Risk Factors Comparison 2024-02-29 to 2023-03-09 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: ~~● We~~ **• Cortrophin Gel is our first rare disease pharmaceutical product. To the extent we are not able to continue to achieve commercial success with this product, including expanding the market and gaining market share, our business, financial condition, and results of operations will be negatively impacted; • Our approved products, including Cortrophin Gel,** may not achieve **commercialization at levels** ~~the anticipated benefits from our acquisition~~ of ~~Novitium Pharma LLC (" Novitium ")~~ **market acceptance that will continue to allow us to achieve profitability** ; ~~●~~ **• Acquisitions and investments could disrupt our business and harm our financial position and operating results; •** The ~~obligations and~~ **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** ~~liabilities~~ **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 ~~Novitium~~ **our products are manufactured and / or packaged by third parties** , ~~some of~~ 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 ~~be unanticipated~~ **adversely affect** ~~or~~ **our business** ~~unknown, may be greater than we have anticipated, which may diminish the value of Novitium to us~~ ; ~~• ● The uncertain impact that novel coronavirus (" COVID- 19 ") will have on our business and results of operations, including the emergence of variants of the virus; ●~~ The continuing trend toward consolidation of customer groups that could result in declines in the sales volume and prices of our products, and increased fees charged by customers; ~~●~~ **•** Pharmaceutical product quality standards are steadily increasing on all products, and if we cannot meet these standards, we may be required to discontinue marketing and / or recall products from the market; ~~●~~ **•** Federal and state false claims litigation brought against us by private individuals and the government could result in civil and criminal penalties, damages, fines and other related actions; ~~●~~ **•** The use of legal, regulatory, and legislative strategies by competitors could result in increased costs to develop and market our products, delay new product introductions and reduce profit potential; ~~●~~ **•** Third- party payer actions may prevent us from effectively marketing our products or cause us to decrease pricing; ~~●~~ **•** Continuing studies of our products could produce results that could have a negative impact on our business; ~~●~~ **•** Healthcare reform legislation could have a material adverse effect on our business, financial position, and operating results; ~~●~~ **•** Barriers in achieving anticipated revenue growth and profitability could have a material adverse effect on our business, financial position, and operating results; **• We may** ~~● Cortrophin Gel is our first rare disease pharmaceutical product. To the extent we are~~ not ~~able to~~ achieve **the anticipated benefits from** ~~commercial success with this product, including gaining market share,~~ our **acquisition** ~~business, financial condition, and results~~ of **Novitium Pharma LLC** ~~operations will be negatively impacted; ● The limited number of suppliers for our active pharmaceutical ingredients~~ (" ~~API~~ **Novitium** ") ~~could result in lengthy delays in production if we need to change suppliers~~ ; ~~● Several~~ **• The obligations and liabilities** of ~~the products~~ **Novitium, some of which may be unanticipated or unknown, may be greater than** we have **anticipated, which may diminish** ~~acquired cannot be manufactured in our facilities and we must secure and maintain qualified and compliant contract manufacturers. Noncompliance by these~~ -- **the value of Novitium** ~~contract manufacturers or our inability~~ to ~~find qualified contract manufacturers could result in~~ us ~~being unable to commercialize these products~~ ; ~~Several of~~ **• Public health outbreaks, epidemics,** ~~our~~ - **or** ~~products are manufactured~~ **pandemics (such as COVID- 19) have adversely affected** and ~~/~~ **may in the future adversely affect** ~~or~~ **our business** ~~packaged by third parties, which we cannot control and could result in us being unable to market and distribute products~~ ; ~~●~~ **•** The Food and Drug Administration (" FDA ") does not provide guidance on safety labeling for products that are marketed without approved New Drug Applications (" NDAs ") or Abbreviated New Drug Applications (" ANDAs "), which could increase our potential liability with respect to failure- to- warn claims for these products; ~~●~~ **• 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 ~~, ● Acquisitions and investments could disrupt our business and harm our financial position and operating results~~ ; ~~●~~ **•** Our Medicaid rebate accruals have increased and continue to increase due to our acquisitions and subsequent sales of branded products and authorized generics of branded products; ~~●~~ **•** Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions; ~~●~~ **•** We face vigorous competition from other pharmaceutical manufacturers that threatens the commercial acceptance and pricing of our products; • ~~● Our approved products, including Cortrophin Gel, may not achieve commercialization at levels of market acceptance that allow us to achieve profitability; ●~~ We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products; ~~●~~ **•** Production at any or all of our ~~four~~ **three** current manufacturing facilities could be interrupted, which could cause us to fail to deliver product on a timely basis; ~~●~~ **•** We rely on third parties to assist with our clinical studies. If these parties do not perform or are non- compliant, it could negatively impact the clinical trial and potential

