manage our exposure to changes in LIBOR-based interest rates underlying total borrowings under term facilities related to our Prior Credit Agreement. The interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Facility with Truist Bank, the interest rate swap with a notional value of $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 $151.5 million

and $165.8 million at December 31, 2022 and 2021, 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 $1.4 million. If our Revolving Facility were fully drawn and interest rates increased or decreased by 1%, interest expense would have increased or decreased by approximately $0.4 million. The interest rate swap provides an effective fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. As a result of the interest rate swap, our exposure to interest rate volatility is minimized.

We are exposed to risks associated with changes in interest rates. The returns from certain of our cash and cash equivalents will vary as short-term interest rates change. A 100 basis-point adverse movement (decrease) in short-term interest rates would decrease the interest income earned on our cash balance in the year ended December 31, 2022 by approximately $37,000.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated and Indian rupee-denominated transactions from ANI Pharmaceuticals Canada Inc. and our Indian subsidiary from the Canadian dollar to the U.S. dollar and the Indian-rupee to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the quarter ended December 31, 2022.

We are exposed to risks associated with foreign currency exchange rate risks as we remeasure certain Canadian dollar-denominated and Indian rupee-denominated transactions from ANI Pharmaceuticals Canada Inc. and our Indian subsidiary from the Canadian dollar to the U.S. dollar and the Indian-rupee to the U.S. dollar. Changes in exchange rates can positively or negatively impact our revenue, income, assets, liabilities, and equity. Currency exchange rates did not have a material impact on our revenue, income, assets, liabilities, or equity during the year ended December 31, 2022.

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, 2022 and 2021, and the related consolidated statements of operations, comprehensive (loss)/income, mezzanine equity and stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2022, 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, 2022, based on criteria established in the Internal Control - Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated March 9, 2023 expressed an adverse 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 matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which they relate.

Evaluation of Certain Assumptions Impacting the Chargeback Accrual

As described in Note 1 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, 2022, are approximately $148.6 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 significant judgment required by management with respect to measurement 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 assumptions.

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 actual information, and executed third-party contract. We performed a sensitivity analysis of the Company's 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
March 9, 2023

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, 2022, 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, because of the effect of the material weaknesses described in the following paragraph on the achievement of the objectives of the control criteria, ANI Pharmaceuticals, Inc. and Subsidiaries has not maintained effective internal control over financial reporting as of December 31, 2022, based on criteria established in the Internal Control - Integrated Framework (2013) issued by COSO.

A material weakness is a control deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weaknesses have been identified and included in management's assessment.

The Company did not maintain an effective control environment in the Novitium subsidiary as a result of the following:

- Lack of adequate personnel resources in Novitium team to implement appropriate process controls addressing Novitium activity.
- Turnover in key finance personnel at Corporate that were tasked with driving / managing implementation of internal controls at Novitium, including the Corporate Controller. While the Company hired seasoned temporary personnel in these corporate positions, the Company did not have adequate bandwidth to maintain focus on compliance with internal controls.
- Delays in execution of the extraction of the Procure to Pay cycle integration plan for the subsidiary, including creation of the Accounts Payable centers of excellence whereby processes at Novitium would be combined with legacy processes.

These factors contributed to the weaknesses in control activities, specifically, the following process areas related to activity at Novitium did not have effective controls in place and were not operating effectively for a sufficient amount of time:

- Purchase to Pay (Purchasing, Accounts Payable and Cash Disbursements)
- Manufacturing and Inventory
- Human Resources/Payroll
- Financial Statement Close (limited to those pertaining to the Novitium subsidiary level that were not incorporated into overall Company controls)
- Information technology general controls

The areas noted above had one or more of the following specific compliance exceptions:

- Certain controls were not implemented as designed.
- Documented controls not being performed consistently for all applicable transactions.
- Control performance not being adequately documented and evidenced.
- Materiality thresholds used in certain control performance were not consistent with documented control design.
- Controls not in place nor operating for a sufficient amount of time/number or instances.
- Changes to control performance upon employee turnover.
- Information technology general controls ("ITGC") which could result in misstatements potentially impacting all financial statement accounts or disclosures. Specifically, Novitium user access controls were not appropriately designed and maintained to adequately restrict user and privileged access to financial applications and data to the appropriate personnel.

The Company also identified a material weakness related to the control activities prescribed in ITGC. Specifically, the evaluation of the ITGC's identified that user access controls were not operating effectively to adequately restrict user access to the network and financial applications and data.

These material weaknesses were considered in determining the nature, timing, and extent of the audit tests applied in our audit of the December 31, 2022 financial statements, and this report does not affect our report dated March 9, 2023, on those financial statements.

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, 2022 and 2021, and the related consolidated statements of operations, comprehensive (loss)/income, mezzanine equity and stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2022, and the related notes, and our report dated March 9, 2023 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 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
March 9, 2023

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

	December 31, 2022	*December 31, 2021*
Assets		
Current Assets		
Cash and cash equivalents	$ 48,228	$ 100,300
Current restricted cash	5,006	—
Accounts receivable, net of $161,052 and $105,260 of adjustments for chargebacks and other allowances at December 31, 2022 and 2021, respectively	165,438	128,526
Inventories, net	105,355	81,693
Prepaid income taxes	3,827	3,667
Assets held for sale	8,020	—
Prepaid expenses and other current assets	8,387	7,589
Total Current Assets	344,261	321,775
Non-current Assets		
Property and equipment	75,958	75,627
Accumulated depreciation	(32,712)	(22,956)
Property and equipment, net	43,246	52,671
Non-current restricted cash	—	5,001
Deferred tax assets, net of deferred tax liabilities and valuation allowance	81,363	67,936
Intangible assets, net	251,635	294,122
Goodwill	28,221	27,888
Derivatives and other non-current assets	11,361	2,205
Total Assets	$ 760,087	$ 771,598
Liabilities, Mezzanine Equity, and Stockholders' Equity		
Current Liabilities		
Current debt, net of deferred financing costs	$ 850	$ 850
Accounts payable	29,305	22,967
Accrued royalties	9,307	6,225
Accrued compensation and related expenses	10,312	8,522
Accrued government rebates	10,872	5,492
Returned goods reserve	33,399	35,831
Accrued expenses and other	5,394	7,650
Total Current Liabilities	99,439	87,537
Non-current Liabilities		
Non-current debt, net of deferred financing costs and current component	285,669	286,520
Non-current contingent consideration	35,058	31,000
Derivatives and other non-current liabilities	1,381	7,801
Total Liabilities	$ 421,547	$ 412,858
Commitments and Contingencies (Note 13)		
Mezzanine Equity		
Convertible Preferred Stock, Series A, $0.0001 par value, 1,666,667 shares authorized; 25,000 shares issued and outstanding at December 31, 2022 and December 31, 2021	24,850	24,850
Stockholders' Equity		
Common Stock, $0.0001 par value, 33,333,334 shares authorized; 17,643,497 shares issued and 17,494,466 outstanding at December 31, 2022; 16,912,401 shares issued and 16,829,739 shares outstanding at December 31, 2021	1	1
Class C Special Stock, $0.0001 par value, 781,281 shares authorized; 10,864 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Preferred Stock, $0.0001 par value, 1,666,667 shares authorized; 0 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	—	—
Treasury stock, 149,031 shares of common stock, at cost, at December 31, 2022 and 82,662 shares of common stock, at cost, at December 31, 2021	(5,094)	(3,135)
Additional paid-in capital	403,901	387,844
Accumulated deficit	(97,286)	(47,765)
Accumulated other comprehensive income/(loss), net of tax	12,168	(3,055)
Total Stockholders' Equity	313,690	333,890
Total Liabilities, Mezzanine Equity, and Stockholders' Equity	$ 760,087	$ 771,598

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,		
	2022	***2021***	***2020***
Net Revenues	$ 316,385	$ 216,136	$ 208,475
Operating Expenses			
Cost of sales (excluding depreciation and amortization)	138,785	100,610	87,157
Research and development	22,318	11,369	16,001
Selling, general, and administrative	124,044	84,294	64,986
Depreciation and amortization	56,972	47,252	44,638
Contingent consideration fair value adjustment	3,758	500	—
Legal settlement expense	—	8,750	—
Purified Cortrophin Gel pre-launch charges	—	780	11,263
Restructuring activities	5,679	—	—
Intangible asset impairment charge	112	2,374	446
Total Operating Expenses	351,668	255,929	224,491
Operating Loss	(35,283)	(39,793)	(16,016)
Other Expense, net			
Interest expense, net	(28,052)	(11,922)	(9,452)
Other income/(expense), net	670	(4,343)	(494)
Loss Before Benefit for Income Taxes	(62,665)	(56,058)	(25,962)
Benefit for income taxes	14,769	13,455	3,414
Net Loss	$ (47,896)	$ (42,603)	$ (22,548)
Dividends on Series A Convertible Preferred Stock	$ (1,625)	$ (190)	$ —
Net Loss Available to Common Shareholders	$ (49,521)	$ (42,793)	$ (22,548)
Basic and Diluted Loss Per Share:			
Basic Loss Per Share	$ (3.05)	$ (3.40)	$ (1.88)
Diluted Loss Per Share	$ (3.05)	$ (3.40)	$ (1.88)
Basic Weighted-Average Shares Outstanding	16,260	12,596	11,964
Diluted Weighted-Average Shares Outstanding	16,260	12,596	11,964

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

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

	Years Ended December 31,		
	2022	***2021***	***2020***
Net loss	$ (47,896)	$ (42,603)	$ (22,548)
Other comprehensive income/(loss), net of tax:			
Foreign currency translation adjustment	(112)	12	—
Gains/(losses) on interest rate swap	15,335	8,370	(6,566)
Total other comprehensive income/(loss), net of tax	15,223	8,382	(6,566)
Total comprehensive loss, net of tax	$ (32,673)	$ (34,221)	$ (29,114)

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, 2022, 2021, and 2020
(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, 2019	$ —	—	$ 1	12,105	$ —	$ 200,800	15	$ (723)	$ (4,871)	$ 17,584	$ 212,791
Cumulative Effect of Change in Accounting Principle, Net of Tax	—	—	—	—	—	—	—	—	—	(8)	(8)
Stock-based Compensation Expense	—	—	—	—	—	12,936	—	—	—	—	12,936
Treasury Stock Purchases for Restricted Stock Vests	—	—	—	—	—	—	61	(1,523)	—	—	(1,523)
Issuance of Common Shares upon Stock Option and ESPP Exercise	—	—	—	21	—	618	—	—	—	—	618
Issuance of Restricted Stock Awards	—	—	—	304	—	—	—	—	—	—	—
Other comprehensive income	—	—	—	—	—	—	—	—	(6,566)	—	(6,566)
Net Loss	—	—	—	—	—	—	—	—	—	(22,548)	(22,548)
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

