

Risk Factors Comparison 2025-02-28 to 2024-02-29 Form: 10-K

Legend: **New Text** ~~Removed Text~~ ~~Unchanged Text~~ **Moved Text** **Section**

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

- **Our approved products, including Cortrophin Gel, ILUVIEN and YUTIQ, may not achieve commercialization at levels of market acceptance that will continue to allow us to achieve profitability;**
- Cortrophin Gel is our first rare disease pharmaceutical product. To the extent we are not able to continue to achieve commercial success with this product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted;
- ~~Our approved products, including Cortrophin Gel,~~ **We may fail to realize the benefits expected from our acquisition of Alimera and the combined company** may not achieve commercialization at levels of ~~perform as we or the~~ market **expects** acceptance that will continue to allow us to achieve profitability;
- ~~Acquisitions and investments could disrupt our business and harm our financial position and operating results;~~
- The limited number of suppliers for our API could result in lengthy delays in production if we need to change suppliers;
- Several of the products we have acquired cannot be manufactured in our facilities and we must secure and maintain qualified and compliant contract manufacturers. Noncompliance by these contract manufacturers or our inability to find qualified contract manufacturers could result in us being unable to commercialize these products;
- Several of our products are manufactured and / or packaged by **single-sourced** third parties, which we cannot control and could result in us being unable to market and distribute products;
- We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business;
- **Medicaid rebate accruals** have increased and continue to increase due to our acquisitions and subsequent sales of branded products and authorized generics of branded products;
- Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions;
- We **face vigorous competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of our products;**
- **We** expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products;
- Production at any or all of our three current manufacturing facilities could be interrupted, which could cause us to fail to deliver product on a timely basis;
- We rely on third parties to assist with our clinical ~~trials~~ **studies**. If these parties do not perform or are non-compliant, it could negatively impact the clinical trial and potential of regulatory approval;
- ~~further~~ **Further**, we may be required to audit or redo previously completed trials or recall already- approved commercial products;
- ~~Clinical trials for our products may not generate the outcomes we expect, may take longer or be more costly to complete than we anticipate;~~
- We may be adversely affected by the expiration of patents that protect key aspects of our products in the near- to medium- term;
- Inability to protect our intellectual property in the U.S. and foreign countries could negatively affect sales of our branded products;
- ~~If~~ **With the exception of patents on a limited number of products** we fail to comply **do not own or license any material patents associated** with our obligations in the **majority of agreements under which we license development or our commercialization rights to products, and or our ability to protect and control unpatented trade secrets, know-how, and other technology technological innovation is limited** from third parties, we could lose license rights that are material to our business;
- Our success is largely dependent upon certain key employees, including members of our senior management, the loss of whom could adversely affect our operations;
- We rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology could harm our ability to operate the business effectively;
- We are involved in and may become involved in legal proceedings from time to time, which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources;
- We are susceptible to product liability claims that may not **be covered by insurance, which, if successful, could require us to pay substantial sums;**
- ~~Our~~ **The obligations and liabilities** continuing trend toward consolidation of customer groups **Alimera, some of which may be unanticipated or unknown, may be greater than we have anticipated, which may diminish the value of Alimera to us;**
- **Our operations in an international market subject us to additional regulatory oversight both in the international market and in the U. S., as well as, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating result results in declines in;**
- **Our operations, including the those resulting from sales volume and prices of our products acquisition of Alimera, and its international operations, will subject us to political and economic risks, increased- increase fees charged by customers- our exposure to potential liability under anti- corruption, trade protection, tax, and other laws and regulations;**
- **Future acquisitions and investments could disrupt our business and harm our financial position and operating results;**
- Pharmaceutical product quality standards are steadily increasing on all products, and if we cannot meet these standards, we may be required to discontinue marketing and / or recall products from the market;
- Federal and state false claims litigation brought against us by private individuals and the government could result in civil and criminal penalties, damages, fines and other related actions;
- The use of legal, regulatory, and legislative strategies by competitors could result in increased costs to develop and market our products, delay new product introductions and reduce profit potential;
- Third- party payer actions may prevent us from effectively marketing our products or cause us to decrease pricing;
- ~~Continuing studies of our products could produce results that could have a negative impact on our business;~~
- Healthcare reform legislation could have a material adverse effect on our business, financial position, and operating results;
- ~~Barriers in achieving anticipated revenue growth and profitability could have a material adverse effect on our business, financial position, and operating results;~~
- ~~We may not achieve the anticipated benefits from our acquisition of Novitium Pharma LLC (“ Novitium ”);~~
- The obligations

and liabilities of Novitium, some of which may be unanticipated or unknown, may be greater than we have anticipated, which may diminish the value of Novitium to us; • Public health outbreaks, epidemics, or pandemics (such as COVID- 19) have adversely affected and may in the future adversely affect our business; • **The continuing trend toward consolidation of customer groups could result in declines in the sales volume and prices of our products, and increased fees charged by customers**; • The Food and Drug Administration (“ FDA ”) does not provide guidance on safety labeling for products that are marketed without approved New Drug Applications (“ NDAs ”) or Abbreviated New Drug Applications (“ ANDAs ”), which could increase our potential liability with respect to failure-to- warn claims for these products; • Four of our products are marketed without approved NDAs or ANDAs and we can offer no assurances that the FDA will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected; • If the Drug Enforcement Administration (“ DEA ”) does not approve supply of the API we need to manufacture our controlled substances, we may be unable to manufacture controlled substances, which would eliminate our revenue on these products; • Our **Medicaid rebate accruals have increased and continue..... 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** **Our indebtedness** **and principal payments under liabilities could limit the cash flow available for** our Credit Agreement with **Truist operations and expose us to risks that could adversely affect our business, financial condition and results of operation**; • **To service our indebtedness, we will be required to generate** a significant amount of cash; • We previously identified material weaknesses in our internal control over financial reporting, and the failure to maintain an effective system of internal controls and procedures may cause investors to lose confidence in our financial reporting; • Our **New Credit Facility Agreement** 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; • **Certain risks relating to our 2. 25 % Convertible Senior Notes due 2029 and related capped call transactions; and** • Raising additional funds by issuing additional equity securities may cause dilution to our current stockholders. Raising additional funds by entering into additional credit or other borrowing facilities or issuing debt may subject us to covenants and other requirements that may restrict our operations; • Our operations in an international market subject us to additional regulatory oversight both in the international market and in the U. S., as well as, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results; and • Our operations, including those resulting from our acquisition of Novitium and its international operations, will subject us to political and economic risks, increase our exposure to potential liability under anti- corruption, trade protection, tax, and other laws and regulations. The following are significant factors known to us that could materially harm our business, financial position, or operating results or could cause our actual results to differ materially from our anticipated results or other expectations, including those expressed in any forward- looking statement made in this report. The risks described are not the only risks facing us. Additional risks and uncertainties not currently known to us, or that we currently deem to be immaterial, also may adversely affect our business, financial position, and operating results. If any of these risks actually occur, our business, financial position, and operating results could suffer significantly. As a result, the market price of our common stock could decline and investors could lose all or part of their investment. Risks Related to our Business 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, **including Cortrophin Gel, ILUVIEN and YUTIQ,** may not achieve commercialization at levels of market acceptance that **will continue to** allow us to achieve profitability **and we may face substantial competition from competitors that discover, develop or commercialize competing products before or more successfully than we do** which could have a material adverse effect on our business, financial position, and operating results. **The development and commercialization of new drugs is highly competitive, and the commercial success of our products or any of our future products or product candidates will depend on several factors, including our ability to differentiate any such products or product candidates from our competitors’ current or future products, including the creation of generic competitive products.** We seek to develop, license, or acquire products that we can commercialize at levels of market acceptance that would allow us to recoup our costs, grow market share, and achieve profitability. **However, we face competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to our current products and to any future products or product candidates that we may develop or commercialize in the future.** Even if we are able to obtain regulatory approvals for our pharmaceutical products, if we fail to predict accurately demand for such products, **or our competitors more effectively develop competitive products, that have few or less severe adverse side effects and have higher rates of acceptance by physicians**, our business, financial position, and operating results could be adversely affected. Levels of market acceptance for our products could be impacted by several factors, including but not limited to: • 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 Cortrophin Gel is our first rare disease pharmaceutical product. To the extent our ongoing and continuing efforts to commercialize this product are unsuccessful, our business, financial condition and results of operations will be