of regulatory approval; Further, we may be required to audit or redo previously completed trials or recall already- approved commercial products; ~~•~~ • Inability to protect our intellectual property in the U. S. and foreign countries could negatively affect sales of our branded products; ~~• We have very~~ **• With the exception of patents on a** limited ~~staffing~~ **number of products we do not own or license any material patents associated with the majority of our products,** and ~~are~~ **our ability to protect and control unpatented trade secrets, know- how, and other technological innovation is limited; • Our success is largely** dependent upon **certain** key employees, **including members of our senior management,** the loss of whom could adversely affect our operations; ~~•~~ • We rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology could harm our ability to operate the business effectively; ~~•~~ • We are involved in and may become involved in legal proceedings from time to time, which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources; ~~•~~ • We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums; ~~•~~ • Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods; ~~•~~ • Making interest and principal payments under our Credit Agreement with Truist requires a significant amount of cash; ~~•~~ • We **previously** identified material weaknesses in our internal control over financial reporting **, and** ~~. If we do not effectively remediate these~~ -- **the failure** ~~material weaknesses or if we otherwise fail~~ to maintain **an** effective **system of** internal ~~control~~ **controls** ~~over~~ **and procedures may cause investors to lose confidence in our** financial reporting ~~, we may not be able to accurately report our financial results or prevent fraud~~ ; ~~•~~ • Our Credit Facility contains restrictive and financial covenants and if are not in compliance with these covenants, our outstanding indebtedness under this facility could be accelerated and the lenders could terminate their commitments under the facility; ~~•~~ • Raising additional funds by issuing additional equity securities may cause dilution to our current stockholders. Raising additional funds by entering into additional credit or other borrowing facilities or issuing debt may subject us to covenants and other requirements that may restrict our operations; **•** ~~and •~~ Our **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 ~~the global nature of~~ 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, ~~16also~~ -- **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 ~~BusinessWe~~ -- **Business** may not achieve the anticipated benefits from..... prevent unlawful activity in the future. 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 ~~five~~ **eight** years to the development of this product since we acquired the rights to the product in 2016. We have invested and continue to invest significantly in the commercialization of this product in the U. S, including building out a sales force and developing a patient support program, with a full- scale launch in January 2022 **. In October 2023, we announced FDA approval and commercial availability of a 1- mLvial of Cortrophin Gel, appropriate for adjunctive treatment of certain patients with acute gouty arthritis flares** . The ability for us to generate significant net product revenues from **our** Cortrophin Gel **products** will depend upon our ability to successfully sell the product and numerous other factors, including: ~~•~~ • successfully establishing and maintaining effective sales, marketing, and distribution systems in jurisdictions in which Cortrophin Gel is approved for sale ; **•** ~~18 •~~ successfully establishing and maintaining manufacturing capabilities **with our third- party suppliers and CMOs** and manufacturing adequate commercial quantities of Cortrophin Gel at acceptable cost and quality levels, including maintaining current good manufacturing practice (" cGMP ") and quality systems regulation standards required by various regulatory agencies ; ~~•~~ • broad acceptance of Cortrophin Gel by physicians, patients, and gaining market access share in the healthcare community ; ~~•~~ • the acceptance of pricing and placement of Cortrophin Gel on payers' formularies and the associated tiers ; ~~•~~ • effectively competing with the only other competitor that has an approved adrenocorticotropic hormone (" ACTH ") therapy product on the market, as well as other products that are in development or may be developed in the future as a treatment option ; ~~•~~ • continued demonstration of safety and efficacy of Cortrophin Gel in comparison to competing products or treatment options ; ~~•~~ • our ability to comply with ongoing regulatory obligations and continued regulatory review which may result in significant additional expense and may require labeling changes based on new safety information, post- market studies or clinical trials to evaluate safety risks related to the use of Cortrophin Gel; and ~~•~~ • obtaining, maintaining, enforcing, and defending intellectual property rights and claims. If we do not achieve one or more of these factors, we could experience an inability to successfully commercialize Cortrophin Gel, which would negatively impact our business, financial condition and results of operations. In addition, sales of Cortrophin Gel could be negatively affected by discovery of previously unknown problems with the product, such as adverse events of unanticipated severity or frequency, problems with the facilities where the product is manufactured, or imposition of restrictions on Cortrophin Gel, including requiring withdrawal of the product from the market, by a regulatory agency if it disagrees with the promotion, marketing, or labeling of the product. We are continuing to develop our marketing and sales organization to support Cortrophin Gel and have