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,		
	2022	2021	2020
Cash Flows From Operating Activities			
Net loss	$ (47,896)	$ (42,603)	$ (22,548)
Adjustments to reconcile net loss to net cash and cash equivalents (used in)/provided by operating activities:			
Stock-based compensation	14,599	10,489	12,936
Deferred taxes	(15,253)	(16,754)	(13,205)
Depreciation and amortization	59,653	47,252	44,638
Acquired in-process research and development ("IPR&D")	1,151	—	3,753
Non-cash interest	3,961	2,512	1,876
Contingent consideration fair value adjustment	4,058	500	—
Loss on extinguishment of debt	—	1,458	—
Asset impairment charges	574	2,374	445
Gain on sale of ANDAs	(750)	(1,822)	—
Changes in operating assets and liabilities, net of acquisition:			
Accounts receivable, net	(36,912)	(5,548)	(23,664)
Inventories, net	(23,626)	3,224	(2,759)
Prepaid expenses and other current assets	(798)	127	(1,866)
Accounts payable	5,038	10,166	(2,294)
Accrued royalties	3,082	(267)	1,323
Current income taxes payable, net	(160)	(7,573)	4,982
Accrued government rebates	5,380	(3,078)	(1,075)
Returned goods reserve	(2,399)	6,503	10,369
Accrued expenses, accrued compensation, and other	(905)	(3,638)	2,356
Net Cash and Cash Equivalents (Used in)/Provided by Operating Activities	(31,203)	3,322	15,267
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	(7,579)	(21,081)	(62,187)
Acquisition of property and equipment, net	(8,876)	(2,557)	(6,135)
Proceeds from the sale of long-lived assets	750	2,649	—
Net Cash and Cash Equivalents Used in Investing Activities	(15,738)	(105,483)	(68,322)
Cash Flows From Financing Activities			
Payments on Term Loan and Delayed Draw Term Loan agreements	—	(10,862)	—
Payments on borrowings under credit agreements	(3,000)	—	(8,034)
Payments on Revolver agreement	—	—	(7,500)
Borrowings under Prior Revolver agreement	—	24,000	15,000
Repayment of Prior Credit Facility	—	(200,148)	—
Borrowings under the Credit Facility	—	300,000	—
Proceeds from issuance of convertible preferred stock	—	25,000	—
Series A convertible preferred stock dividends paid	(1,625)	(190)	—
Proceeds from issuance of common stock in public offering	—	75,000	—
Cash paid for costs of share issuances	—	(5,416)	—
Proceeds from stock option exercises and ESPP purchases	1,458	2,069	618
Payments of debt issuance costs	—	(13,968)	—
Treasury stock purchases for restricted stock vests	(1,959)	(890)	(1,523)
Net Cash and Cash Equivalents (Used in)/Provided by Financing Activities	(5,126)	194,595	(1,439)
Net Change in Cash and Cash Equivalents	(52,067)	92,434	(54,494)
Cash and cash equivalents, beginning of period	105,301	12,867	67,361
Cash and cash equivalents, end of period	$ 53,234	$ 105,301	$ 12,867
Reconciliation of cash, cash equivalents, and restricted cash, beginning of period			
Cash and cash equivalents	100,300	7,864	62,332
Restricted cash	5,001	5,003	5,029
Cash, cash equivalents, and restricted cash, beginning of period	105,301	12,867	67,361
Reconciliation of cash, cash equivalents, and restricted cash, end of period			
Cash and cash equivalents	48,228	100,300	7,864
Restricted cash	5,006	5,001	5,003
Cash, cash equivalents, and restricted cash, end of period	53,234	105,301	12,867
Supplemental disclosure for cash flow information:			
Cash paid for interest, net of amounts capitalized	$ 21,477	$ 9,705	$ 6,931
Cash paid for income taxes	$ 288	$ 10,371	$ 4,984
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	$ —	$ 391
Property and equipment purchased and included in accounts payable	$ 452	$ 152	$ 172

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. Our team is focused on delivering growth by building a successful Purified Cortrophin Gel franchise, strengthening our generics business with enhanced development capability, innovation in established brands and leveraging our manufacturing capabilities. Our four pharmaceutical manufacturing facilities, of which two are located in Baudette, Minnesota, one is located in East Windsor, New Jersey, and one is located in Oakville, Ontario, are together capable of producing oral solid dose products, as well as semi-solids, liquids and topicals, controlled substances, and potent products that must be manufactured in a fully-contained environment. On June 2, 2022, we announced that we intend to cease operations at our Oakville, Ontario, Canada manufacturing plant by first quarter 2023. This action is part of ongoing initiatives to capture operational synergies following our acquisition of Novitium Pharma LLC ("Novitium") in November 2021. We have transitioned the majority of products manufactured or packaged in Oakville to one of our three U.S.-based manufacturing sites and are on track to cease operations by the end of the first quarter 2023. We are seeking to find potential buyers for the Oakville site.

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").

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

We have subsidiaries located in Canada and India. The Canada-based subsidiary conducts its transactions in U.S. dollars and Canadian dollars, but its functional currency is the U.S. dollar. The Indian-based subsidiary generally conducts its transactions in Indian rupees, which is also its functional currency. The results of any non-U.S. dollar transactions and balances are remeasured in U.S. dollars at the applicable exchange rates during the period and resulting foreign currency transaction gains and losses are included in the determination of net income. Our gain or loss on transactions denominated in foreign currencies and the translation impact of local currencies to U.S. dollars was immaterial for the years ended December 31, 2022, 2021, and 2020. Unless otherwise noted, all references to "$" or "dollar" refer to the U.S. dollar.

Use of Estimates

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

We are subject to risks and uncertainties as a result of the novel coronavirus ("COVID-19") pandemic. We are unable to predict the impact that the COVID-19 pandemic will continue to have on our future business, financial condition, and results of operations due to numerous uncertainties. These uncertainties include the occurrence of recurring outbreaks and their severity and the duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact and the direct and indirect economic effects of the pandemic and containment measures, among others. We remain unable to predict the future impact on our estimates and assumptions. There was no material impact to these estimates or assumptions in our consolidated financial statements as of and for the years ended December 31, 2022 and 2021. Actual results could differ from those estimates, which may change our estimates in future periods. We continue to closely monitor the impact of the COVID-19 pandemic on our business.

Leases

At the inception of a contract we determine if the arrangement is, or contains, a lease. Right-of-use ("ROU") assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease 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.

We have made certain accounting policy elections whereby we (i) do not recognize ROU assets or lease liabilities for short-term leases (those with original terms of 12-months or less) and (ii) combine lease and non-lease elements of our operating leases. Operating lease ROU assets are included in other non-current assets and operating lease liabilities are included in accrued expenses and other and derivatives and other non-current liabilities in our consolidated balance sheets. As of December 31, 2022, we did not have any finance leases.

Comprehensive Income/(Loss)

Comprehensive (loss)/income, which is reported in the statement of comprehensive (loss)/income, consists of net (loss)/income, changes in fair value of our interest rate swap, and other comprehensive (loss)/income, net of tax, which consists of foreign currency translation.

Credit Concentration

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

During the years ended December 31, 2022 and 2021 we had three customers that accounted for 10% or more of net revenues. As of December 31, 2022, accounts receivable from these customers totaled 82% of accounts receivable, net.

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

	Years Ended December 31,		
	2022	2021	2020
Customer 1	26 %	29 %	31 %
Customer 2	18 %	23 %	24 %
Customer 3	15 %	16 %	19 %

Vendor Concentration

We source the raw materials for products, including active pharmaceutical ingredients ("API"), from both domestic and international suppliers. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. As a result, we are dependent upon our current vendors to supply reliably the API required for on-going product manufacturing. During the year ended December 31, 2022, we purchased approximately 19% of our inventory from one supplier. As of December 31, 2022, our amount payable to this supplier was $10.9 million. During the year ended December 31, 2021, no single vendor

represented at least 10% of inventory purchases. During the year ended December 31, 2020, we purchased approximately 10% of our inventory from one supplier.

Revenue Recognition

We recognize revenue using the following steps:

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

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

All revenue recognized in our 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)	**2022**	**2021**	**2020**
Sales of generic pharmaceutical products	$ 210,121	$ 143,571	$ 147,257
Sales of established brand pharmaceutical products	39,463	47,561	47,960
Sales of rare disease pharmaceutical products	41,686	—	—
Sales of contract manufactured products	16,106	10,042	9,221
Royalties from licensing agreements	5,367	11,795	1,396
Product development services	2,949	1,310	1,858
Other	693	1,857	783
Total net revenues	$ 316,385	$ 216,136	$ 208,475

Timing of Revenue Recognition	**Years Ended December 31,**		
(in thousands)	**2022**	**2021**	**2020**
Performance obligations transferred at a point in time	$ 313,436	$ 214,826	$ 206,617
Performance obligations transferred over time	2,949	1,310	1,858
Total	$ 316,385	$ 216,136	$ 208,475

During the year ended December 31, 2022, we did not incur, and therefore did not defer, any material incremental costs to fulfill contracts. We recognized a decrease of $2.2 million of net revenue from performance obligations satisfied in prior periods during the year ended December 31, 2022, consisting primarily of revised estimates for variable consideration, including chargebacks, rebates, returns, and other allowances, related to prior period sales. As of December 31, 2022, we did not have any contract assets related to revenue recognized based on percentage of completion but not yet billed. We did not have deferred revenue at December 31, 2022. We had less than $0.1 million

of deferred revenue at December 31, 2021. For the years ended December 31, 2022 and 2021, we recognized less than $0.1 million of revenue that was included in deferred revenue as of December 31, 2021 and 2020.

Revenue from Sales of Generic and Branded Pharmaceutical Products

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

Revenue from Distribution Agreements

From time to time, we enter into marketing and distribution agreements with third parties in which we sell products under Abbreviated New Drug Applications ("ANDAs") or New Drug Applications ("NDAs") owned or licensed by these third parties. These products are sold under our own label. We have assessed and determined that we control 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, we recognize revenue on a gross basis when control has passed to the customer and we have satisfied our performance obligation. Under these agreements, we pay these 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 our consolidated statements of operations and are accrued in accrued royalties in our consolidated balance sheets until payment has occurred.

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

Chargebacks

Chargebacks, primarily from wholesalers, result from arrangements we have with indirect customers establishing prices for products which the indirect customer purchases through a wholesaler. Alternatively, we may pre-authorize wholesalers to offer specified contract pricing to other indirect customers. Under either arrangement, we provide 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").

Chargeback credits are calculated as follows:

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, we adjust ASPs based on anticipated changes in the factors above.

The difference between ASP and WAC is recorded as a reduction in both gross revenues in our consolidated statements of operations and accounts receivable in the consolidated balance sheets, at the time we recognize revenue from the product sale.

To evaluate the adequacy of our chargeback accruals, we obtain on-hand inventory counts from the wholesalers. This inventory is multiplied by the chargeback amount, the difference between ASP and WAC, to arrive at total

expected future chargebacks, which is then compared to the chargeback accruals. We continually monitor chargeback activity and adjust ASPs when we believe that actual selling prices will differ from current ASPs.

Government Rebates

Our government rebates reserve consists of estimated payments due to governmental agencies for purchases made by third parties under various governmental programs. The two largest government programs that impact our net revenue and our government rebates reserve are federal and state Medicaid rebate programs and Medicare.

We participate in certain qualifying federal and state Medicaid rebate programs whereby discounts and rebates are provided to participating programs after the final dispensing of the product by a pharmacy to a Medicaid plan participant. Medicaid rebates are typically billed up to 120 days after the product is shipped. 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. Our 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 and rebate billing, our 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 our products are also covered under Medicare. We, like all pharmaceutical companies, must provide a discount for any products sold under NDAs to Medicare Part D participants. This applies to all products sold under NDAs, regardless of whether the products are marketed as branded or generic. Our estimates for these discounts are based on historical experience with Medicare rebates for our products. While such experience has allowed for reasonable estimations in the past, history may not always be an accurate indicator of future rebates. Medicare rebates are typically billed up to 120 days after the product is shipped. As a result of the delay between selling the products and rebate billing, our 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 our government rebate reserves, we review the reserves on a quarterly basis against actual claims data to ensure the liability is fairly stated. We continually monitor our government rebate reserve and adjust our estimates if we believe that actual government rebates may differ from our established accruals. Accruals for government rebates are recorded as a reduction to gross revenues in our consolidated statements of operations and as an increase to accrued government rebates in the consolidated balance sheets.