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

- successfully establishing and maintaining effective sales, marketing, and distribution systems in jurisdictions in which Cortrophin Gel is approved for sale ;
- successfully establishing and maintaining manufacturing capabilities with our third- party suppliers and CMOs and manufacturing adequate commercial quantities of Cortrophin Gel at acceptable cost and quality levels, including maintaining current good manufacturing practice (“ cGMP ”) and quality systems regulation standards required by various regulatory agencies ;
- broad acceptance of Cortrophin Gel by physicians, patients, and gaining market access share in the healthcare community ;
- the acceptance of pricing and placement of Cortrophin Gel on payers’ formularies and the associated tiers ;
- effectively competing with the only other competitor that has an approved adrenocorticotrophic hormone (“ ACTH ”) therapy product on the market, as well as other products that are in development or may be developed in the future as a treatment option ;
- continued demonstration of safety and efficacy of Cortrophin Gel in comparison to competing products or treatment options ;
- our ability to comply with ongoing regulatory obligations and continued regulatory review which may result in significant additional expense and may require labeling changes based on new safety information, post- market studies or clinical trials to evaluate safety risks related to the use of Cortrophin Gel; and
- obtaining, maintaining, enforcing, and defending intellectual property rights and claims. If we do not achieve one or more of these factors, we could experience an inability to successfully commercialize Cortrophin Gel, which would negatively impact our business, financial condition and results of operations. In addition, sales of Cortrophin Gel could be negatively affected by discovery of previously unknown problems with the product, such as adverse events of unanticipated severity or frequency, problems with the facilities where the product is manufactured, or imposition of restrictions on Cortrophin Gel, including requiring withdrawal of the product from the market, by a regulatory agency if it disagrees with the promotion, marketing, or labeling of the product. We are continuing to develop may enter into new lines of business that offer new products and / our- or marketing services and we may sales organization to support Cortrophin Gel and have limited experience in marketing such new prescription rare disease drug products . If we are unable and / or services, which may subject us to continue additional risks. From time to time, we may enter into new lines of business that offer new products and / or services. For example, in September 2024 we acquired Alimera, a global pharmaceutical company that specializes in the commercialization and develop development marketing and sales capabilities of ophthalmic retinal pharmaceuticals, which for Cortrophin Gel, our us is a new line of business will suffer. Our lack of We first established our rare disease sales, marketing or distribution capabilities in 2021 and have limited institutional experience in with or knowledge of such business or other new lines of business we may choose to enter, as well as external factors, such as competitive alternatives, potential conflicts of interest, either real or perceived, and shifting marketing --- market rare disease products preferences, may impact our implementation and operation of such new lines of business . We intend Other risks of implementing new lines of business include: • potential diversion of management' s attention, available cash and other resources from our existing business; • any determination by governmental agencies that any acquisition we undertake is anticompetitive in any relevant market; • unanticipated liabilities or contingencies; • compliance with new or increased regulatory burdens; • potential damage to continue existing customer relationships, lack of customer acceptance or inability to attract new customers; • the cost of develop developing an in- house sales and marketing organization and sales force-, which will would require significant expenditures, management resources , and time . We will have ; and • the inability to compete with effectively in other -- the new line of pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. Future acquisitions and investments could disrupt our business and harm our financial position and operating results. Failure 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 ---- manage time and focus from operating our business..... may undertake, our failure to address these risks or in other -- the implementation or problems encountered in connection with any acquisitions- acquisition and investments of new lines of business or the offering of new products or services could have a material adverse effect on cause us to fail to realize the anticipated benefits of these acquisitions or our investments reputation , cause us to incur unanticipated liabilities, and harm our business generally, results of operations and financial condition . We depend on a limited number of suppliers for API. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. We may experience lengthy delays if we need to change an API supplier, which could have a material impact on business and results of operations. Our ability to manufacture and distribute products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the U. S. During the year ended December 31, 2024, approximately 12 %, of our raw material inventory purchases were from one domestic supplier. During the year ended December 31, 2023, no single vendor represented at least more than 10 % of our raw material inventory purchases. During the year ended December 31, 2022 , we purchased approximately 19 % , of our raw

material inventory **purchases were** from one **domestic** supplier. During the year ended December 31, 2021, no single vendor represented at least 10% of inventory purchases. Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect our ability to manufacture and distribute our products and could result in legal liabilities that could materially affect our ability to realize profits or otherwise harm our business, financial, and operating results. ~~Virtually all of our generic contracts for the supply of pharmaceutical products to customers contain "failure to supply" clauses. Under these clauses, if we are unable to supply the requested quantity of product within a certain period after receipt of a customer's purchase order, the customer is entitled to procure a substitute product elsewhere and we must reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product. Therefore, our ability to source sufficient quantities of API for manufacturing is critical.~~ We source the raw materials for our products from both domestic and international suppliers. Generally, we qualify only a single source of API for use in each product due to the cost and time required to validate and qualify a second source of supply. Any change in one of our API suppliers must usually be approved through a Prior Approval Supplement ("PAS") by the FDA. The process of obtaining an approval of such a PAS can require between four and 18 months. While we also generally qualify a single source for non-API raw materials, the process required to qualify an alternative source of a non-API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare but could occur as a result of a supplier's business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we carefully select suppliers, based on various factors including quality, reliability of supply, and long-term financial stability. Certain of the APIs ~~- API~~ for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections. Several of the products we have acquired cannot be manufactured in our facilities and are manufactured, **packaged** and / or **packaged-distributed** 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~~ **or distributor** fails to comply with federal, state, and local laws and regulations, ~~or third-party manufacturers or distributors sustain delays in production~~ **and distribution of our products**, our business, financial position, and operating results could be materially, adversely affected. We have acquired, and may continue to acquire, a variety of products that we seek to commercialize. Some of these products, including injectables, softgel capsules, and ~~Purified-Cortrophin Gel~~, **as well as ILUVIEN and YUTIQ**, are products that we cannot currently manufacture in our facilities. As a result, we may seek partners to contract manufacture the products on our behalf, and we rely on **single-source** third parties to manufacture, **package** and / or **package-distribute** many of our products. Like our ~~company~~ **Company**, these ~~firms~~ **companies** must comply with cGMPs and other federal, state, and local laws and regulations regarding pharmaceutical manufacturing. Noncompliance by those ~~firms~~ **companies** may result in warning letters, fines, product recalls, and partial or total suspension of production and distribution. If we are unable to find qualified contract manufacturers or **distributors or** if a contract manufacturer **or distributor** fails to comply with federal, state, and local laws and regulations, we may be unable to commercialize these products, which could have a material adverse effect on our business, financial position, and operating results, including an impairment of the acquired product. We expect our reliance on third party manufacturers to continue to increase in the future as we receive approvals for new products to be manufactured through our collaborative arrangements, and as we seek additional growth opportunities outside of the capabilities of our current manufacturing facilities. If we are unable to secure third-party manufacturers for these products on commercially acceptable terms, we may not be able to market and distribute such products at a profit. **In addition, manufacturers and distributors of our products may sometimes encounter difficulties in production and distribution. These problems include failure to meet target production costs and yields, failure to meet product release specifications, including stability of the product, quality assurance system failures, operator error and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Adverse weather conditions and natural disasters may also affect our manufacturers' and distributors' supply chains, which could negatively impact our ability to source materials and components to make our products and, in more severe cases, such as hurricanes, earthquakes, floods, droughts, tornadoes or blizzards, eliminate the availability, or significantly increase the cost, of the components to make our products, sometimes for prolonged periods of time. The response of federal, state and local governmental bodies and agencies to climate change through regulations, mandates, reporting and disclosure requirements, taxes or levies could materially increase our or our manufacturers' cost to operate or obtain product components at a reasonable price, resulting in a material adverse effect on our financial results. Any of these situations could materially and adversely harm our business and financial condition. We cannot assure you that any product quality issues relating to the manufacture and / or distribution of our products or any future product candidates will not occur in the future.** Any delays or difficulties with third-party manufacturers **and / or distributors** could adversely affect the marketing and distribution of these products, or future products, which could have a material adverse effect on our business, financial position, and operating results. We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business. Many of our products are eligible for reimbursement under federal and state health care programs such as Medicaid, Medicare, TRICARE, and / or state pharmaceutical assistance programs, and as a result, certain U. S. federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are, and will be, applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The domestic and foreign laws that may affect our ability to operate include, but are not limited to: (i) the U. S. Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration,