~~no~~ **limited** experience in marketing prescription rare disease drug products. If we are unable to ~~successfully establish~~ **continue to develop** marketing and sales capabilities for Cortrophin Gel, our business will suffer. We **first** ~~have only recently~~ established **our** rare disease sales, marketing or distribution capabilities **in 2021** and have ~~no~~ **limited** institutional experience in marketing rare disease products. We intend to continue to develop an in- house marketing organization and sales force, which will require significant expenditures, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel .Future acquisitions and investments could disrupt our business and harm our financial position and operating results.Our growth will depend,in part,on our continued ability to develop,commercialize,and expand our products,including in response to changing regulatory and competitive pressures.In some circumstances,we have and may continue to grow our business through the acquisition of complementary businesses and technologies rather than through internal development.The identification of suitable acquisition candidates or products can be difficult,time- consuming, ~~and~~ **20and** costly,and we may not be able to successfully complete or successfully execute strategies for identified acquisitions.The risks faced in connection with acquisitions include: ~~•~~ ● diversion of management time and focus from operating our business to addressing acquisition and / or product integration challenges; ~~•~~ ● coordination of research and development and sales and marketing functions; ~~•~~ ● retention of key employees from the acquired company; ~~•~~ ● integration of the acquired company' s accounting information,management,human resources,and other administrative systems; ~~•~~ ● the need to implement or improve controls,procedures,and policies at a business that prior to the acquisition may have lacked effective controls,procedures and policies; ~~•~~ ● difficulties relating to integrating the acquired business; ~~•~~ ● liability for activities of the acquired company and / or products before the acquisition,including patent infringement claims,violations of laws,commercial disputes,tax liabilities and other known and unknown liabilities; ~~•~~ ● unanticipated write- offs or charges;and ~~•~~ ● litigation or other claims in connection with the acquired company or product,including claims from product users,former stockholders,or other third parties.In any acquisition that we may undertake,our failure to address these risks or other problems encountered in connection with any acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments,cause us to incur unanticipated liabilities,and harm our business generally . We depend on a limited number of suppliers for API. Generally, only a single source of API is qualified for use in each product due to the costs and time required to validate a second source of supply. We may experience lengthy delays if we need to change an API supplier, which could have a material impact on business and results of operations. Our ability to manufacture and distribute products is dependent, in part, upon ingredients and components supplied by others, including entities based outside the U. S. During the year ended December 31, ~~2022~~ **2023** ~~, we purchased approximately 19 % of our inventory from one supplier. During the year ended December 31, 2021~~ , no single vendor represented at least 10 % of inventory purchases. During the year ended December 31, ~~2020~~ **2022** , we purchased approximately ~~10~~ **19** % of our inventory from one supplier **. During the year ended December 31, 2021, no single vendor represented at least 10 % of inventory purchases** . Any disruption in the supply of these ingredients or components or any problems in their quality could materially affect our ability to manufacture and distribute our products and could result in legal liabilities that could materially affect our ability to realize profits or otherwise harm our business, financial, and operating results. Virtually all of our generic contracts for the supply of pharmaceutical products to customers contain" failure to supply" clauses. Under these clauses, if we are unable to supply the requested quantity of product within a certain period after receipt of a customer' s purchase order, the customer is entitled to procure a substitute product elsewhere and we must reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product. Therefore, our ability to source sufficient quantities of API for manufacturing is critical. We source the raw materials for our products from both domestic and international suppliers. Generally, we qualify only a single source of API for use in each product due to the cost and time required to validate and qualify a second source of supply. Any change in one of our API suppliers must usually be approved through a Prior Approval Supplement (" PAS ") by the FDA. The process of obtaining an approval of such a ~~19PAS~~ -- **PAS** can require between four and 18 months. While we also generally qualify a single source for non- API raw materials, the process required to qualify an alternative source of a non- API raw material is typically much less rigorous. If we were to change the supplier of a raw material for a product, the cost for the material could be greater than the amount we paid with the previous supplier. Changes in suppliers are rare but could occur as a result of a supplier' s business failing, an issue arising from an FDA inspection, or failure to maintain our required standards of quality. As a result, we carefully select suppliers, based on various factors including quality, reliability of supply, and long- term financial stability. Certain of the APIs for our drug products, including those that are marketed without approved NDAs or ANDAs, are sourced from international suppliers. From time to time, we have experienced temporary disruptions in the supply of certain of such imported API due to FDA inspections. ~~In addition, the COVID- 19 pandemic and associated workforce factors has disrupted certain supply chains and generally led to longer lead times for the procurement of goods that are essential to the manufacture of our products.