Returns

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. Our product returns are settled through the issuance of a credit to the customer. Our 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 our estimates for returns and make adjustments when we believe that actual product returns may differ from the established accruals. Accruals for returns are recorded as a reduction to gross revenues in our 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. We accrue for fees and rebates, by product by wholesaler, at the time of sale based on contracted rates and ASPs.

To evaluate the adequacy of our administrative fee accruals, we obtain on-hand inventory counts from the wholesalers. This inventory is multiplied by the ASPs to arrive at total expected future sales, which is then multiplied by contracted rates. The result is then compared to the administrative fee accruals. We continually monitor administrative fee activity and adjust our accruals when we believe that actual administrative fees will differ from the accruals. Accruals for administrative fees and other rebates are recorded as a reduction in both gross revenues in our consolidated statements of operations and accounts receivable in the consolidated balance sheets.

Prompt Payment Discounts

We often grant sales discounts for prompt payment. The reserve for prompt payment discounts is based on invoices outstanding. We assume, based on past experience, that all available discounts will be taken. Accruals for prompt payment discounts are recorded as a reduction in both gross revenues in our 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, 2022, 2021, and 2020:

	Accruals for Chargebacks, Returns, and Other Allowances				
(in thousands)	**Chargebacks**	**Government Rebates**	**Returns**	**Administrative Fees and Other Rebates**	**Prompt Payment Discounts**
Balance at December 31, 2020 (1)	$ 88,746	$ 7,826	$ 27,155	$ 8,906	$ 3,839
Accruals/Adjustments	492,374	15,308	24,081	35,225	15,633
Credits Taken Against Reserve	(487,054)	(17,642)	(15,405)	(31,031)	(14,830)
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

(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.

Contract Manufacturing Product Sales Revenue

Contract manufacturing arrangements consist of agreements in which we manufacture a pharmaceutical product on behalf of a third party. Our performance obligation is to manufacture and provide pharmaceutical products to customers, typically pharmaceutical companies. The contract manufactured products are sold at pre-determined standalone selling prices and our performance obligations are considered to be satisfied when control of the product is transferred to the customer. Control is transferred to the customer when the product leaves our dock to be shipped to the customer, as our contract manufactured pharmaceutical products are sold on an FOB shipping point basis and the inventory risk and risk of ownership passes to the customer at that time. Payment terms for these sales are generally fewer than two months. We estimate returns based on historical experience. Historically, we have not had material returns for contract manufactured products.

As of December 31, 2022, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open contract manufacturing customer contracts was $4.3 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.

Royalties from Licensing Agreements

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

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

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

Product Development Services Revenue

We provide product development services to customers, which are performed over time. These are services primarily performed at our facility in East Windsor, New Jersey. As of December 31, 2022, we have ceased all manufacturing and packaging and clinical operations at our Oakville, Ontario facility. We have transitioned the product development services at the facility to one of our three U.S.-based manufacturing sites.

The duration of these development projects can be up to three years. Deposits received from these customers are recorded as deferred revenue until revenue is recognized. For contracts with no deposits and for the remainder of contracts with deposits, we invoice customers as our performance obligations are satisfied. We recognize revenue on a percentage of completion basis, which results in contract assets on our balance sheet and that revenue is recognized over time. As of December 31, 2022, the aggregate amount of the transaction price allocated to the remaining performance obligations for all open product development services contracts was immaterial.

Cash, Cash Equivalents, and Restricted Cash

We consider all highly liquid instruments with maturities of three months or less when purchased to be cash equivalents. All interest bearing and non-interest bearing accounts are guaranteed by the Federal Deposit Insurance Corporation ("FDIC") up to $250 thousand. The majority of our cash balances are in excess of FDIC coverage. We consider this to be a normal business risk.

In April 2016, we purchased 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 for $60.0 million in cash and milestone payments based on future gross profits from sales of products under the NDA. Additionally, we transferred $5.0 million to an escrow account as security for future milestone payments. This escrow account balance is included in restricted cash in our consolidated balance sheet as of December 31, 2022.

Accounts Receivable

We extend credit to customers on an unsecured basis. We measure expected credit losses on our financial assets 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. We determine trade receivables to be delinquent when greater than 30 days past due. Receivables are written off when it is determined that amounts are uncollectible. Our allowance for credit losses was immaterial as of December 31, 2022 and 2021.

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. We periodically review and adjust 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:

Buildings and improvements	20	-	40	years
Machinery, furniture, and equipment	1	-	10	years

Construction in progress consists of multiple projects, primarily related to new equipment to expand our manufacturing capability as our 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.

We review 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, 2022, 2021, and 2020. Assets held for disposal are reportable at the lower of the carrying amount or fair value, less costs to sell. No assets were held for disposal as of December 31, 2022 and 2021.

Intangible Assets

Definite-lived intangible assets consist of acquired ANDAs for previously commercialized and marketed drug products, acquired approved ANDAs for generic products yet to be commercialized, an acquired development package for a generic drug product, a license, supply and distribution agreement for a generic drug product, acquired

product rights for generic products, acquired NDAs and product rights for branded products, acquired marketing and distribution rights, acquired customer relationships, and a non-compete agreement. They are stated at cost, net of amortization, generally using the straight-line method over the expected useful lives of the intangible assets.

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 10 years, based on the straight-line method. In the case of certain NDA and product rights, we use an accelerated amortization method 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, 2022, we 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, we recognized an impairment charge of $2.4 million related to a definite-lived ANDA intangible asset. During the year ended December 31, 2020, we recognized an impairment charge of $0.4 million relating to a marketing and distribution right asset. No events or circumstances arose in 2022, 2021, or 2020 that indicated that the carrying value of any of our other definite-lived intangible assets may not be recoverable.

Our indefinite-lived intangible assets other than goodwill include in-process research and development ("IPR&D") projects. IPR&D intangible assets represent the fair value of technology acquired in a business combination for which the technology projects are incomplete but have substance. When an IPR&D project is completed (generally upon receipt of regulatory approval), the asset is then accounted for as a definite-lived intangible asset. We test for impairment of indefinite-lived intangible assets 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. If we determine that the carrying value of the assets may not be recoverable, judgment and estimates are used to assess the fair value of the assets and to determine the amount of any impairment loss. No events or circumstances arose in 2022 that indicated that the carrying value of any of our other indefinite-lived intangible assets may not be recoverable.

Goodwill

Goodwill relates to the 2013 merger with BioSante Pharmaceuticals, Inc. and the acquisitions of WellSpring and Novitium, and represents the excess of the total purchase consideration over the fair value of acquired assets and assumed liabilities, using the purchase method of accounting. Goodwill is not amortized, but is subject to periodic review for impairment. Goodwill is reviewed for impairment annually, as of October 31, and whenever events or changes in circumstances indicate that the carrying amount of the goodwill might not be recoverable. We have determined that goodwill resides in one reporting unit, Generics, Established Brands, and Other.

Before employing detailed impairment testing methodologies, we first evaluate the likelihood of impairment by considering qualitative factors relevant to our reporting unit. When performing the qualitative assessment, we evaluate events and circumstances that would affect the significant inputs used to determine the fair value of the goodwill. Events and circumstances evaluated include macroeconomic conditions that could affect us, industry and market considerations for the generic pharmaceutical industry that could affect us, cost factors that could affect our performance, our financial performance (including share price), and consideration of any company-specific events that could negatively affect us, our business, or the fair value of our business. If we determine that it is more likely than not that goodwill is impaired, we will then apply detailed testing methodologies. Otherwise, we will conclude that no impairment has occurred.

Detailed impairment testing involves comparing the fair value of our Generics, Established Brands, and Other reporting unit to its carrying value, including goodwill. Fair value reflects the price a market participant would be willing to pay in a potential sale of ANI. If the fair value exceeds carrying value, then it is concluded that no goodwill impairment has occurred. If the carrying value of the reporting unit were to exceed its fair value, we would recognize an impairment charge for the amount by which the carrying amount exceeded the reporting unit's fair value. The loss recognized would not exceed the total amount of goodwill allocated to that reporting unit. Based on our evaluations, described in the preceding paragraph, it was more likely than not that the fair value of our Generics, Established Brands, and Other reporting unit is greater than its carrying value as of October 31, 2022 and 2021, and

therefore no quantitative testing for impairment was required. No impairment loss related to goodwill was recognized in the years ended December 31, 2022, 2021, and 2020.

Collaborative Arrangements

At times, we have entered into arrangements with various commercial partners to further business opportunities. In collaborative arrangements such as these, when we are actively involved and exposed to the risks and rewards of the activities and are determined to be the principal participant in the collaboration, we classify third party costs incurred and revenues in our consolidated statements of operations on a gross basis. Otherwise, third party revenues and costs generated by collaborative arrangements are presented on a net basis. Payments between us and the other participants are recorded and classified based on the nature of the payments.

Royalties

We have entered profit-sharing 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. These profit-sharing percentages are recorded in cost of sales in our consolidated statements of operations when the associated revenue is recognized and are recorded in accrued royalties in our consolidated balance sheets when the associated revenue is recognized and until payment has occurred.

Research and Development Expenses

Research and development costs are expensed as incurred and primarily consist of expenses relating to product development. Research and development costs totaled $22.3 million, $11.4 million, and $16.0 million for the years ended December 31, 2022, 2021, and 2020, respectively.

Stock-Based Compensation

We have a stock-based compensation plan that includes stock options and restricted stock, which are awarded in exchange for employee and non-employee director services. From time to time, we may make awards through an inducement grant outside of our plan to induce prospective employees to accept employment with us. These grants are made pursuant to inducement grants outside of our 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 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. We also account for forfeitures as they occur. We recognize excess tax benefits or tax deficiencies as a component of our current period provision for income taxes.

In addition, in July 2016, we commenced administration of our Employee Stock Purchase Plan ("ESPP"). We recognize the estimated fair value of stock-based compensation awards and classify the expense where the underlying salaries are classified.

We incurred $14.3 million, $10.4 million, and $12.8 million of non-cash, stock-based compensation cost for the years ended December 31, 2022, 2021, and 2020, respectively, and $313 thousand, $123 thousand, and $180 thousand of the 2022, 2021, and 2020 expense related to the ESPP, respectively. In 2020, we recognized $3.4 million of stock compensation expense related to the modification of awards of our former President and Chief Executive Officer, pursuant to his termination without good cause.

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.

Income Taxes

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

The measurement of a deferred tax asset is reduced, if necessary, by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized. We have provided a valuation allowance against certain of our state net operating loss ("NOL") carryforwards that are not expected to be used during the carryforward periods. As of December 31, 2022, our valuation allowance is $0.4 million and relates to state NOL 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.

We recognize interest and penalties accrued on any unrecognized tax exposures as a component of income tax expense; we did not have any material amounts accrued as of December 31, 2022, 2021, and 2020. We are subject to taxation in various U.S. jurisdictions, Canada, and India, and all of our income tax returns remain subject to examination by tax authorities due to the availability of NOL carryforwards.

We consider potential tax effects resulting from discontinued operations and for gains and losses in other comprehensive income and record intra-period tax allocations, when those effects are deemed material. We previously entered into an interest rate swap agreement (Note 5) that we have designated as a cash flow hedge designed to manage exposure to changes in LIBOR-based 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 accumulated other comprehensive loss, net of tax in the consolidated balance sheets. Income taxes are allocated to the hedge component of accumulated other comprehensive income based on appropriate intra-period tax allocations when those effects are deemed material.