directly or indirectly, as a means of inducing, or in exchange for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) U. S. federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment to Medicare, Medicaid or other federal healthcare program payers that are false or fraudulent; (iii) new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; (iv) the U. S. Physician Payments Sunshine Act, which among other things, requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually information related to certain " payments or other transfers of value " made to physicians, physician assistants, advanced practice nurses and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members, and similar state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; (v) the government pricing rules applicable to the Medicare and Medicaid programs, the 340B Drug Pricing Program, the U. S. Department of Veterans Affairs program, the TRICARE program, and state price transparency reporting laws; and (vi) state and foreign law equivalents of each of the above U. S. laws, such as anti- kickback and false claims laws which may apply to items or services. Defense of litigation claims and government investigations can be costly, time- consuming, and distract management, and it is possible that we could incur judgments, settlements, deferred or non- prosecution agreements, or corporate integrity agreements that would require us to change the way we operate our business. We are committed to conducting the sales and marketing of our products in compliance with the healthcare fraud and abuse laws, but certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and / or criminal sanctions. Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that govern our activities, such as federal and state anti- kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn and construed by the courts. While we manage our business activities to comply with these statutory provisions, due to their breadth, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the DOJ, the Office of Inspector General at the U. S. Department of Health and Human Services, and other agencies have increased their enforcement activities with respect to the manufacturing, sales, marketing, research and similar activities of pharmaceutical companies in recent years, and many pharmaceutical companies have been subject to government investigations related to these practices. A determination that we are in violation of these and / or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacturing and / or distribution activities, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. Any of these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows. **If we fail to comply with data protection laws and regulations, we could be subject to government enforcement actions (which could include civil or criminal penalties), private litigation and / or adverse publicity, which could negatively affect our operating results and business.** We are subject to **certain data protection laws and regulations. In the U. S., numerous federal and state laws and regulations, including state data breach notification laws, state health information and / or genetic privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health related and other personal information security. In California, the California Consumer Privacy Act (" CCPA ") establishes certain requirements for data use and sharing transparency, and provides California residents certain rights concerning the use, disclosure, and retention of their personal data. The California Privacy Rights Act currently in effect, significantly amends the CCPA. Virginia, Colorado, Utah, and Connecticut have enacted privacy laws similar to the CCPA that impose new obligations or limitations in areas affecting our business, and similar laws are under consideration in other states. These laws and regulations, policies are evolving and contractual subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. The obligations related to data privacy comply with the CCPA and security evolving legislation may involve, among other things, updates to our notices and changes the development of new processes. We may be subject to fines, penalties, or private actions in the event of non- compliance with such laws. In addition, we may obtain health information from third parties (e. g., healthcare providers who prescribe our product) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, policies (collectively, contractual " HIPAA "). HIPAA imposes privacy and security obligations on covered entity health care providers, health plans, and health care clearinghouses failure to comply with such requirements, as well as any breach their " business associates " — certain persons or entities that create, receive, maintain, or transmit protected health information in connection with providing a specified service or performing a function on behalf of unsecured a covered entity. Although we are not directly subject to HIPAA, we could be subject to criminal penalties if we knowingly receive individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA.**

Further at the federal level, the Federal Trade Commission (“FTC”) also sets expectations for failing to take appropriate steps to keep consumers’ personal information secure protected by law, could subject us to significant costs, fines, penalties (civil and criminal), and civil litigation which may have a material adverse effect on our or failing business, financial condition or results of operations. As regulatory focus on privacy issues continues to increase, and laws and regulations concerning provide a level of security commensurate to promises made to individual about the security of the their protection of personal information expand (such as in a privacy notice) may constitute unfair or deceptive acts or practices in violation of Section 5 (a) of the Federal Trade Commission Act (“FTC Act”). The FTC expects a company’s data security measures to be reasonable and become more appropriate in light of the sensitivity and volume of consumer information it holds, the size and complex complexity of its, these potential risks to our business could intensify. In addition, the interpretation and application the cost of consumer, available tools to improve security and reduce vulnerabilities. Individually identifiable health related information is considered sensitive data that merits stronger safeguards. With respect to privacy, the FTC also sets expectations that companies honor the privacy promises made to individuals about how the company handles consumers’ personal information; any failure to honor promises, such as the statements made in a privacy policy or on a website, may also constitute unfair or deceptive acts or practices in violation of the FTC Act. While we do not intend to engage in unfair or deceptive acts or practices, the FTC has the power to enforce promises as it interprets them, and events that we cannot fully control, such as data breaches, may result in FTC enforcement. Enforcement by the FTC under the FTC Act can result in civil penalties or enforcement actions. EU Member States and other jurisdictions where we operate have adopted data protection laws and regulations, which impose significant compliance obligations. For example, the General Data Protection Regulation (GDPR) imposes strict obligations and restrictions on the ability to collect, analyze and transfer personal data, including health data from clinical trials and adverse event reporting. Switzerland has adopted laws that impose restrictions and obligations similar to the GDPR. The obligations and restrictions under the GDPR and Switzerland’s laws concern, in some instances the consent of the individuals to whom the personal data relate, the processing details disclosed to the individuals, the sharing of personal data with third parties, the transfer of personal data out of the EEA or Switzerland, contracting requirements (such as with clinical trial sites and vendors), and security breach notifications, as well as substantial potential fines, in some cases up to 4 % of annual global turnover, for breaches of the data protection obligations. Data protection authorities from the different EU Member States and the EEA may interpret the GDPR and applicable related national laws differently which could effectively result in requirements additional to those currently understood to apply under the GDPR. In addition, guidance on implementation and compliance practices may be updated or otherwise revised, which adds to the complexity of processing personal data in the EU. When processing personal data of subjects in the EU, we have to comply with applicable data protection and electronic communications laws. In particular, as we rely on service providers processing personal data of subjects in the EU, we have to enter into suitable contract terms with such providers and receive sufficient guarantees that such providers meet the requirements of the applicable data protection laws, particularly the GDPR which imposes specific and relevant obligations. Enforcement by EU and U. K. regulators is active, and failure to comply with the GDPR or applicable Member State law may result in substantial fines. Legal mechanisms to allow for the transfer of personal data from the EEA or U. K. to the U. S. may impact our ability to transfer personal data or otherwise may cause us to incur significant costs to do so legally. On July 16, 2020, the European Court of Justice ruled that the Privacy Shield is an invalid data transfer mechanism and confirmed that the Standard Contractual Clauses (“SCCs”) remain valid. If companies are often uncertain relying on the SCCs as their transfer mechanism to transfer personal information from the EEA to the U. S. (or to other jurisdictions not recognized as adequate by the EU), contradictory, they must be incorporated into new and existing agreements within prescribed timeframes. The U. K. adopted versions of their own SCCs. Updating agreements to incorporate these new SCCs for the EEA and U. K. may require significant time and resources to implement, including through adjusting our operations, conducting requisite data transfer assessments, and revising our contracts. Companies that have not taken steps to demonstrate that their SCCs and personal data recipients in flux the U. S. or other non-adequate jurisdictions are suitable to receive the personal data may be subject to enforcement actions by competent authorities in the EU for failure to comply with related data privacy rules. Additionally, the European Commission adopted a draft adequacy decision for the EU- U. S. Data Privacy Framework, which complicates reflects the assessment by the European Commission of the U. S. legal framework. The draft decision concludes that the U. S. ensures an adequate level of protection for personal data transferred from the EU to U. S. companies. After an approval process, the European Commission is expected to adopt the final adequacy decision, which will allow data to flow freely from the EU to the U. S. If we or our distributors fail to comply with applicable data privacy laws concerning, or if the legal mechanisms we or our distributors rely upon to allow, the transfer of personal data from the EEA or Switzerland to the U. S. (or other countries not considered by the European Commission to provide an adequate level of data protection) are not considered adequate, we could be subject to government enforcement actions, including an order to stop transferring the personal data outside of the EEA and significant penalties against us. Moreover, our business could be adversely impacted if our ability to transfer personal data out of the EEA or Switzerland to the U. S. is restricted, which could adversely impact our operating results. Failure to comply with data protection laws and regulations could result in unfavorable outcomes, including increased compliance efforts costs, delays or impediments in the development of new products, increased operating costs, diversion of management time and attention, government enforcement actions and create liability for us (which could include civil, administrative, and / or criminal penalties), private litigation and / or adverse publicity that could negatively affect our operating results and business. Our anticipated revenue growth and profitability, if achieved, is dependent upon our ability to develop, license or acquire, and commercialize new products on a