Earnings (Loss) per Share

Basic earnings (loss) per share is computed by dividing net income (loss) available to common shareholders 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 shareholders 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, unvested restricted stock awards under the treasury stock method, and convertible preferred stock using the if-converted method. For periods of net loss, diluted loss per share is calculated similarly to basic loss per share.

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

Earnings per share for the years ended December 31, 2022, 2021, and 2020 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,		
	2022	2021	2020	2022	2021	2020
Net loss	$ (47,896)	$ (42,603)	$ (22,548)	$ (47,896)	$ (42,603)	$ (22,548)
Net income allocated to participating securities	—	—	—	—	—	—
Dividends on Series A convertible preferred stock	(1,625)	(190)	—	(1,625)	(190)	—
Net loss available to common shareholders	$ (49,521)	$ (42,793)	$ (22,548)	$ (49,521)	$ (42,793)	$ (22,548)
Basic Weighted-Average Shares Outstanding	16,260	12,596	11,964	16,260	12,596	11,964
Dilutive effect of stock options and ESPP				—	—	—
Diluted Weighted-Average Shares Outstanding				16,260	12,596	11,964
Loss per share	$ (3.05)	$ (3.40)	$ (1.88)	$ (3.05)	$ (3.40)	$ (1.88)

The number of anti-dilutive shares, which have been excluded from the computation of diluted earnings (loss) per share, were 2.6 million, 1.7 million, and 1.3 million for the years ended December 31, 2022, 2021, and 2020, respectively. For the years ended December 31, 2022, 2021 and 2020, all potentially dilutive shares were anti-dilutive and excluded from the calculation of diluted loss per share because we recognized a net loss.

Hedge Accounting

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

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

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 acquisition date, we recorded this contingent consideration 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 our internal forecasts and long-term plans. We remeasure the fair value of the contingent consideration each reporting period using Level 3 inputs, as discussed further below. Changes in fair value, which incorporate changes in assumptions and the passage of time, are recognized as an operating expense in our consolidated statement 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 of Financial Instruments

Our consolidated balance sheets include various 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 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. 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.

See Note 9 for additional information regarding fair value.

Restructuring Activities

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

Recent Accounting Pronouncements

Recent Accounting Pronouncements Not Yet Adopted

In December 2022, the Financial Accounting Standards Board issued ASU 2022-06, which extended the sunset date of the reference rate reform in ASU 848 from December 31, 2022, to December 31, 2024. We have not adopted the guidance and are currently evaluating the impact, if any, that the adoption of this guidance will have on our consolidated financial statements.

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

2. BUSINESS COMBINATION

Summary

On November 19, 2021, we completed our previously announced acquisition of all of the interests of Novitium pursuant to the terms of the Agreement and Plan of Merger, 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 acquisition date, the contingent consideration had a fair value of $30.8 million. The fair value of the contingent consideration was $35.1 million and $31.0 million as of December 31, 2022 and 2021, respectively. Refer to Note 9 for changes in contingent consideration and changes in fair value. Total consideration including cash, restricted shares and contingent consideration was valued at $206.5 million.

Purchase consideration consisted of the following:

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

The cash consideration was funded in part by borrowings under our new credit facility (Note 4) and through issuance of PIPE convertible preferred stock shares (Note 10). We acquired Novitium due to its proven track record of being a research and development growth engine capable of fueling sustainable growth, to expand our research and development pipeline via niche opportunities, to enhance our contract development and manufacturing organization ("CDMO") business and U.S. based manufacturing capacity, and to diversify our revenue base.

The following presents the final allocation of the purchase price to the assets acquired and liabilities assumed on November 19, 2021:

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

The net assets were recorded at their estimated fair value. In valuing acquired assets and liabilities, fair value estimates were based primarily on future expected cash flows, market rate assumptions for contractual obligations, and appropriate discount rates. In connection with the acquisition, we recognized $46.9 million of indefinite-lived

in-process research and development intangible assets, $67.4 million of acquired ANDA intangible assets, and $24.9 million of customer relationship intangible assets.

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

Novitium operations generated $90.3 million and $7.7 million of revenue during the years ended December 31, 2022 and 2021, respectively.

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.

	Years Ended December 31,	
(in thousands)	**2021**	**2020**
Net revenues	$ 272,888	$ 260,951
Net loss	$ (31,740)	$ (48,814)

Transaction Costs

In conjunction with the acquisition, we incurred approximately $9.4 million in transaction costs, all of which were expensed in 2021 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 contain restrictions on their transfer for periods from three to 24 months following the completion of the acquisition. A Finnerty model was used to value the restricted shares. It includes inputs of not readily observable market data, which are Level 3 inputs. These unobservable inputs include ANI stock volatility with a range of 65% to 71%, and the discounted lack of marketability with a range of 7.5% to 21.5% depending on the length of restriction.

3. RESTRUCTURING

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

For the 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, for the year ended December 31, 2022, respectively. There were also $0.4 million of other costs year to date. As of December 31, 2022, $1.4 million of the severance and other employee benefits are unpaid and accrued. These costs are recorded as restructuring activities, an operating item, in the accompanying 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. We expect to incur additional charges of approximately $0.3 million in severance costs, $1.2 million in asset-related accelerated depreciation and $0.2 million to $0.4 million in other charges over the next three months. These costs are part of the Generics, Established Brands, and Other segment.

In conjunction with the planned exit of our Canadian facility, we have determined that the land and building at our Oakville, Ontario, Canada plant will be sold together over the transition period and meet the criteria to be classified as held for sale as of December 31, 2022. The land and building have a net carrying value of $8.0 million, which is presented as assets held for sale on the accompanying consolidated balance sheets. These assets are part of the Generics, Established Brands, and Other segment.

4. 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 between ANI and Novitium, repay our existing credit facility, and pay fees, costs and expenses incurred in connection with the merger. Proceeds of the Revolving Facility are expected to be used, subject to certain limitations, for working capital and other general corporate purposes.

The Term Facility matures in November 2027 and the Revolving Facility in November 2026. Each permits both base rate borrowings ("ABR Loans") and Eurodollar rate borrowings ("Eurodollar Loans"), plus a spread of (a) 5.00% above the base rate in the case of ABR Loans under the Term Facility and 6.00% above the LIBOR Rate (or alternate benchmark rate as defined in the Credit Agreement) in the case of LIBOR loans under the Term Facility and (b) 3.75% above the base rate in the case of ABR Loans under the Revolving Facility and 4.75% above the LIBOR Rate (as defined in the Credit Facility) in the case of loans under the Revolving Facility. The interest rate under the Term Facility was 10.39% at December 31, 2022. The Credit Facility has a subjective acceleration clause in case of a material adverse effect. The Term Facility includes a repayment schedule, pursuant to which $750 thousand of the loan will be paid in quarterly installments during the twelve months ended December 31, 2023. As of December 31, 2022, $3.0 million of the loan is recorded as current borrowings in the consolidated balance sheets. As of December 31, 2022, we have not drawn on the Revolving Facility and $40.0 million remained available for borrowing.

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

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

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

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

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

	Non-Current	
(in thousands)	December 31, 2022	December 31, 2021
Non-current borrowing on debt	$ 294,000	$ 297,000
Deferred financing costs	(8,331)	(10,480)
Non-current debt, net of deferred financing costs and current component	$ 285,669	$ 286,520

As of December 31, 2022, we had a $297.0 million balance on the Term Facility. Of the $0.9 million of unamortized deferred debt issuance costs allocated to the Revolving Facility, $0.6 million is included in other non-current assets in the consolidated balance sheets, and $0.3 million is included in prepaid expenses and other current assets in the consolidated balance sheets.

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

(in thousands)	Term Facility
2023	$ 3,000
2024	3,000
2025	3,000
2026	3,000
2027	3,000
2028 and thereafter	282,000
Total	$ 297,000

The following table sets forth the components of total interest expense related to the Term Facility and the Term Loan, DDTL, and Revolver under our Prior Credit Agreement recognized in our consolidated statements of operations for the year ended December 31:

	Years Ended December 31,		
(in thousands)	2022	2021	2020
Contractual coupon	$ 26,150	$ 11,129	$ 8,847
Amortization of finance fees	2,363	914	720
Capitalized interest	(95)	(98)	(88)
	$ 28,418	$ 11,945	$ 9,479

5. DERIVATIVE FINANCIAL INSTRUMENT AND HEDGING ACTIVITY

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 (or alternate benchmark rate as defined in the Credit Agreement) underlying total borrowings under term facilities related to our Prior Credit Agreement. The interest rate swap matures in December 2026. Concurrent with the termination of the Prior Credit Agreement and entry into the Credit Agreement with Truist Bank, the interest rate swap with a notional value of $168.6 million at origin on November 19, 2021 was novated and Truist Bank is the new counterparty. The swap is used to manage changes in LIBOR-based interest rates underlying a portion of the borrowing under the Term Facility. The interest rate swap provides an effective

fixed interest rate of 2.26% and has been designated as an effective cash flow hedge and therefore qualifies for hedge accounting. The notional amount of the interest rate swap was $151.5 million and $165.8 million as of December 31, 2022 and 2021, respectively, and decreases quarterly by approximately $4.0 million until December 2023, after which it remains static until maturity in December 2026. As of December 31, 2022, the fair value of the interest rate swap asset was recorded in other non-current assets in the consolidated balance sheets was $8.8 million. As of December 31, 2022, $12.2 million was recorded in accumulated other comprehensive loss, net of tax in the consolidated balance sheets.

During the year ended December 31, 2022, the change in fair value of the interest rate swaps was a gain of $14.3 million. During the year ended December 31, 2022, gains on the interest rate swap of $15.2 million were recorded in accumulated other comprehensive loss, net of tax in our consolidated statements of comprehensive (loss)/income. Differences between the hedged LIBOR rate and the fixed rate are recorded as interest expense in the same period that the related interest is recorded for the Term Facility based on the LIBOR rate. In the year ended December 31, 2022 and 2021, $2.3 million and $4.8 million, respectively, of interest expense was recognized in relation to the interest rate swaps. Included in these amounts for the years ended December 31, 2022 and 2021 are reclassifications out of accumulated other comprehensive income/loss of $2.8 million and $3.5 million in expense, respectively, related to terminated and de-designated cash flow hedges.

6. INVENTORIES

Inventories consist of the following as of December 31:

(in thousands)	December 31, 2022	December 31, 2021
Raw materials	$ 70,497	$ 51,350
Packaging materials	7,760	5,475
Work-in-progress	1,889	652
Finished goods	35,487	31,969
	115,633	89,446
Reserve for excess/obsolete inventories	(10,278)	(7,753)
Inventories, net	$ 105,355	$ 81,693

7. PROPERTY AND EQUIPMENT

Property and equipment consist of the following as of December 31:

(in thousands)	December 31, 2022(1)	December 31, 2021(1)
Land	$ 1,549	$ 5,947
Buildings	16,659	19,970
Machinery, furniture, and equipment	53,146	46,769
Construction in progress	4,604	2,941
	75,958	75,627
Less: accumulated depreciation	(32,712)	(22,956)
Property and equipment, net	$ 43,246	$ 52,671

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

Depreciation expense for the years ended December 31, 2022, 2021, and 2020 totaled $7.4 million, $5.5 million, and $4.8 million, respectively. During the years ended December 31, 2022, 2021, and 2020 there was $0.1 million of interest capitalized into construction in progress.

8. GOODWILL AND INTANGIBLE ASSETS

Goodwill

As a result of our 2013 merger with BioSante Pharmaceuticals, Inc. ("BioSante"), we recorded goodwill of $1.8 million. As a result of our acquisition of WellSpring Pharma Services Inc., we recorded additional goodwill of $1.7 million in 2018. From our acquisition of Novitium in 2021, we recorded goodwill of $24.6 million. We have two operating segments, which are the same as our two reporting units, Generics, Established Brands, and Other reporting unit and the Rare Disease reporting unit. All of the goodwill is recorded in our Generics, Established Brands, and Other reporting unit.

For the goodwill impairment analyses performed at October 31, 2022 and 2021, we performed qualitative assessments to determine whether it was more likely than not that our goodwill asset was 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, we evaluated events and circumstances that would affect the significant inputs used to determine the fair value of the goodwill. Based on our assessments of the aforementioned factors, it was determined that it was more likely than not that the fair value of our one reporting unit is greater than its carrying amount as of October 31, 2022 and 2021, and therefore no quantitative testing for impairment was required.

In addition to the qualitative impairment analysis performed at October 31, 2022, there were no events or changes in circumstances that would have reduced the fair value of our reporting unit below its carrying value from October 31, 2022 to December 31, 2022. No impairment loss was recognized during the years ended December 31, 2022, 2021, and 2020, and the balance of goodwill was $28.2 million and $27.9 million as of December 31, 2022 and 2021, respectively.

Intangible Assets

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

	December 31, 2022		December 31, 2021		Weighted Average
(in thousands)	Gross Carrying Amount	Accumulated Amortization	Gross Carrying Amount	Accumulated Amortization	Amortization Period
Definite-Lived Intangible Assets:					
Acquired ANDA intangible assets	$ 195,862	$ (75,606)	$ 168,536	$ (54,079)	8.3 years
NDAs and product rights	242,372	(162,188)	242,372	(138,835)	9.9 years
Marketing and distribution rights	17,157	(13,309)	17,157	(12,347)	5.5 years
Non-compete agreement	624	(602)	624	(513)	7.0 years
Customer relationships	24,900	(4,150)	24,900	(593)	7.0 years
Indefinite-Lived Intangible Assets:					
In process research and development	26,575	—	46,900	—	Indefinite
Total Intangible Assets, net	$ 507,490	$ (255,855)	$ 500,489	$ (206,367)	8.9 years

During 2022, $20.3 million was reclassified from IPR&D to ANDA intangible assets upon completion of projects and launch of related products. We also added $7.2 million in ANDA intangible assets related to the July 21, 2022 transaction with Oakrum Pharma, LLC (Note 9). These assets will be amortized over a seven-year useful life.

Indefinite-Lived Intangible Assets impairment analysis was performed as of October 31, 2022. We 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, we evaluated events and circumstances that would affect the significant inputs used to determine the fair value of the assets. Based on our 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, 2022, and therefore no quantitative testing for impairment was

required. In addition to the qualitative impairment analysis performed, there were no events or changes in circumstances that would have reduced the fair value of assets below their carrying value from October 31, 2022 to December 31, 2022. During the year ended December 31, 2022, we recognized a full impairment of a definite-lived ANDA asset with a remaining carrying value of $0.1 million.

Amortization expense was $49.5 million, $41.8 million, and $39.9 million for the years ended December 31, 2022, 2021, and 2020, respectively. Refer to Note 9 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)	
2023	$ 51,792
2024	50,996
2025	48,893
2026	35,574
2027	26,663
2028 and thereafter	37,717
Total	$ 251,635

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.

9. FAIR VALUE DISCLOSURES

Fair value is the price that would be received from the sale of an asset or paid to transfer a liability assuming an orderly transaction in the most advantageous market at the measurement date. U.S. GAAP establishes a hierarchical disclosure framework 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 our funds. The fair value of short-term financial instruments (primarily accounts receivable, prepaid expenses, accounts payable, accrued expenses, and other current liabilities) approximate their carrying values because of their short-term nature. The Term Facility bears an interest rate that fluctuates with the changes in LIBOR and, because the variable interest rates approximate market borrowing rates available to us, we believe the carrying values of these borrowings approximated their fair values at December 31, 2022 and 2021.

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

Contingent Value Rights

Our contingent value rights (“CVRs”), which were granted coincident with our merger with BioSante Pharmaceuticals, Inc. and expire in June 2023, are considered to be contingent consideration and are classified as liabilities. As such, the CVRs were recorded as purchase consideration at their estimated fair value, using Level 3 inputs, and are marked to market each reporting period until settlement. The fair value of CVRs is estimated using the present value of management’s projection of the expected payments pursuant to the terms of the CVR agreement, which is the primary unobservable input. If our projection or expected payments were to increase substantially, the value of the CVRs could increase as a result. The present value of the liability was calculated using a discount rate of 15%. We determined that the fair value of the CVRs was immaterial as of December 31, 2022 and 2021. We also determined that the changes in such fair value were immaterial for the years ended December 31, 2022, 2021, and 2020.

Interest Rate Swap

The fair value of our interest rate swap is estimated based on the present value of projected future cash flows using the LIBOR forward rate curve. In 2023, we expect that this will be replaced by a forward rate curve for an alternate benchmark rate as defined in the Credit Agreement. 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 $8.8 million asset at December 31, 2022.

Contingent Consideration

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

The discounted cash flow method used to value this contingent consideration includes inputs of not readily observable market data, which are Level 3 inputs. As of the November 19, 2021 acquisition date, the contingent consideration had a fair value of $30.8 million. The fair value of the contingent consideration was $35.1 million and $31.0 million as of December 31, 2022 and 2021, respectively, and is reflected as a non-current accrued contingent consideration liability in the consolidated balance sheet.

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

Payment Type	Valuation Technique	Unobservable Input	Assumptions
Profit-based milestone payments	Probability-weighted discounted cash flow	Discount rate	13.0%
		Projected fiscal year of payment	2024-2029
Product development-based milestone payments	Probability-weighted discounted cash flow	Discount rate	8.8%
		Probability of payment	95.0%
		Projected fiscal year of payment	2024

The following table presents the changes in contingent consideration balances classified as Level 3 balances for the year ended December 31, 2022 and 2021:

(in thousands)	Years Ended December 31, 2022	2021
Beginning balance	$ 31,000	$ —
Initial valuation	—	30,800
Measurement period adjustment	300	—
Change in fair value	3,758	200
Ending balance	$ 35,058	$ 31,000

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

(in thousands) Description	Fair Value at December 31, 2022	Level 1	Level 2	Level 3
Assets				
Interest rate swap	$ 8,759	$ —	$ 8,759	$ —
Liabilities				
Contingent consideration	$ 35,058	$ —	$ —	$ 35,058
CVRs	$ —	$ —	$ —	$ —

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

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

We have 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

We have 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

We measure our long-lived assets, including property and equipment, ROU assets, intangible assets, and goodwill, at fair value on a non-recurring basis. These assets are recognized at fair value when they are deemed to be other-than-temporarily impaired. During the year ended December 31, 2022, we recognized an impairment charge of $0.1 million related to a definite-lived ANDA intangible asset. During the year ended December 31, 2021, we recognized an impairment charge of $2.4 million related to a definite-lived ANDA intangible asset. There were no other fair value impairments recognized in the years ended December 31, 2022 and 2021.

Acquired Non-Financial Assets Measured at Fair Value

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 December 2022. The ANDA's 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, 2022, and therefore no impairment loss was recognized for the year ended December 31, 2022.

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, 2022 and therefore no impairment loss was recognized for the years ended December 31, 2021 and 2022.

In July 2020, we acquired an ANDA and certain related inventories from a private company for total consideration of $4.3 million. We also incurred and paid $0.1 million in transaction costs directly related to the acquisition. We accounted for this transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $3.0 million as an acquired ANDA intangible asset and $1.4 million in inventory at fair value. 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 ANDA was being amortized in full over its useful life of seven years. During the fourth quarter 2021, we recognized a full impairment of the remaining $2.4 million carrying value of the asset, as it was determined that the asset would not generate future cash flows.

In January 2020, we completed the acquisition of the U.S. portfolio of 23 generic products and API and finished goods related to certain of those products from Amerigen Pharmaceuticals, Ltd. ("Amerigen") for a purchase consideration of $56.8 million and up to $25.0 million in contingent payments over the subsequent four years from the acquisition. The product portfolio at the time of the acquisition included ten commercial products, three approved products with launches pending, four filed products and four in-development products as well as a license to commercialize two approved products. Payments were made using cash on hand and through borrowings of $15.0 million under our Revolver. We also incurred and paid $0.7 million in transaction costs directly related to the acquisition. We accounted for the transaction as an asset acquisition and capitalized the transaction costs directly related to the acquisition. We recognized $38.5 million as acquired ANDA intangible assets and $6.7 million as acquired marketing and distribution rights related to the licensed products, which are being amortized over their useful lives of seven years. We also recognized $3.8 million of the purchase price 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 two asset categories and in-process research and development based on relative fair value, which was determined using Level 3 unobservable inputs. To determine the fair value of the acquired intangible assets and in-process research and development, we used the present value of the estimated cash flows related to the products, using a discount rate of 8%. We also recognized $8.4 million in inventory at fair value, including $1.7 million of API and $6.7 million of finished goods. 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. Contingent liabilities will be accrued when they are both estimable and probable. The intangible assets 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, 2022 and therefore no impairment loss was recognized for the years ended December 31, 2020, 2021, and 2022.

10. MEZZANINE AND STOCKHOLDERS' EQUITY

Stockholders' Equity

Authorized shares

We are authorized to issue up to 33.3 million shares of common stock with a par value of $0.0001 per share, 0.8 million shares of class C special stock with a par value of $0.0001 per share, and 1.7 million shares of undesignated preferred stock with a par value of $0.0001 per share at December 31, 2022 and 2021.

There were 17.6 million and 17.5 million shares of common stock issued and outstanding as of December 31, 2022, respectively, and 16.9 million and 16.8 million shares of common stock issued and outstanding as of December 31, 2021, respectively. During 2021, we issued 1.5 million shares related to a public offering of our common stock and 2.5 million shares as consideration for our acquisition of Novitium.

There were 11 thousand shares of class C special stock issued and outstanding as of December 31, 2022 and 2021. Each share of class C special stock entitles its holder to one vote per share. Each share of class C special stock

is exchangeable, at the option of the holder, for one share of our common stock, at an exchange price of $90.00 per share, subject to adjustment upon certain capitalization events. Holders of class C special stock are not entitled to receive dividends or to participate in the distribution of our assets if we were to liquidate, dissolve, or wind-up the company. The holders of class C special stock have no cumulative voting, preemptive, subscription, redemption, or sinking fund rights.

Mezzanine Equity

PIPE Shares

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

The PIPE Shares accrue dividends at 6.50% per year on a cumulative basis, payable in cash or in-kind, and will also participate, on a pro-rata basis, in any dividends that may be declared with respect to our common stock. The PIPE Shares are convertible into our common shares at the conversion price of $41.47 (i) beginning two years after their issuance date, at the election of ANI (in which case the PIPE Investor must convert all of the PIPE Shares), if the volume-weighted average price of our common stock for any 20 trading days out of 30 consecutive trading days exceeds 170% of the conversion price, and (ii) at any time after issuance, at the election of the PIPE Investor. As of December 31, 2022, the PIPE shares are currently convertible into a maximum of 602,901 shares of our common stock.