timely basis in relation to our competitors' product introductions, and to address all regulatory requirements applicable to the development and commercialization of new products. Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business, financial position, and operating results. Our future revenues and profitability are dependent upon our ability to successfully develop, license or acquire, and commercialize pharmaceutical products in a timely manner. Product development is inherently risky and time-consuming. Likewise, product licensing involves inherent risks, including uncertainties due to matters that may affect the achievement of milestones, as well as the possibility of contractual disagreements with regard to the supply of product meeting specifications and terms such as license scope or termination rights. The development and commercialization process also requires substantial time, effort, and financial resources. Additionally, we have entered profit-sharing or royalty arrangements with third parties in which we sell products under ANDAs or NDAs owned or licensed by these third parties. Under these agreements, we pay these third parties a specified percentage of the gross profit earned on sales of the products, and such percentages in certain cases increase as additional gross profit is earned. Any increases in these percentages would impact our future profitability. We may not be successful in commercializing products on a timely basis, if at all, which could adversely affect our business, financial position, and operating results. The FDA must approve any new prescription product before it can be marketed in the U. S. The process of obtaining regulatory approval to manufacture and market branded and generic pharmaceutical products is rigorous, time consuming, costly, and largely unpredictable. We may be unable to obtain requisite approvals on a timely basis for branded or generic products that we may develop, license, or acquire. Moreover, if we obtain regulatory approval for a drug, we may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed, which in turn could restrict the potential market for the drug. Also, for products pending approval, we may obtain raw materials or produce batches of inventory. In the event that regulatory approval is denied or delayed, we could be exposed to the risk of any such inventory becoming obsolete. The timing and cost of obtaining regulatory approvals could adversely affect our product introduction plans, business, financial position, and operating results. The approval process for generic pharmaceutical products often results in the FDA granting simultaneous final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires. This often forces a generic firm to face immediate competition when it introduces a generic product into the market. Additionally, further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product. These circumstances generally result in significantly lower prices, as well as reduced margins, for generic products compared to branded products. New generic market entrants generally cause continued price and margin erosion over the generic product life cycle. As a result, we could be unable to grow or maintain market share with respect to our generic pharmaceutical products, which could have a material adverse effect on our ability to market that product profitably and on our business, financial position, and operating results. Furthermore, if we are unable to address all regulatory requirements applicable to the development and commercialization of new products in a timely manner, our product introduction plans, business, financial position, and operating results could be materially adversely affected. The FDA regulates and monitors all promotion and advertising of prescription drugs after approval. All promotion must be consistent with the conditions of approval and submitted to the agency. Failure to adhere to FDA promotional requirements can result in enforcement letters, warning letters, changes to existing promotional material, and corrective notices to healthcare professionals. Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties, state governments and the federal government, significant civil and criminal penalties, and compliance agreements that require a company to change current practices and prevent unlawful activity in the future. Our ~~branded products may become subject to increased generic competition. Many of our branded products have not been patent-protected for several years and no longer have market exclusivity. As a result, they face competition from lower priced generic products which may reduce and limit the sales of our mature brand products. Additionally, increased focus by the FDA on approval of generic products may accelerate this trend. If generic products are substituted for these branded products, our revenue from these products will decrease, which could have an adverse effect on our business, financial position, and operating results.~~ Our Medicaid rebate accruals have increased and continue to increase due to our acquisitions and subsequent sales of branded products and authorized generics of branded products, and the estimates on which our accruals are based are subject to change. Any such change could have a material adverse effect on our business, financial position, and operating results. Our Medicaid rebate accruals have increased significantly due to our acquisitions and subsequent sales of branded products and authorized generics of branded products. We accrue for these rebates at the time of sale based on our estimates of the amount of our product that will be prescribed to Medicaid beneficiaries. The resulting accruals are significant, and as Medicaid utilization trends change, we may need to change our estimates accordingly. We cannot guarantee that actual results will not differ from our estimates. In addition, the Patient Protection and Affordable Care Act ("PPACA") included a significant expansion of state Medicaid programs. As more individuals become eligible for coverage under these programs, Medicaid utilization of our products could increase, resulting in a corresponding increase in our rebate payments. Increases in Medicaid rebate payments could decrease our revenues from product sales, which in turn could adversely affect our business, financial position, and operating results. Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions. Any such change could have a material adverse effect on our business, financial position, and operating results. Our accruals for the rebates under the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions. We accrue for these rebates at the time of sale based on our estimates of the amount of product that will be prescribed to patients in the Medicare Coverage Gap Discount program, which is primarily for the benefit of persons aged 65 years and over. As we acquire and launch additional products, many of which, are often used by patients in the 65 and older age range, our estimates of these rebates have grown. Increases in Medicare Coverage Gap Discount rebates, and legislative changes to the Medicare Coverage Gap Discount Program, could decrease our revenues from product sales, which in turn could adversely affect our business, financial position, and operating results. We have entered into distribution agreements under which..... position, and operating

results. We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products. Failure to successfully introduce products into the market could have a material adverse effect on our business, financial position, and operating results. We conduct research and development primarily to enable us to manufacture and market approved products in accordance with applicable regulations. Research and development is expensive and time-consuming. As we seek to develop new products, or re-commercialize products that were previously approved, our research expenses will increase, potentially significantly, and we cannot be certain that we will recover our investment in a product, even if that product is commercialized. If we spend significant resources on research and development efforts and are not able to introduce new products, our business, financial position, and operating results may be materially adversely affected. We produce the majority of our products in three manufacturing facilities. Production at any or all of these facilities could be interrupted, which could cause us to fail to deliver sufficient product to customers on a timely basis and have a material adverse effect on our business, financial position, and operating results. Our internal manufacturing operations are currently based in three facilities. We have transitioned the products manufactured or packaged in Oakville to one of our three U. S.- based manufacturing sites, and we are seeking to find potential buyers for the Oakville site. While these three remaining facilities are sufficient for our current needs, the facilities are highly specialized and any damage to or need for replacement of all or any significant function of our facilities could be very costly and time-consuming and could impair or prohibit production and shipping. A significant disruption at any of the facilities, even on a short-term basis, whether due to a labor strike, adverse quality or compliance observation, vandalism, natural disaster, fire, storm or other environmental damage, or other events could impair our ability to produce and ship products on a timely basis and, among other consequences, could subject us to “failure to supply” claims from our customers, as discussed below. Although we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses because of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. Any of these events could have a material adverse effect on our business, financial position, and operating results. Virtually all of our contracts for the supply of generic products to our customers contain “failure to supply” clauses which require us to reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product in the event we failed to deliver the requested quantity within a specified period of time. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements and can be far in excess of the revenue that we would otherwise have received on the sale of our own product. Therefore, our ability to produce and ship a sufficient quantity of product on a consistent basis is critical. Failure to deliver products could have a material adverse effect on our business, financial position, and operating results.

The NEW DAY clinical trial may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME, fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, take longer or be more costly to complete than we currently anticipate or fail to change physician prescribing practices. We are conducting our NEW DAY clinical trial, which is a multicenter, single-masked, randomized, controlled trial designed to generate prospective data evaluating ILUVIEN as a baseline therapy in the treatment of DME and demonstrate its potential advantages over the current standard of care of repeat anti-VEGF (aflibercept) injections. The NEW DAY clinical trial is fully enrolled as of May 2023 with 300 treatment-naïve, or almost naïve, DME patients in approximately 42 sites around the U. S. The NEW DAY clinical trial may fail to demonstrate the efficacy of ILUVIEN as baseline therapy in patients with early DME, fail to generate data demonstrating the benefits of ILUVIEN when compared to the current leading therapy for DME, or take longer or be more costly to complete than we currently anticipate, and / or fail to change physician prescribing practices despite a successful result. The occurrence of any of these events could materially and adversely affect our business, financial condition and cash flows, and results of operations. We rely on third parties to assist with our clinical studies-trials. If these third parties do not perform as required or expected, or if they are not in compliance with FDA rules and regulations, our clinical studies-trials may be extended, delayed or terminated, or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the products being tested in such studies-trials. Further, we may be required to audit or redo previously completed trials or recall already-approved commercial products. We rely on third parties, such as medical institutions, clinical investigators, and contract laboratories, to assist with our clinical studies-trials. We are responsible for confirming that our studies-trials are conducted in accordance with applicable regulations and that each of our clinical studies-trials is conducted in accordance with our general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording, and reporting the results of clinical studies-trials, to assure that data and reported results are accurate and that the clinical study-trial participants are adequately protected. Our reliance on these third parties does not relieve us of these responsibilities. If the third parties assisting us with our clinical studies-trials do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA’s good clinical practice regulations, do not adhere to our protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical studies-trials may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the products being tested in such studies-trials. For our already-approved commercial products, we may be required to audit or redo previously completed trials or recall our products from the market, which could have a material adverse effect on our business, financial position, and operating results. **Clinical trials With the exception of patents or for our products may not generate the outcomes we expect, may take longer or be more costly to complete than we anticipate. From time to time, we initiate or participate in clinical trials for our products and may in the future participate in clinical trials or studies for other products. The timing of patent-patient applications enrollment in these trials, and related costs to Veregen, can baelofen, and hydrochlorothiazide products, we do not own or license any material patents associated with our products, and our ability to protect and control unpatented trade secrets, know-how, and other technological innovation is limited. Generally, the branded**

pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. Except for licenses for patent technology for Veregen, and ownership of patents and patent applications relating to our baclofen and hydrochlorothiazide products, we do not own or license any material patents associated with our products and therefore do not enjoy the same level of intellectual property protection with respect to such products as would a pharmaceutical manufacturer that markets a patented product. We have limited ability to protect and control trade secrets, know-how, and other technological innovation, all of which are unpatented. Others independently may develop similar or better proprietary information and techniques and disclose them publicly. In addition, others may gain access to our trade secrets, and we may not be **unpredictable** able to protect our rights to our unpatented trade secrets. In addition, confidentiality agreements and other measures may not provide protection for..... could require significant capital investments to remediate any such **trials** failure, problem or breach, all of which could adversely affect our **or studies** business, financial position, and operating results. We are currently involved in and may **be more expensive** from time to time become involved in legal proceedings, some of which may be result in substantial losses, government enforcement actions, damage to our **or business and reputation** **take longer than we expect**, and place a strain on **data may be inconclusive**, our **or such studies** internal resources. We are currently involved in and **trials** in the future may **fail to change physician prescribing practices. Further** become involved in legal proceedings in the ordinary course of our business, as a party or non-**the outcome of continuing post** 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..... other retailers, customers, patients and clinical trial **trials** participants. Even unsuccessful product liability claims could require us to spend money on litigation, divert management's time, damage our reputation and impair the marketability of our products. In addition, although we believe that we have adequate product liability insurance coverage, we cannot be certain that our insurance will, in fact, be sufficient to cover such claims or that we will be able to obtain or maintain adequate insurance coverage in the future at acceptable prices. A successful product liability claim that is excluded from coverage or exceeds our policy limits could require us to pay substantial sums. Additionally, insurance coverage for product liability may become prohibitively expensive in the future or may not be available at all, and as a result, we may not be able to maintain adequate product liability insurance coverage to mitigate the risk of large claims, or we may be required to maintain a larger self-insured retention that we would otherwise choose. Currency fluctuations and changes in exchange rates could have a material adverse effect on our business, financial position, and operating results. A portion of our transactions are denominated in a foreign currency, the Indian rupee. Because we engage in certain transactions in a foreign currency, we are subject to the effects of exchange rate fluctuations. If the U. S. dollar depreciates against the Indian rupee, the expenses we recognize from Indian-denominated transactions made by our Indian subsidiary could be translated at an unfavorable rate, leading to foreign exchange losses. Foreign exchange gains or losses as a result of exchange rate fluctuations in any given period could harm our operating results and negatively impact our financial position and results of operations. We may not achieve the anticipated benefits from our acquisition of Novitium, which could have a material adverse effect on our business, financial position, and operating results. On November 19, 2021, the Company completed its previously announced acquisition (the "Acquisition") of Novitium pursuant to the terms of the Agreement and Plan of Merger, dated as of March 8, 2021 (the "Merger Agreement"), by and among the Company, Novitium, Nile Merger Sub LLC, a Delaware limited liability company, and certain other parties, with Novitium becoming a wholly owned subsidiary of ANI. We may not realize the potential benefits from the Acquisition that we or the market expects. Risks associated with the Acquisition include: • failure to effectively manage our expanded operations, which were materially increased by the Acquisition; • diversion of management's attention, the disruption or interruption of, or the loss of momentum in, the businesses of ANI and Novitium or inconsistencies in standards, controls, procedures, and policies, any of which could adversely affect our ability to maintain relationships with customers, partners, and employees or our ability to achieve the anticipated benefits of the acquisition; • loss of key employees; and • failure to maintain relationships with third parties, including Novitium's and our pre-existing customers, which relationships may be affected by customer preferences or public attitudes about the Acquisition. Any adverse changes in these relationships could adversely affect our business, financial condition, and results of operations. The obligations and liabilities of Novitium, some of which may be unanticipated or unknown, may be greater than we have anticipated, which may diminish the value of Novitium to us. Novitium's obligations and liabilities, some of which may not have been disclosed to us or may not be reflected or reserved for in Novitium's historical financial statements, may be greater than we have anticipated. The obligations and liabilities of Novitium could have a material adverse effect on Novitium's business or Novitium's value to us or on our business, financial condition, or results of operations. Under the Merger Agreement relating to the Novitium acquisition, we have only limited indemnification with respect to obligations or liabilities of Novitium, whether known or unknown. In addition, even in cases where we are able to obtain indemnification, we may discover liabilities greater than the contractual limits or the financial resources of the indemnifying party. In the event that we are responsible for liabilities substantially in excess of any amounts recovered through rights to indemnification or alternative remedies that might be available to us, or any applicable insurance, we could suffer severe consequences that would substantially reduce our earnings and cash flows or otherwise materially and adversely affect our business, financial condition, or results of operations. Risks Related to our Industry Public health outbreaks, epidemics, or pandemics (such as **NEW DAY** the COVID-19 pandemic) have adversely affected and **SYNCHRONICITY** may in the future adversely affect our business. The COVID-19 pandemic previously adversely affected us in the years ended December 31, 2021 and 2020, and the COVID..... also have the effect of heightening many - **may** of the other risks described in this..... Any determination that we have failed -- **fail** to comply with those obligations could subject us to penalties and sanctions, which could adversely affect our business,..... risk-based approach and will not take **longer** action against us.

However, we..... 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..... resulting waste products. We cannot completely -- **complete** 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 **or any damages that result**, and any resulting liability could exceed our..... condition. Continuing studies of our products could produce negative results, **which could require requiring us to submit reports to the FDA of adverse events involving the use of our products and we may be required** to implement risk management programs, or discontinue product marketing **as a result**. In addition, ongoing post-approval drug safety surveillance of our products could result in the submission of adverse event reports to the FDA. 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. **In the event of an accident, we could be held liable for any damages that result**, and any resulting liability could exceed our resources. We may also incur significant costs in complying with environmental laws and regulations in the future. We are also subject to laws generally applicable to businesses, including but not limited to, federal, state, and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination, and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle-blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, financial position, and operating results. Any of our products that are distributed, tested or marketed outside the U.S. are also subject to extensive regulation by foreign governments, whether or not we have obtained FDA approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding U.S. regulation. Our operations in an international market subject us to additional regulatory oversight both in the international market and in the U.S., as well as, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results. We are subject to certain risks associated with having assets and operations located in **a foreign jurisdictions- jurisdiction, including our operations in India**. Our operations in **India foreign jurisdictions** may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results. Additionally, involvement in a war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in (i) delays or cancellations of customer orders, (ii) a general decrease in consumer spending on healthcare technology, (iii) our inability to effectively market and distribute our products internationally (iv) our inability to timely engage with and collect payment from our customers or (v) our inability to access capital markets, our business and results of operations could be materially and adversely affected. For example, in response to the continued conflict between Russia and Ukraine, the United States has imposed and may further impose, and other countries may additionally impose, broad sanctions or other restrictive actions against governmental and other entities in Russia. Additionally, further escalation of geopolitical tensions, such as the conflict in **the middle east Israel and Gaza** and the surrounding areas, and conflicts related to the attacks on cargo ships in the Red Sea, could have a broader impact that extends into other markets where we do business. We are unable to predict **whether acts of international terrorism or the involvement in a war or other military actions by the United States and / or the countries in which we sell or distribute our products will result in any long- term commercial disruptions or if such involvement or responses will have any long- term material adverse effect on our business, results of operations, or financial condition. Continuing studies of our products** Healthcare reform and changes in pharmaceutical pricing, reimbursement and coverage, by governmental authorities and third-party payors may materially affect our business, financial position and operating results. In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of, and reimbursement for healthcare services in the U. S. generally and prescription drug coverage, reimbursement and pricing specifically, and it is likely that federal and state legislatures will continue to advocate change to the healthcare system generally and to prescription drug coverage, reimbursement and pricing specifically. At the federal level, the American Rescue Plan Act eliminated the cap on Medicaid Drug Rebate Program rebates beginning January 1, 2024. As such, we could end up owing additional rebates to state Medicaid programs related to utilization of our drug products negatively impacting profitability. States continue to look for ways to save on Medicaid spend specifically related to prescription drugs. As such, states are increasingly expanding or change supplemental rebates programs to secure additional rebates from manufacturers in exchange for drug coverage and to limit coverage of certain drugs for certain Medicaid patients or to all Medicaid patients. To the extent the Centers for Medicare & Medicaid Services entertains waivers to federal requirements under the Medicaid program to allow states Medicaid programs such flexibility, coverage of and payment for our drugs utilized by Medicaid beneficiaries could be negatively impacted. Passage of the Inflation Reduction Act (**"IRA"**) has brought sweeping change to Medicare coverage of and reimbursement for prescription drugs. Most notably, CMS is able to directly negotiate the reimbursement for certain prescription drugs reimbursed under Medicare Part D or B to be effective for the 2026 plan year. If a manufacturer's drug is selected for negotiation, the manufacturer must negotiate a Maximum Fair Price with CMS or be liable for an excise tax of 65 **%** to 95 **percent %** of Medicare utilization based on the prior year. While no ANI drugs have currently been selected for

negotiation, ANI continues to evaluate the implications of direct negotiation on its products in the future and potential repercussions of competitive products being selected for direct negotiation. In addition, as previously noted, there are numerous legal challenges to the direct negotiation provisions of the IRA. If any of those challenges are successful, this could change the current competitive landscape for manufacturers generally and may change the dynamics of the Medicare Part D marketplace potentially resulting in increased premiums, fewer Part D plans and sponsors and increased pressure on manufacturers to offer formulary placement rebates and additional price concessions. In addition, under the IRA the Part D benefit design will be altered and the coverage gap discount program replaced by a new manufacturer discount program pursuant to which manufacturers will provide a 10 percent discount off the negotiated price for applicable drugs (branded drugs and biologics manufactured by companies that have Part D discount agreements) after the deductible is satisfied through the catastrophic phase of the benefit. In the catastrophic phase, manufacturers will provide a 20 percent discount off negotiated price. Any pharmaceutical product marketed under an NDA, regardless of whether the product is marketed as a “generic,” is subject to the manufacturer discount requirement. This could increase discounts due on Medicare Part D utilization of our drug products. Lastly, the IRA imposed additional rebates on manufacturers including ANI to the extent certain drug pricing metrics are rising faster than inflation. These new inflation rebates are similar to those imposed on manufacturers under Medicaid and could result in additional rebates due from us on Medicare utilization of our products.