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

There were 25,000 shares of Series A convertible preferred stock outstanding as of December 31, 2022 and 2021.

11. STOCK-BASED COMPENSATION

Employee Stock Purchase Plan

In July 2016, we commenced administration of the ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan. The Board of Directors and shareholders approved a maximum of 0.2 million shares of common stock, which were reserved and made available for issuance under the ESPP. Under the ESPP, participants can purchase shares of our stock at a 15% discount. We issued 29 thousand, 14 thousand, and 13 thousand shares in the years ended December 31, 2022, 2021, and 2020, respectively.

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

(in thousands)	Years Ended December 31,		
	2022	2021	2020
Cost of sales	$ 50	$ 15	$ 21
Research and development	41	21	36
Selling, general, and administrative	222	87	123
	$ 313	$ 123	$ 180

Stock Incentive Plan

Equity-based service awards are granted under the ANI Pharmaceuticals, Inc. Amended and Restated 2022 Stock Incentive Plan (the "2022 Plan"), which was approved by our stockholders at the 2022 Annual Meeting of Stockholders (the "Annual Meeting") held on April 27, 2022. Prior to this approval, we had been granting equity-based incentive awards under our Sixth Amended and Restated 2008 Stock Incentive Plan (the "2008 Plan"), which was renamed and was amended and restated to become the 2022 Plan. This amendment and restatement, among other things, increased the number of shares reserved for issuance thereunder by 1,150,000 shares. As of December 31, 2022, 1.1 million shares of our common stock were available for issuance under the 2022 Plan.

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

We measure the cost of equity-based service awards 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. We recognize stock-based compensation expense ratably over the vesting periods of the awards.

The following table summarizes stock-based compensation expense incurred under the Stock Incentive Plans and Inducement Grant and included in our consolidated statements of operations:

(in thousands)	Years Ended December 31,		
	2022	2021	2020
Cost of sales	$ 482	$ 5	$ 115
Research and development	710	543	561
Selling, general, and administrative	13,094	9,818	12,080
	$ 14,286	$ 10,366	$ 12,756

We recognized income tax benefits of $1.7 million, $1.0 million, and $1.6 million for stock-based compensation-related tax deductions in our 2022, 2021, and 2020 consolidated statements of operations,

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. Upon exercise of an option, we issue new shares of our common stock or issue shares from treasury stock.

For 2022, 2021, and 2020, the fair value of each option grant was estimated using the Black-Scholes option-pricing model, using the following assumptions:

	Years Ended December 31,		
	2022	2021	2020
Expected option life (years)	5.50 - 6.25	5.50 - 6.25	5.50 - 6.25
Risk-free interest rate	1.71% - 2.83%	0.68% - 1.39%	0.31% - 1.63%
Expected stock price volatility	48.4% - 50.0%	48.2% - 49.5%	49.2% - 51.2%
Dividend yield	—	—	—

We use 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. We calculated an estimated volatility rate based on our historical stock price. We have not issued a cash dividend on our common shares in the past nor do we 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, 2022, 2021, and 2020 is presented below:

(in thousands, except per share and remaining term data)	Option Shares	Weighted Average Exercise Price	Weighted Average Grant-date Fair Value	Weighted Average Remaining Term (years)	Aggregate Intrinsic Value
Outstanding December 31, 2019	757	$ 54.21		7.2	$ 6,761
Granted	231	30.29	$ 14.39		
Exercised	(8)	36.81			216
Forfeited	(44)	54.54			
Expired	—	—			
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 at 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
Exercisable at December 31, 2022	686	$ 49.31		4.9	$ 2,003

As of December 31, 2022, there was $3.2 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 2.0 years. During the year ended December 31, 2022, we received $0.7 million in cash from the exercise of stock options and recorded less than $0.1 million tax provision related to these exercises. During the year ended December 31, 2021, we received $1.7 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, 2020, we received $0.3 million in cash from the exercise of stock options and recorded a $43 thousand 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 our 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 our stock on the date of grant.

A summary of RSA activity under the Plan during the years ended December 31, 2022, 2021, and 2020 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, 2019	192	$ 61.46	2.6
Granted	305	44.42	
Vested	(127)	58.88	
Forfeited	(18)	51.53	
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

As of December 31, 2022, there was $31.2 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 2.6 years.

12. 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 our tax provision (benefit) from the Canadian, Indian, and Israeli taxing jurisdictions.

We are required to establish a valuation allowance 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. We consider the projected future taxable income and tax planning strategies in making this assessment.

As of December 31, 2022 and 2021, our consolidated valuation allowance was $0.4 million, related solely to deferred tax assets for net operating loss carryforwards in certain U.S. state jurisdictions.

Our total provision for income taxes consists of the following for the years ended December 31, 2022, 2021, and 2020:

(in thousands)	2022	2021	2020
Current income tax provision:			
Federal	$ 152	$ 1,296	$ 9,232
State	249	1,320	559
Foreign	66	691	—
Total	467	3,307	9,791
Deferred income tax benefit			
Federal	(13,382)	(12,163)	(14,125)
State	(1,722)	(5,122)	744
Foreign	(128)	336	345
Total	(15,232)	(16,949)	(13,036)
Change in valuation allowance	(4)	187	(169)
Total benefit for income taxes	$ (14,769)	$ (13,455)	$ (3,414)

The difference between our expected income tax provision from applying U.S. Federal statutory tax rates to the pre-tax income and actual income tax provision relates primarily to the effect of the following:

	As of December 31,		
	2022	2021	2020
US Federal statutory rate	21.0 %	21.0 %	21.0 %
State taxes, net of Federal benefit	3.2 %	3.3 %	1.9 %
Foreign taxes	0.1 %	(1.0)%	(0.1)%
Change in valuation allowance	— %	(0.3)%	0.7 %
Stock-based compensation	(1.4)%	(1.7)%	(2.5)%
Non-deductible costs	(0.5)%	(0.8)%	(3.5)%
Change in state apportionment factors, state and foreign rates	(0.1)%	5.5 %	(7.3)%
Research and experimentation and charitable credits	1.4 %	0.9 %	0.9 %
Transfer pricing and other	(0.1)%	(2.9)%	2.0 %
Effective income tax rate	23.6 %	24.0 %	13.1 %

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

(in thousands)	As of December 31, 2022	2021
Deferred tax assets:		
Accruals and advances	$ 9,233	$ 10,149
Stock-based compensation	6,041	5,108
Accruals for chargebacks and returns	15,344	18,371
Inventory	5,292	5,983
Intangible asset	33,431	23,470
Net operating loss carryforwards	5,994	6,038
Other	16,548	8,758
Total deferred tax assets	$ 91,883	$ 77,877
Deferred tax liabilities:		
Depreciation	$ (5,776)	$ (6,601)
Intangible assets	—	(11)
Other	(4,298)	(2,879)
Total deferred tax liabilities	$ (10,074)	$ (9,491)
Valuation allowance	(446)	(450)
Deferred tax assets, net of deferred tax liabilities and valuation allowance	$ 81,363	$ 67,936

As of December 31, 2022, we had U.S. federal net operating loss carryforwards of approximately $22.6 million, all of which arose as a result of the 2013 merger with BioSante Pharmaceuticals, Inc. and from our taxable loss in 2021 and 2022. Our net operating loss carryforwards related to our 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; our current annual limitation is approximately $0.8 million per year. Our net operating losses that arose in 2021 and 2022 do not expire and are not limited by Section 382. Additionally, as of December 31, 2022, we have total net operating losses in Canada of $1.7 million that expire through 2038.

We are subject to income taxes in numerous jurisdictions in the U.S., Canada, and India. Significant judgment is required in evaluating our tax positions and determining our provision for income taxes. We establish liabilities for tax-related uncertainties based on estimates of whether, and the extent to which, additional taxes will be due. These liabilities are established when we believe that certain positions might be challenged despite our belief that our tax return positions are fully supportable. We adjust these liabilities 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. We identified no material uncertain income tax positions as of December 31, 2022 and 2021.

We are subject to income tax audits in all jurisdictions for which we file tax returns. Tax audits by their nature are often complex and can require several years to complete. All of our income tax returns remain subject to examination by tax authorities due to the availability of net operating loss carryforwards.

13. COMMITMENTS AND CONTINGENCIES

Operating Leases

All our existing leases as of December 31, 2022 are classified as operating leases. As of December 31, 2022, we have 13 material operating leases for facilities and office equipment with remaining terms expiring from 2025 through 2027 and a weighted average remaining lease term of 2.6 years. Many of our existing leases have fair value renewal options, none of which are considered certain of being exercised or included in the minimum lease term. Discount rates used in the calculation of our lease liability ranged between 3.99% and 8.95%.

Rent expense for the years ended December 31, 2022 and 2021 consisted of the following:

(in thousands)	Year Ended December 31, 2022	2021
Operating lease costs	$ 701	$ 240
Variable lease costs	236	48
Total lease costs	$ 937	$ 288

A maturity analysis of our operating leases follows:

(in thousands)	
Future payments:	
2023	$ 798
2024	868
2025	470
2026	89
2027	34
Total	$ 2,259
Discount	(194)
Lease liability	2,065
Current lease liability, included in accrued expenses and other in the consolidated balance sheets	(684)
Non-current lease liability, included in derivatives and other non-current liabilities in the consolidated balance sheets	$ 1,381

Vendor Purchase Minimums

We have a supply agreement with one vendor that includes purchase minimums. Pursuant to this agreement, we will be required to purchase a total of $0.1 million of API from this vendor during the year ended December 31, 2023.

Government Regulation

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

Unapproved Products

Two of our products, Esterified Estrogen with Methyltestosterone ("EEMT") and Opium Tincture, are marketed without approved NDAs or ANDAs. During the years ended December 31, 2022, 2021, and 2020, net revenues for these products totaled $14.2 million, $16.2 million, and $16.9 million, respectively.

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

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, 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.

In addition, one group of products that we manufacture on behalf of a contract customer is marketed by that customer without an approved NDA. If the FDA took enforcement action against such customer, the customer may be required to seek FDA approval for the group of products or withdraw them from the market. Our contract manufacturing revenues for the group of unapproved products for the years ended December 31, 2022, 2021, and 2020 were $2.6 million, $2.4 million, and $2.8 million, respectively.

Legal proceedings

We are involved, and from time to time may become involved, in various disputes, governmental and/or regulatory inquiries, investigations, government reimbursement related actions and litigation. These matters are complex and subject to significant uncertainties. Due to the inherent unpredictability of legal matters, including litigation, governmental and regulatory matters, particularly where the damages sought are substantial or indeterminate or when the proceedings, investigations or inquiries are in the early stages, we cannot accurately predict the outcome, or the effects of the legal proceedings described below. While we believe that we have valid claims and/or defenses in the litigation and other matters described below, litigation is inherently unpredictable, and the outcome of the proceedings could result in losses, including substantial damages, fines, civil or criminal penalties and injunctive or administrative remedies. We intend to vigorously prosecute and/or defend these matters, as appropriate; however, from time to time, we may settle or otherwise resolve these matters on terms and conditions that we believe are in our best interests. Resolution of any or all claims, investigations, and legal proceedings, individually or in the aggregate, could have a material adverse effect on our results of operations and/or cash flows in any given accounting period or on our overall financial condition.

Some of these matters with which we are involved are described below and in our 2021 Form 10-K, and unless otherwise disclosed, we are unable to predict the outcome of the matter or to provide an estimate of the range of reasonably possible material losses. We record accruals for loss contingencies to the extent we conclude it is probable that a liability has been incurred and the amount of the loss can be reasonably estimated.