Certain U. S. states have implemented statutes aimed at prescription drug price transparency and some of those laws would permit state run boards or agencies to cap reimbursement for certain prescription drugs in the states. Such laws could negatively impact our financial performance and could result in us terminating distribution of certain products in certain states or regions. Inflation could have a material adverse effect on our business, financial position, and operating results. Inflationary pressures are currently being experienced and may continue to exist in the U. S. and key worldwide markets. The rate of inflation may significantly increase input costs for our products and, given the competitive nature of the **markets in which we compete, including branded, generic, and rare disease pharmaceutical markets in which we compete, we and** may not be able to pass those costs on to our customers. Risks Related to Accounting, Tax, and SEC Rules and Regulations We have increased exposure to tax liabilities, including foreign tax liabilities. We are subject to, or potentially subject to, income taxes as well as non-income based taxes in various U. S. jurisdictions, Canada, and India, **the United Kingdom, Ireland, Portugal, and Germany**. Significant judgment is required in determining our international provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. In addition, we have potential tax exposures resulting from the varying application of statutes, regulations, and interpretations, which include exposures on intercompany terms of cross-border arrangements between our U. S. operations and our Indian subsidiary in relation to various aspects of our business, including research and development services, tech transfers, and contract manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions; such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and which could have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations. **We are subject to certain risks associated with having assets and operations located in foreign jurisdictions. Our international operations may be adversely affected by general economic conditions and economic and fiscal policy, including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results.** Our expanded international operations from the **Novitium acquisition-Alimera Merger** increased our exposure to potential liability under anti-corruption, trade protection, tax, and other laws and regulations. The Foreign Corrupt Practices Act and other anti-corruption laws and regulations (“Anti-Corruption Laws”) prohibit corrupt payments by our employees, vendors, or agents. From time to time, we receive inquiries from authorities in the U. S. and elsewhere about our business activities outside of the U. S. and our compliance with Anti-Corruption Laws. While we devote substantial resources to our compliance programs and have implemented policies, training, and internal controls designed to reduce the risk of corrupt payments, our employees, vendors or agents may violate our policies and with the acquisition of **Novitium-Alimera**, our expanded international operations would significantly increase our exposure to potential liability. Our failure to comply with Anti-Corruption Laws could result in significant fines and penalties, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business, and damage to our reputation. Operations outside of the U. S. may be affected by changes in trade production laws, policies, and measures, and other regulatory requirements affecting trade and investment. We are also subject to **Indian foreign tax regulations in certain foreign locations**. Such regulations may not be clear, not consistently applied and subject to sudden change, particularly with regard to international transfer pricing. Our earnings could be reduced by changes to such tax regulations or changing interpretation of such tax regulations. The international nature of **our Novitium’s** operations (including those **the acquisition of Alimera its Indian subsidiary Novitium Labs Private Limited**) will subject us to political and economic risks that could adversely affect our business, results of operations, or financial condition. The risks presented by international operations include: • limitations on ownership or participation in local enterprises; • price controls, exchange controls, and limitations on repatriation of earnings; • transportation delays and interruptions; • the application of additional legal, regulatory and taxation regimes to our operations; • political, social, and economic instability and disruptions in applicable regions, including as a result of war, such as the conflict between Russia and the Ukraine, the conflict between Israel and Gaza, and conflicts related to the attacks on cargo ships in the Red Sea; • acts of terrorism; • government embargoes or foreign trade restrictions; • imposition of duties and tariffs and other trade barriers; • import and export controls; • labor unrest and current and changing regulatory environments; • fluctuations in foreign current exchange and interest rates; • difficulties in staffing and managing multi-national operations; • limitations on our ability to enforce legal rights and remedies. If we are unable to successfully manage these and other risks associated with managing the expansion of our business to the jurisdictions in which Novitium **and Alimera operate-operate**, including India, the risks could have a material adverse effect on our business,

results of operations, or financial condition. Failure to comply with applicable transfer pricing and similar regulations could have a material adverse effect on our financial position and operating results. We are subject to complex transfer pricing and other tax regulations in the United States and **India other foreign locations** designed to ensure that appropriate levels of income are reported as earned and are taxed in the appropriate taxing jurisdictions. Although we believe that we are in substantial compliance with all applicable regulations and restrictions, we are subject to the risk that governmental authorities could audit our transfer pricing and related practices and assert that additional taxes are owed. In the event that such audits or assessments are concluded adversely against us, we may or may not be able to offset or mitigate the consolidated effect of any such assessments. Changes in estimates regarding the fair value of goodwill or intangible assets may result in an adverse impact to our business, financial position, and operating results. We test goodwill for impairment annually, or more frequently if changes in circumstances indicate that the carrying amount of goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. We perform our annual assessment of goodwill based on our two reporting units. If we determine that the carrying value of our assets may not be recoverable, we assess, using judgment and estimates, the fair value of our assets and to determine the amount of any impairment loss, if any. Changes in judgments and estimates may result in the recognition of an impairment loss, which could have a material negative impact on our business, financial position, and operating results. While our testing in fiscal **2023-2024** did not result in an impairment charge related to goodwill, there can be no assurances that our goodwill will not be impaired in the future. Our material definite-lived intangible assets consist of ANDAs for previously marketed generic products, NDAs and product rights for our branded products, product rights related to certain generic products, and a non-compete agreement. These assets are being amortized over their useful lives of seven to **10 twelve** years. For these definite-lived intangible assets, we perform an impairment analysis when events or circumstances indicate that the carrying value of the assets may not be recoverable. An impairment loss is recognized if, based on our impairment analysis, the carrying amount of the asset is not recoverable and its carrying amount exceeds its fair value. Any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicate a reduction in carrying value may give rise to impairment in the period that the change becomes known. An impairment charge could have a material negative impact on our business, financial position, and operating results. **No-We recorded** impairment losses **were recognized of \$ 7.6 million** in the year ended December 31, **2023-2024**. Our management is required to devote substantial time to comply with public company regulations. If we are unable to comply with these regulations, investors could lose confidence in us, which could have a material adverse effect on our stock price, business, financial position, and operating results. As a public company, we are required to comply with significant legal, accounting, and other requirements, and as a result, we incur significant regulatory compliance-related expenses. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and The Nasdaq Stock Market, impose various requirements on public companies, including those related to corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Some members of management do not have significant experience in addressing these requirements. Moreover, these rules and regulations have increased our legal and financial compliance costs relative to those of previous years and make some activities more time consuming and costly. The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The Committee of Sponsoring Organizations of the Treadway Commission (“COSO”) provides a framework for companies to assess and improve their internal control systems. Our compliance with these requirements has required that we incur substantial accounting and related expenses and expend significant management efforts. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act, are unable to assert that our internal controls over financial reporting are effective, or identify deficiencies that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the SEC, or other regulatory authorities, which would require additional financial and management resources and could damage our reputation. Further, if we identify any material weaknesses or deficiencies that aggregate to a material weakness in our internal controls, we will have to implement appropriate changes to these controls, which may require specific compliance training for our directors, officers and employees, require the hiring of additional finance, accounting, legal and other personnel, entail substantial costs to modify our existing accounting systems and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and could materially impair our ability to operate our business. Any of these events could have a material adverse effect on our business, financial position, and operating results. ~~We previously identified material weaknesses in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, any of which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. As of December 31, 2022, we identified material weaknesses related to ineffective control environment at our Novitium subsidiary, subsequent to the acquisition of Novitium in November 2021, and information technology general controls (“ITGCs”) in the areas of user access over certain information technology systems that support our financial reporting processes. These material weaknesses continued into 2023 and were fully remediated as of December 31, 2023. For a detailed summary of these material weaknesses, including our remediation steps, please refer to Item 9A—Controls and Procedures. As of December 31, 2023 management has concluded that the Company’s~~

internal control over financial reporting was effective. If we are unable to maintain effective internal control over financial reporting or disclosure controls and procedures, our ability to record, process, and report financial information accurately and to prepare financial statements within required time periods could be adversely affected, which could subject us to litigation, investigations, or penalties; negatively affect our liquidity, our access to capital markets, perceptions of our creditworthiness, our ability to complete acquisitions, our ability to maintain compliance with covenants under our debt instruments or derivative arrangements regarding the timely filing of periodic reports, or investor confidence in our financial reporting, any of which may divert management resources or cause our stock price to decline. Further, remediation of a material weakness does not provide assurance that our remediation or other controls will continue to operate properly or remain adequate. Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods. We, like other generic drug manufacturers, have agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates. Under many of these arrangements, we may match lower prices offered to customers by competitors. If we choose to lower our prices, we generally give the customer a credit on the products that the customer is holding in inventory, which could reduce sales revenue for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesalers with whom we have contracts for their sales to hospitals, group purchasing organizations, pharmacies, or other customers. A chargeback is the difference between the price at which we invoice the wholesaler and the price that the wholesaler's end-customer pays for a product. Although we establish reserves based on prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances, and chargebacks will not exceed our estimates. Risks Related to our Debt Making

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

- increasing our vulnerability to adverse economic and industry conditions;
- limiting our ability to obtain additional financing;
- requiring the dedication of a substantial portion of our cash flow from operations to service our indebtedness, which will reduce the amount of cash available for other purposes;
- limiting our flexibility to plan for, or react to, changes in our business;
- diluting the interest interests of our existing stockholders as a result of issuing shares of our common stock upon conversion of our 2.25 % Convertible Senior Notes due 2029 (“ Senior Notes ”);
- placing us at a competitive disadvantage with competitors that are less leveraged than us or have better access to capital; and principal payments
- making it more difficult for us to satisfy our obligations with respect to our indebtedness, and any failure to comply with the obligations under any of our debt instruments, including restrictive covenants, could result in an event of default under the New Credit Facility Agreement, the indenture governing our Senior Notes and the agreements governing our other indebtedness. In connection with the completion of the Merger, we entered into the New Credit Agreement consisting of a \$ 300-325.0 million term loan and a \$ 40-75.0 million revolving credit facility, requires a significant amount of cash. In connection with the completion of the Novitium acquisition, we entered into a \$ 300.0 million term loan and a \$ 40.0 million revolving credit facility. The New Credit Facility Agreement, 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 Merger. In addition, in August 2024 the Company completed and terminate and repay our previous offering of \$ 316.25 million aggregate principal amount of senior Senior credit facilities Notes at an interest rate of 2.25 % per annum, payable semi-annually in arrears on March 1 and September 1 of each year, beginning on March 1, 2025. In order to service the debt-indebtedness we have incurred, and may in the future incur, under this facility the New Credit Agreement, as well as the Senior Notes, we will require a significant amount of cash. Our ability to make scheduled payments of principal and interest depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future, and we may otherwise be unable to maintain cash reserves sufficient to service our debt-indebtedness, including the Senior Notes and indebtedness incurred under the New Credit Agreement, and our cash needs may increase in the future. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt-indebtedness, or obtaining additional debt-indebtedness or equity financing on terms that may not be favorable to us or available to us at all. Our ability to refinance any such debt-indebtedness will depend on the capital markets and our financial condition at that time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default under our current or future indebtedness. Any Our indebtedness could have significant negative consequences for our stockholders and our business and any event of default or inability to otherwise satisfy our obligations could have a material adverse effect on our future operating results and financial condition. Our New Credit Agreement contains restrictive and financial covenants and if we are not in compliance with these covenants, our outstanding indebtedness under this facility could be accelerated and the lenders could terminate their commitments under the facility. The New Credit Agreement contains customary covenants that require maintenance of a leverage ratio at or below specified thresholds and restricts our ability to make certain distributions with respect to our capital stock, prepay other debt, make certain investments, encumber our assets, incur additional indebtedness, make capital expenditures, engage in certain business combinations, transfer, lease or dispose of our assets, alter the character of our business in any material respect or undertake various other corporate activities. Therefore, as a practical matter, these covenants, and any other additional restrictive covenants that may be included in the terms of any future indebtedness, restrict our ability to engage in or benefit from such activities. In addition, we pledged our assets in order to secure our repayment obligations under the New Credit Agreement. This pledge may reduce our operating flexibility because it restricts

our ability to dispose of our assets or engage in other transactions that may be beneficial to us. If we are unable to comply with the covenants in the New Credit Agreement **or any future indebtedness**, we will be in default, which could result in the acceleration of our outstanding indebtedness and termination of funding commitments by the lenders. If such an acceleration occurs, we may not be able to repay our debt and we may not be able to borrow sufficient additional funds to refinance our debt, which would have a material adverse effect on our business, financial position, and operating results. ~~Changes in the method~~ **Our variable rate indebtedness subjects us to interest rate risk, which could cause our debt service obligations to increase and our net income and cash flows to correspondingly decrease. Borrowings under our New Credit Agreement are at variable rates of determining London Interbank Offered interest and expose us to interest rate risk. If interest rates were to increase, our debt service obligations on the variable rate indebtedness referred to above would increase even if the principal amount borrowed remained the same, and our net income and cash flows will correspondingly decrease. Our New Credit Agreement references the Secured Overnight Financing Rate ("LIBOR" "SOFR"), as the primary benchmark rate or for our variable rate indebtedness. We are also currently party to, and in the replacement future, we may enter into additional, interest rate swaps that involve the exchange of LIBOR floating for fixed rate interest payments, in order to reduce interest rate volatility. However, we may not maintain interest rate swaps with respect to all of our variable rate indebtedness, and alternative any swaps we enter into may not fully mitigate our interest rate risk. Additionally, SOFR is a relatively new reference rate and with a limited history, such as and changes in SOFR have, on occasion, been more volatile than changes in other benchmark or market rates. As a result, the amount of interest we may pay on our variable rate indebtedness is difficult to predict. Shares of our common stock issuable upon conversion of the Senior Notes may dilute the ownership interest of our common stockholders or may adversely affect the market price of our common stock. The conversion of the Senior Notes may dilute the ownership interests of our stockholders. Upon conversion of the Senior Notes, we will generally have the right to elect to settle our conversion obligation in excess of the principal amount of any converted Senior Notes by paying or delivering, as applicable, cash, shares of our common stock, or a combination of cash and shares of our common stock. If we elect to settle our conversion obligation in excess of the principal amount of any converted Senior Notes in shares of our common stock or a combination of cash and shares of our common stock, any sales in the public market of shares of our common stock issuable upon such conversion could adversely affect prevailing market prices of our common stock. Also, the existence of the Senior Notes may encourage short-selling by market participants because the conversion of the Senior Notes could be used to satisfy short positions, or anticipated conversion of the Senior Notes into, in part, shares of common stock could depress the price of our common stock. We may be unable to raise the funds necessary to repurchase the Senior Notes for cash following a fundamental change or to pay the cash amounts due upon maturity or conversion of the Senior Notes, and our other indebtedness limits our ability to repurchase the Senior Notes or to pay the cash amounts due upon their maturity or conversion. Holders of the Senior Notes may, subject to limited exceptions, require us to repurchase their Senior Notes following a fundamental change at a cash repurchase price generally equal to the principal amount of the Senior Notes to be repurchased, plus accrued and unpaid interest, if any. Upon maturity of the Senior Notes, we must pay their principal amount and accrued and unpaid interest in cash, unless they have been previously repurchased, redeemed or converted. In addition, all conversions of Senior Notes will be settled partially or entirely in cash. We may not have enough available cash or be able to obtain financing at the time we are required to repurchase the Senior Notes or pay the cash amounts due upon their maturity or conversion. In addition, applicable law, regulatory authorities and the agreements governing our other indebtedness may restrict our ability to repurchase the Senior Notes or to pay the cash amounts due upon their maturity or conversion. The New Credit Agreement contains restrictive covenants that limit our ability to repay other indebtedness. Our failure to repurchase Senior Notes or to pay the cash amounts due upon their maturity or conversion when required will constitute a default under the indenture governing the Senior Notes. A default under the indenture or the fundamental change itself could also lead to a default under agreements governing our other indebtedness, which may result in that other indebtedness becoming immediately payable in full. We may not have sufficient funds to satisfy all amounts due under the other indebtedness and the Senior Notes. Provisions in the indenture governing the Senior Notes could delay or prevent an otherwise beneficial takeover of us. Certain provisions in the Senior Notes and the indenture governing the Senior Notes could make a third-party attempt to acquire us more difficult or expensive. For example, if a takeover constitutes a fundamental change, then, subject to limited exceptions, holders of the Senior Notes will have the right to require us to repurchase their Senior Notes for cash. In addition, if a takeover constitutes a make-whole fundamental change, then we may be required to temporarily increase the conversion rate. In either case, and in other cases, our obligations under the Senior Notes and the indenture governing the Senior Notes could increase the cost of acquiring us or otherwise discourage a third party from acquiring us or removing incumbent management, including in a transaction that holders of the Senior Notes or holders of our common stock may view as favorable. The conversion of the Senior Notes could impair our financial position and liquidity. Because we must settle at least a portion of our conversion obligation in cash, the conversion of the Senior Notes could materially and adversely affect our financial position and liquidity. Before June 1, 2029, holders of the Senior Notes will have the right to convert their Senior Notes only upon the occurrence of certain events. From and after June 1, 2029, holders of the Senior Notes may convert their Senior Notes at any time at their election until the close of business on the second scheduled trading day immediately before the maturity date. However, many of the conditions that permit the conversion of Senior Notes before June 1, 2029 are beyond our control. We could be required to expend a significant amount of cash to settle conversions, which could significantly harm our financial position and liquidity. The accounting method for the Senior Notes could adversely affect our reported financial condition and results. In accordance with applicable accounting standards, the Senior Notes are reflected as a liability on our balance sheets, with**