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

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

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

Commercial Litigation

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

On December 3, 2020, class action complaints were filed against the Company on behalf of putative classes of direct and indirect purchasers of the drug Bystolic. On December 23, 2020, six individual purchasers of Bystolic, CVS, Rite Aid, Walgreen, Kroger, Albertsons, and H-E-B, filed complaints against the Company. On March 15, 2021, the plaintiffs in these actions filed amended complaints. All amended complaints are substantively identical. The plaintiffs in these actions allege that, beginning in 2012, Forest Laboratories, the manufacturer of Bystolic, entered into anticompetitive agreements when settling patent litigation related to Bystolic with seven potential manufacturers of a generic version of Bystolic: Hetero, Torrent, Alkem/Indchemie, Glenmark, Amerigen, Watson, and various of their corporate parents, successors, subsidiaries, and affiliates. ANI itself was not a party to patent litigation with Forest concerning Bystolic and did not settle patent litigation with Forest. The plaintiffs named the Company as a defendant based on the Company's January 8, 2020 Asset Purchase Agreement with Amerigen. The complaints alleged that the 2013 patent litigation settlement agreement between Forest and Amerigen violated federal and state antitrust laws and state consumer protection laws by delaying the market entry of generic versions of Bystolic. Plaintiffs alleged they paid higher prices as a result of delayed generic competition. Plaintiffs sought damages, trebled or otherwise multiplied under applicable law, injunctive relief, litigation costs and attorneys' fees. The complaints did not specify the amount of damages sought from the Company or other defendants and the Company at this early stage of the litigation cannot reasonably estimate the potential damages that the plaintiffs will seek. The cases have been consolidated in the United States District Court for the Southern District of New York as In re Bystolic Antitrust Litigation, Case No. 20-cv-005735 (LJL). On April 23, 2021, the Company and other defendants filed motions to dismiss the amended complaints. On January 24, 2022, the court dismissed all claims brought by the plaintiffs without prejudice. The court granted the plaintiffs until February 22, 2022 to file amended complaints, which were filed in federal court in the Southern District of New York, on that date. The newly amended complaints contain substantially similar claims. On April 19, 2022, the Company and other defendants filed motions to dismiss the newly amended complaints. On May 23, 2022, the plaintiffs filed oppositions to the motions to dismiss and, on June 24, 2022, the Company and other defendants filed replies to those oppositions. On February 21, 2023, the Company and the defendants' motions to dismiss all actions were granted with prejudice. Plaintiffs have thirty days to file an appeal.

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

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

On October 3, 2022, Azurity Pharmaceuticals, Inc. filed a complaint in the United States District Court for the District of New Jersey against ANI's wholly owned subsidiary, Novitium Pharma, LLC, asserting that Novitium's manufacture, use, sale, importation and/or offer to sell Bionpharma Inc.'s ("Bionpharma") enalapril maleate oral solution drug product (the "Product") infringes U.S. Patents No. 11,040,023 and 11,141,405. The complaint seeks injunctive relief, and an award of Azurity's costs and expenses. On October 12, 2022, Bionpharma filed a motion in United States District Court for the District of New Jersey to intervene on Novitium's behalf in the litigation and on October 14, 2022, Novitium and Bionpharma filed a joint motion to transfer venue to the District of Delaware, which motion to transfer was granted on January 23, 2023. 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. ANI and Novitium dispute 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 asserts a public nuisance claim and a negligence claim against the generic ranitidine manufacturer defendants, including ANI and Novitium. The public nuisance claim asserts that the widespread sale of ranitidine products in the state created a public nuisance that requires a state-wide medical monitoring program of New Mexico residents for the development of colorectal cancer, stomach cancer, gastrointestinal disorders and liver disease. As damages, New Mexico asks that the defendants fund this medical monitoring program. The negligence claims assert that the defendants were negligent in selling the product, essentially alleging that it was unreasonable to have the product on the market. With respect to that claim, New Mexico asserts that it paid for ranitidine products through state-funded insurance and health-care programs. On December 15, 2020, the case was removed to federal court and transferred to the *In re Zantac* multidistrict litigation ("MDL") pending in the United States District Court for the Southern District of Florida. New Mexico moved for remand to state court. The MDL court granted the remand motion on February 25, 2021. On April 16, 2021, New Mexico filed an amended complaint in the New Mexico First Judicial District Court in Santa Fe County. It did not name ANI in the amended complaint, effectively voluntarily dismissing ANI from the action. Novitium is named as a Defendant in the amended complaint. According to Novitium's records, Novitium did not ship any ranitidine product to New Mexico, and received no funds from any state funded health care plan or Medicaid. The Defendants filed a motion to dismiss the claims asserted in the New Mexico litigation based primarily on preemption. The motion was denied in August 2021. A motion for reconsideration was denied on September 22, 2022. The case is currently in discovery.

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 MDL concerning ranitidine-containing drugs pending in the Southern District of Florida before Judge Robin L. Rosenberg, *In re Zantac MDL*, 20 MDL 2924. A Master Personal Injury Complaint ("MPIC") in that MDL that was filed on June 22, 2020 also named ANI and Novitium as defendants. ANI was dismissed from the *Koepsel* case on August 21, 2020 and was dismissed from the MPIC on September 8, 2020. On December 31, 2020, after ANI was dismissed, the district court dismissed the MPIC claims against generic

manufacturer defendants partially with prejudice and partially with leave to replead. The failure to warn and design defect claims were dismissed with prejudice on preemption grounds. An Amended Master Personal Injury Complaint was filed on February 8, 2021, which did not name ANI but did name Novitium. By opinion dated July 8, 2021, the district court dismissed all claims against the generic manufacturer defendants with prejudice on preemption grounds. That decision is on appeal to the Eleventh Circuit Court of Appeals. 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.

ANI and Novitium were named in other individual personal injury complaints filed in MDL 20 MD 2924 in which plaintiffs allege that they developed cancer after taking prescription and over the counter medication containing ranitidine. ANI was served with complaints in five of those additional cases: *Cooper v. Boehringer Ingelheim Pharmaceuticals, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-81130-RLR (served September 30, 2020), *Lineberry v. Amneal Pharmaceuticals, LLC, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-81079-RLR (served August 20, 2020), *Lovette v. Amneal Pharmaceuticals, LLC, et al.*, MDL No. 20-MD-2924, Case No. 9:20-cv-81040-RLR (served August 26, 2020), *Hightower v. Pfizer, et al,* MDL No. 20-MD-2924, Case No. 9-20-cv-82214-RLR (served December 16, 2020) and *Bird v. Boehringer Ingelheim Pharmaceuticals, et al.*, MDL No. 20-MD-2924, Case No. 9-20-cv-80837-RLR (served December 30, 2020). ANI informed counsel for the plaintiffs that ANI did not sell an over the counter ranitidine product and sold a generic prescription ranitidine product for a limited two-month period of time, from July 2019 to September 2019. ANI's product was voluntarily recalled in January 2020. Each of the plaintiffs in the five pending cases alleges a cancer diagnosis prior to the time that ANI sold ranitidine, and we have informally sought dismissal from these cases on that basis. ANI was voluntarily dismissed from the *Cooper*, *Lineberry* and *Lovette* actions on November 20, 2020, 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. 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 200 short form complaints.

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 generic manufacturer defendants filed a motion to dismiss on preemption grounds. That motion is pending.

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. Those pre-trial proceedings are pending in the Circuit Court of Cook County before Judge Daniel A. Trevino. On January 12, 2023, Judge Trevino directed the plaintiffs to dismiss the multi-plaintiff actions and refile each individual plaintiff action under a separate case number. The Keller Postman firm has communicated that it is complying with that directive. At a status conference held on February 16, 2023, the court required that the plaintiffs re-file within 60 days. The court also authorized use of a master complaint, which is due within 21 days. The Keller Postman attorneys requested authority to bypass formal service of process for the refiled single-plaintiff actions, and serve the new complaints by email on outside counsel. Judge Trevino authorized email service. As of February 21, 2023, ANI and Novitium had not yet been served with any of the single-plaintiff complaints.

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 before Judge Evelio Grillo in Alameda County. By order dated January 19, 2023, Judge Grillo 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. As of February 21, 2023, ANI and Novitium had not yet been served with any of these single-plaintiff complaints. As of February 21, 2023, the Company is aware of three single-plaintiff cases in which Novitium is named as a defendant: *David Duncan v. GSK Holdings*, No. T23-507; *Charmaine Sili v. GSK Holdings*, No. T23-355; and *Charles Crippen v. Boehringer,* No. T23-349.

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 court has not yet set a deadline for responsive pleadings.

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.

14. PURIFIED CORTROPHIN GEL PRE-LAUNCH CHARGES

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

Prior to the third quarter 2019, all purchases of material, including pig pituitary glands and API, related to the re-commercialization efforts were consumed in research and development activities and recognized as research and development expense in the period in which they were incurred. In the third quarter of 2019, we began purchasing materials that are intended to be used commercially in anticipation of FDA approval of Cortrophin Gel and the resultant product launch. The FDA granted approval of the sNDA of this product on October 29, 2021. Prior to FDA approval, under U.S. GAAP, we were prohibited from capitalizing these pre-launch purchases of materials as inventory, and accordingly, they were charged to expense in the period in which they were incurred. Subsequent to approval, these purchases are recorded as inventory at net realizable value. During the years ended December 31, 2021 and 2020, we recognized $0.8 million and $11.3, million, respectively, of charges for the purchase of materials. We also incurred other charges 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, we 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 2020.

15. RELATED PARTY TRANSACTIONS

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

In August 2020, we appointed Jeanne Thoma as a director of the Company. Ms. Thoma is the former Chief Executive Officer of SPI Pharmaceuticals, Inc. ("SPI"), who retired in October 2020. SPI supplies ingredients to the Company. We made payments totaling approximately $352,000 in the year ended 2020, to SPI, related to the purchase of ingredients.

In connection with our acquisition of Novitium, we entered into employment agreements with the two executives and founders of Novitium, Muthusamy Shanmugam and Chad Gassert. Both serve as executive officers of the Company and Mr. Shanmugam was also appointed to the board of directors. Mr. Shanmugam holds a minority interest in Scitus Pharma Services ("Scitus"), which provides clinical research services to Novitium, majority

interest in SS Pharma LLC ("SS Pharma"), which acquires and supplies API to Novitium, 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 our payments to related parties is presented below:

	Years Ended December 31,		
	2022	2021(1)	2020
Scitus Pharma Services	$ 2,074,773	$ —	$ —
SS Pharma LLC	3,668,542	—	—
Esjay Pharma LLC	101,468	24,989	—
Nuray Chemical Private Limited	1,110,158	364,620	—
	$ 6,954,941	$ 389,609	$ —

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

As of December 31, 2022, the outstanding balances due to Scitus and SS Pharma were $45 thousand and $170 thousand, respectively. There was no outstanding balance due to Nuray at December 31, 2022.

16. SEGMENT REPORTING

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

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

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

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

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

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

(in thousands)	Year Ended December 31, 2022	2021	2020
Net Revenues			
Generics, Established Brands, and Other	$ 274,698	$ 216,136	$ 208,475
Rare Disease	41,687	—	—
Total net revenues	$ 316,385	$ 216,136	$ 208,475
Segment earnings/(loss) before interest, taxes, depreciation and amortization ("EBITDA") and reconciliation to (loss)/income before income taxes			
Generics, Established Brands, and Other	78,958	63,418	78,790
Rare Disease	(18,348)	(18,571)	(15,620)
Depreciation and amortization	(56,973)	(47,252)	(44,638)
Corporate and other unallocated expenses[1]	(38,920)	(37,388)	(34,548)
Total operating loss	$ (35,283)	$ (39,793)	$ (16,016)
Interest expense, net	(28,052)	(11,922)	(9,452)
Other income/(expense), net	670	(4,343)	(494)
Loss before benefit for income taxes	(62,665)	(56,058)	(25,962)

(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

Our operations are located in the United States, Canada, and India. The majority of the assets of the Company are located in the United States.