the carrying amount equal to the principal amount of the Senior Notes, net of issuance costs. The issuance costs are treated as a debt discount for accounting purposes, which will be amortized into interest expense over the term of the Senior Notes. As a result of this amortization, the interest expense that we recognize for the Senior Notes for accounting purposes is greater than the cash interest payments we pay on the Senior Notes, which results in lower reported income. In addition, the shares underlying the Senior Notes are reflected in our diluted earnings per share using the “if converted” method. Under that method, if the conversion value of the Senior Notes exceeds their principal amount for a reporting period, then we will calculate our diluted earnings per share assuming that all of the Senior Notes were converted at the beginning of the reporting period and that we issued shares of our common stock to settle the excess. The after-tax interest expense associated with the Senior Notes will not be added back to the numerator of the diluted earnings per share calculation for these purposes. However, if reflecting the Senior Notes in diluted earnings per share in this manner is anti-dilutive, or if the conversion value of the Senior Notes does not exceed their principal amount for a reporting period, then the shares underlying the Senior Notes will not be reflected in our diluted earnings per share. The application of the if-converted method may reduce our reported diluted earnings per share, and accounting standards may change in the future in a manner that may adversely affect our diluted earnings per share. Furthermore, if any of the conditions to the convertibility of the Senior Notes is satisfied, then we may be required under applicable accounting standards to reclassify the liability carrying value of the Senior Notes as a current, rather than a long-term, liability. This reclassification could be required even if no holders of our Senior Notes convert their Senior Notes and could materially reduce our reported working capital. The capped call transactions may affect the value of the Senior Notes and our common stock. In connection with the pricing of the Senior Notes, we entered into privately negotiated capped call transactions with certain option counterparties. The capped call transactions are expected generally to reduce the potential dilution to our common stock upon any conversion of the Senior Notes and / or offset any potential cash payments we are required to make in excess of the principal amount of converted Senior Notes, as the case may be, with such reduction and / or offset subject to a cap. The option counterparties and / or their respective affiliates may modify their hedge positions by entering into or unwinding various derivatives with respect to our common stock and / or purchasing or selling our common stock or other securities of ours in secondary market transactions prior to the maturity of the Senior Notes (and are likely to do so during any observation period related to outstanding debt-a conversion of Senior Notes). This activity could also cause In July 2023, we amended our- or avoid an increase or a decrease in the market price of our common stock or the Senior Notes. We are subject to counterparty risk with respect to the capped call transactions, and the capped call may not operate as planned. The option counterparties are, or are affiliates of, financial institutions, and we are subject to the risk that they might default under the capped call transactions. Our exposure to the Credit-credit Agreement to transition risk of the option counterparties is not secured by any collateral. Global economic conditions have from LIBOR time to SOFR due time resulted in the actual or perceived failure or financial difficulties of many financial institutions, including the bankruptcy filing by Lehman Brothers Holdings Inc. and its various affiliates. If an option counterparty becomes subject to insolvency proceedings, we will become an unsecured creditor in the those cessation of LIBOR pursuant proceedings with a claim equal to the terms of Amendment No-our exposure at that time under our transactions with that option counterparty. †-Our exposure depends on many factors, but, generally, the Credit Agreement. SOFR increase in our exposure will be applied to correlated with increases in the Credit Facility market price for- or the interest period (volatility of our common stock. In addition, upon a default by an option counterparty, we may suffer adverse tax consequences and more dilution than we currently anticipate with respect to our common stock. We can provide no assurances as to defined in the Credit Agreement) beginning on August 1 financial stability or viability of any option counterparty. In addition, the capped 2023 and will replace all call LIBOR transactions are complex, and they may not operate as planned. For example, the terms - We have no of the capped call transactions may be subject to adjustment, modification or, in some cases, renegotiation if certain corporate or other material financing agreements transactions occur. Accordingly, these transactions may not operate as we intend if we are required to adjust their terms as a result of transactions in the future or upon unanticipated developments that use LIBOR as an interest index. There is no guarantee that the transition from LIBOR to SOFR will not result in financial market disruptions, significant increases in benchmark rates, or borrowing costs to borrowers. While we will continue to use SOFR, certain factors may impact SOFR, including factors causing SOFR to cease to exist, new methods of calculating SOFR to be established, or the use of alternative reference rates. These consequences are not entirely predictable and could have an adverse adversely affect impact on our financing costs and our results of operations. As such, the future functioning of the capped call transactions SOFR at this time remains uncertain. Risks Related to our Common Stock Our principal stockholders, directors, and executive officers own a significant percentage of our stock and will be able to exercise meaningful influence over our business. Our current principal stockholders, directors, and executive officers beneficially own approximately 13-10 % of our outstanding capital stock entitled to vote as of December 31, 2023-2024. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions, or other extraordinary transactions. They may also have interests that differ from stockholders generally and may vote in a way with which other stockholders disagree and which may be adverse to their interests. This concentration of ownership may have the effect of delaying, preventing, or deterring a change of control of ANI, could deprive stockholders of an opportunity to receive a premium for their common stock as part of a sale of ANI, and might ultimately affect the market price of our common stock -Raising additional funds by issuing additional equity securities may cause dilution to our current stockholders. Raising additional funds by entering into additional credit or other borrowing facilities or issuing debt may subject us to covenants and other requirements that may restrict our operations. We may seek to raise additional funds through the issuance of equity or equity-linked securities. If we

were to raise funds through the issuance of equity or equity-linked securities, the percentage ownership of our stockholders could be diluted, potentially significantly, and these newly issued securities may have rights, preferences, or privileges senior to those of our existing stockholders. In addition, the issuance of any equity securities could be at a discount to the then-prevailing market price of our common stock. If we require new debt financing, there is no assurance that such a transaction will be available on terms acceptable to us, or at all. In addition, we could be subject to onerous repayment terms or covenants that restrict our ability to operate our business and make distributions to our stockholders. These restrictive covenants may include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock, or make investments. We can offer no assurance that any equity or debt financing transaction will be available on terms acceptable to us, or at all. Provisions in our charter documents and Delaware law could discourage or prevent a takeover, even if such a transaction would be beneficial to our stockholders. Provisions of our certificate of incorporation and bylaws, as well as provisions of Delaware law, could make it more difficult for a third party to acquire ANI, even if doing so would be beneficial to our stockholders. These provisions include: • authorizing the issuance of “blank check” preferred shares that could be issued by our board of directors to increase the number of outstanding shares and thwart a takeover attempt; • prohibiting cumulative voting in the election of directors, which would otherwise allow less than a majority of stockholders to elect director candidates; • advance notice provisions and information submission requirements in connection with stockholder proposals and director nominations that may prevent or hinder any attempt by our stockholders to bring business to be considered by our stockholders at a meeting or replace our board of directors; and • as a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents certain stockholders holding more than 15 % of our outstanding common stock from engaging in certain business combinations without approval of the holders of at least two-thirds of our outstanding common stock not held by such 15 % or greater stockholder. Any provision of our certificate of incorporation and bylaws or Delaware law that has the effect of delaying, preventing, or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock and could also affect the price that some investors are willing to pay for our common stock.

General Risk Factors We use a variety of estimates, judgments, and assumptions in preparing our consolidated financial statements. Estimates, judgments, and assumptions are inherently subject to change, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses, and income. Any such changes could have a material adverse effect on our business, financial position, and operating results. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (“U. S. GAAP”) requires us to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the period. There are inherent uncertainties involved in estimates, judgments and assumptions, and any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position, and operating results. In the consolidated financial statements included in the periodic reports filed with the SEC, estimates, judgments, and assumptions are used for, but not limited to, **variable consideration determined based on accruals for chargebacks, administrative fees and rebates, government rebates, returns and other allowances, income tax provision or benefit, deferred taxes and valuation allowance, stock-based compensation, revenue recognition, allowance for inventory obsolescence, valuation of financial instruments and intangible assets, accruals for contingent liabilities, including contingent consideration and contingent value rights in acquisitions, fair value of long-lived assets, determination of right-of-use assets and lease liabilities**, allowance for credit losses, ~~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~~ **long-lived** assets. Actual results could differ from those estimates. Estimates, judgments, and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses, and income. Any such changes could have a material adverse effect on our business, financial position, and operating results. The market price of our common stock has been volatile, and an investment in our common stock could decline in value. The market price of our common stock has increased and decreased significantly and is likely to continue to fluctuate in the future. From time to time, the securities of small capitalization pharmaceutical companies, including ANI, experience significant market price fluctuations, often unrelated to these companies’ operating performance. In particular, the market price of our common stock may fluctuate significantly due to a variety of factors, including, but not limited to, regulatory or legal developments with respect to our industry, variations in our financial results or those of companies that are perceived to be similar to us, and rumors or new announcements by third parties, many of which are beyond our control and that may not be related to our operating performance. In addition, the occurrence of any of the risks described in this report or in subsequent reports we file with the SEC could have a material adverse impact on the market price of our common stock. Securities class action litigation is sometimes brought against a company following periods of volatility in the market price of its securities or for other reasons. Securities litigation, whether with or without merit, could result in substantial costs and divert management’s attention and resources, which could harm our business, financial position, and operating results, as well as the market price of our common stock. **57**