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

(in thousands) Location of Operations	Years Ended December 31, 2022	2021	2020
United States	$ 312,427	$ 211,893	$ 202,881
Canada	3,958	4,243	5,594
Total Revenue	$ 316,385	$ 216,136	$ 208,475

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

(in thousands)	December 31, 2022	December 31, 2021
United States	$ 40,343	$ 38,564
Canada[1]	1,856	13,831
India	1,047	276
Total property and equipment, net	$ 43,246	$ 52,671

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

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, 2022. Due to the material weaknesses in internal control over financial reporting as described below, our principal executive officer and principal financial officers concluded that, as of the end of the period covered by this report, our disclosure controls and procedures were not effective.

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, 2022. 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). This assessment resulted in management identifying certain material weaknesses in internal control over financial reporting as described below. As a result, management has concluded that, as of December 31, 2022, our internal control over financial reporting is not effective.

Notwithstanding the identified material weaknesses, management has concluded that the Consolidated Financial Statements included in this Annual Report on Form 10-K present fairly, in all material respects, the Company's financial position, results of operations and cash flows for the periods disclosed in conformity with U.S. GAAP.

The Company's independent registered public accounting firm, EisnerAmper LLP, who audited the consolidated financial statements included in this Annual Report on Form 10-K issued an adverse opinion on the effectiveness of the Company's internal control over reporting. EisnerAmper LLP's report is included herein.

Material Weaknesses in Internal Control over Financial Reporting

Upon evaluation of our internal control over financial reporting we identified certain material weaknesses in our controls at our Novitium subsidiary. We completed the acquisition of Novitium in November of 2021 and shortly thereafter, began the integration of Novitium's policies, processes, people, technology, and operations into our system of internal control over financial reporting. In 2022, we completed the integration of Novitium's order to cash cycle into ANI's system of procedures and contracts, and the controls were successfully tested and found to be operating as prescribed, however, we found material weaknesses in other key processes.

The Company did not maintain an effective control environment in the Novitium subsidiary as a result of the following:

- Lack of adequate personnel resources in Novitium team to implement appropriate process controls addressing Novitium activity.
- Turnover in key finance personnel at Corporate that were tasked with driving / managing implementation of internal controls at Novitium, including the Corporate Controller. While we have seasoned temporary personnel in these corporate positions, we did not have adequate bandwidth to maintain focus on compliance with internal controls.
- Delays in execution of the extraction of the Procure to Pay cycle integration plan for the subsidiary, including creation of the Accounts Payable centers of excellence whereby processes at Novitium would be combined with legacy processes.

These factors contributed to the weaknesses in the following control activities, specifically, the following process areas related to activity at Novitium did not have effective controls in place and were not operating effectively for a sufficient amount of time:

- Purchase to Pay (Purchasing, Accounts Payable, and Cash Disbursements)
- Manufacturing and Inventory
- Human Resources/Payroll
- Financial Statement Close (limited to those pertaining to the Novitium subsidiary level that were not incorporated into overall Company controls)
- Information technology general controls

The areas noted above had one or more of the following specific compliance exceptions:

- Certain controls were not implemented as designed.
- Documented controls not being performed consistently for all applicable transactions.
- Control performance not being adequately documented and evidenced.
- Materiality thresholds used in certain control performance were not consistent with documented control design.
- Controls not in place nor operating for a sufficient amount of time/number or instances.
- Changes to control performance upon employee turnover.
- Information technology general controls ("ITGC") which could result in misstatements potentially impacting all Novitium related financial statement accounts and disclosures. Specifically, Novitium user access controls were not appropriately designed and maintained to adequately restrict user and privileged access to financial applications and data to the appropriate personnel.

In addition to the above Material Weaknesses related to our Novitium subsidiary, we also identified a material weakness in our ITGC. Specifically, our evaluation of our ITGC's identified that user access controls were not

operating effectively to adequately restrict user access to our network and financial applications and data. The Company attributes the findings primarily due to significant turnover in its IT personnel during the year.

We determined that the designed internal controls were not operating effectively as detailed above, 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 in the four Novitium related process areas noted above as well as overall ITGC related to user access.

Remediation of Material Weaknesses

The Company is committed to the planning and implementation of remediation efforts to address the material weaknesses. The Company is in the process of establishing formal processes through which it intends to remediate the identified material weaknesses and enhance the Company's overall control environment, including the following:

Novitium Related:

- Refine and complete its plan to incorporate procure to pay cycle into the overall company controls.
- For those controls that remain at the Novitium subsidiary, review the existing control documentation and revise and upgrade as appropriate to address all identified risks.
- 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.
- Implement its ERP and other systems as appropriate to support the internal control structure.
- 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.

ITGC Related:

- Management will ensure proper staffing of IT personnel and 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.

When fully implemented, the Company believes that the measures described above will appropriately remediate the identified material weaknesses, although management may determine that taking additional measures to remediate the material weaknesses may be necessary.

As part of its remediation efforts, the Company will continue to implement and document associated policies, procedures and internal controls and will test the ongoing operating effectiveness of the new and existing policies, procedures and internal controls in future periods.

Management intends to begin the above remediation efforts immediately and expects all remediation efforts to be completed in 2023. While the material weaknesses cannot be considered completely remediated until the applicable policies, procedures, and internal controls have operated for a sufficient period of time, management has determined that our timetable for completing the remediation efforts in 2023 will provide sufficient time to provide its assessment over the effectiveness of internal controls as of December 31, 2023.

Changes in Internal Control over Financial Reporting

Other than the material weaknesses and remediation efforts discussed above, there were no changes in our internal control over financial reporting during the quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 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 2023 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, 2022 and 2021, the related consolidated statements of operations, statements of comprehensive income, changes in stockholders' equity, and cash flows for each of the years ended December 31, 2022, 2021, and 2020, 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 116.

ANI PHARMACEUTICALS, INC.

EXHIBIT INDEX TO ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2022

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	Asset Purchase Agreement, dated as of December 26, 2013, by and between ANI Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc. (2)	Incorporated by reference to Exhibit 2.2 to ANI's Annual Report on Form 10-K as filed for the fiscal year ended December 31, 2013 (File No. 001-31812)
2.3	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, 2022 (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)

Exhibit No.	Exhibit	Method of Filing
10.1	Generic Wholesale Service Agreement, dated as of May 1, 2006, between ANI Pharmaceuticals, Inc. and Cardinal Health, First Amendment to Generic Wholesale Service Agreement, dated as of July 10, 2008, Letter Agreement, dated as of July 10, 2008, regarding assignment of the Generic Wholesale Service Agreement to ANIP Acquisition Company, d/b/a ANI Pharmaceuticals, Inc., Letter from Cardinal Health, dated December 22, 2008 Regarding Increase in Base Service Fee, and Second Amendment to Generic Wholesale Service Agreement, dated May 7, 2012 (2)	Incorporated by reference to Exhibit 10.59 to ANI's Registration Statement on Form S-4 as filed with the Securities and Exchange Commission on December 11, 2012 (File No. 333-185391)
10.2*	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)
10.3	Amendment No. 2 to Asset Purchase Agreement, dated as of July 10, 2015, between Teva Pharmaceuticals, Inc. 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 September 30, 2015 (File No. 001-31812)
10.4	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)
10.5*	ANI Pharmaceuticals, Inc. 2016 Employee Stock Purchase Plan	Incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement on Schedule 14A filed with the Commission on April 14, 2016
10.6	Asset Purchase Agreement between H2-Pharma, 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, 2016 (File No. 001-31812)
10.7	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)
10.8*	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)
10.9	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, 2017 (File No. 001-31812)

Exhibit No.	Exhibit	Method of Filing
10.10	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, 2017 (File No. 001-31812)
10.11	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)
10.12	Stock Purchase Agreement by and among WellSpring Pharma Services Inc., WSP Pharma Holdings, LLC, ANI Pharmaceuticals Canada 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, 2018 (File No. 001-31812)
10.13	Amended and Restated Credit Agreement between Citizens Bank, N.A. and ANI Pharmaceuticals, Inc. (2)	Incorporated by reference to Exhibit 10.22 to ANI's Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (File No. 001-31812)
10.14	Amendment No. 4 to Asset Purchase Agreement between ANI Pharmaceuticals, Inc. and Teva Pharmaceuticals USA, Inc.	Incorporated by reference to Exhibit 10.1 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2019 (File No. 001-31812)
10.15	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)
10.16	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).
10.17*	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)
10.18*	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)
10.19*	Employment Agreement between Nikhil Lalwani and ANI Pharmaceuticals, Inc., dated July 24, 2020	Incorporated by reference to Exhibit 10.1 to ANI's Current Report on Form 8-K filed August 3, 2020 (File No. 001-31812)
10.20*	Inducement Stock Option Award Agreement, effective as of September 8, 2020, between ANI Pharmaceuticals, Inc. and Nikhil Lalwani	Incorporated by reference to Exhibit 10.2 to ANI's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2020 (File No. 001-31812)
10.21	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
10.22	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)
10.23*	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)
10.24	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, 2022 (File No. 001-31812)
10.25	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, 2022 (File No. 001-31812
10.26*	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, 2022 (File No. 001-31812Filed herewith
10.27*	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, 2022 (File No. 001-31812
10.28*	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, 2022 (File No. 001-31812
10.29*	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)
10.30*	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)
10.31	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)
10.32	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)

10.34*	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)
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
101	The following financial information from this annual report on Form 10-K for the fiscal year ended December 31, 2022, 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

Exhibit No.	**Exhibit**	**Method of Filing**
104	The cover page from the Company Annual Report on Form 10-K for the year ended December 31, 2022 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: March 9, 2023

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

Date: March 9, 2023

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)	March 9, 2023
/s/ Stephen P. Carey Stephen P. Carey	Senior Vice President, Finance and Chief Financial Officer (principal financial and accounting officer)	March 9, 2023
/s/ Muthusamy Shanmugam Muthusamy Shanmugam	Director, Head of Research and Development and Chief Operating Officer of New Jersey Operations	March 9, 2023
/s/ Patrick D. Walsh Patrick D. Walsh	Director and Chairman of the Board of Directors	March 9, 2023
/s/ Thomas J. Haughey Thomas J. Haughey	Director	March 9, 2023
/s/ David B. Nash, M.D., M.B.A. David B. Nash, M.D., M.B.A.	Director	March 9, 2023
/s/ Robert E. Brown, Jr. Robert E. Brown, Jr.	Director	March 9, 2023
/s/ Jeanne Thoma Jeanne Thoma	Director	March 9, 2023
/s/ Antonio Pera Antonio Pera	Director	March 9, 2023
/s/ Renee Tannenbaum Renee Tannenbaum	Director	March 9, 2023

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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 North American 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 concerning the Company's possible or assumed future actions, business strategies, events, or results of operations, are forward- looking statements. In some instances, these statements may be preceded by, followed by or include the words "believes," "estimates," "expects," "projects," "forecasts," "may," "will," "should," "seeks," "plans," "scheduled," "anticipates" or "intends" or the negatives of these terms or variations of them or similar terminology.

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.