~~ Several of the products we have acquired cannot be manufactured in our facilities and are manufactured and / or packaged by third parties, which we cannot control. If we are unable to secure or maintain qualified contract manufacturers for those products or if a contract manufacturer fails to comply with federal, state, and local laws and regulations, our business, financial position, and operating results could be materially, adversely affected. We have acquired, and may continue to acquire, a variety of products that we seek to commercialize. Some of these products, including injectables, softgel capsules, and Purified Cortrophin Gel, are products that we cannot currently manufacture in our facilities. As a result, we may seek partners to contract manufacture the products on our behalf, and we rely on third parties to manufacture and / or package many of our products. Like our company, these firms must comply with cGMPs and other federal, state, and local laws and regulations regarding pharmaceutical manufacturing. Noncompliance by those firms may result in warning letters, fines, product recalls, and partial or total suspension of production and distribution. If we are unable to find qualified contract manufacturers or if a contract manufacturer fails to comply with federal, state, and local laws and regulations, we may be unable to commercialize these products, which could have a material

adverse effect on our business, financial position, and operating results, including an impairment of the acquired product. We expect our reliance on third party manufacturers to continue to increase in the future as we receive approvals for new products to be manufactured through our collaborative arrangements, and as we seek additional growth opportunities outside of the capabilities of our current manufacturing facilities. If we are unable to secure third- party manufacturers for these products on commercially acceptable terms, we may not be able to market and distribute such products at a profit. Any delays or difficulties with third- party manufacturers could adversely affect the marketing and distribution of these products, or future products, which could have a material adverse effect on our business, financial position, and operating results violate **may not achieve** these -- **the anticipated benefits from** laws without our knowledge,a governmental authority may impose civil and / or **our acquisition** criminal sanctions.Any adverse outcome in these types of actions **Novitium** , **which** 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, **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 cash flows **results of operations** . **The obligations and liabilities of Novitium,** Some **some** of **which may be unanticipated** the statutes and regulations that govern our -- **or** activities **unknown** , **may be greater** 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 **than we** 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 **anticipated** increased their enforcement activities with respect to the manufacturing , **which** sales,marketing,research and similar activities of pharmaceutical companies in recent years,and many -- **may** pharmaceutical companies **diminish the value of Novitium to us.Novitium' s obligations and liabilities,some of which may not** have been subject **disclosed** to government investigations **us or may not be** related **reflected or reserved** to these practices.A determination that we are in violation of these and / or **for** other government regulations and legal requirements may result in civil damages and penalties **Novitium' s historical financial statements** , **may be greater than we have anticipated** 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 **The obligations and liabilities** of **Novitium** these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business,financial condition,results of operations and cash flows.We are subject to certain privacy laws,information security laws,regulations,policies and contractual obligations related to data privacy and security and changes in such laws,regulations,policies,contractual obligations and failure to comply with such requirements,as well as any breach of unsecured identifiable personal information protected by law,could subject us to significant costs,fines,penalties (civil and criminal),and civil litigation which may have a material adverse effect on **Novitium' s business or Novitium' s value to us or on** our business,financial condition **,** or results of operations. **Under** As regulatory focus on privacy issues continues to increase,and laws and regulations concerning the protection of personal information expand and become more complex,these -- **the** potential risks **Merger Agreement relating** to **the Novitium acquisition,we have only limited indemnification with respect to obligations** our - **or** business could intensify **liabilities of Novitium,whether known or unknown** .In addition, **even in cases where we** the interpretation and application of consumer,health- related,and data protection laws are often uncertain **able to obtain indemnification** , contradictory,and **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 flux **excess of any amounts recovered through rights to indemnification or alternative remedies that might be available to us** , which complicates compliance efforts **or any applicable insurance,we could suffer severe consequences that would substantially reduce our earnings and cash flows or otherwise materially and adversely affect our business,financial condition,or results of operations** .Our anticipated revenue growth and profitability,if achieved,is dependent upon our ability to develop,license or acquire,and commercialize new products on a timely basis in relation to our competitors' product introductions,and to address all regulatory requirements applicable to the development and commercialization of new products.Our failure to do so successfully could impair our growth strategy and plans and could have a material adverse effect on our business,financial position,and operating results.Our future revenues and profitability are dependent upon our ability to successfully develop,license or acquire,and commercialize pharmaceutical products in a timely manner.Product development is inherently risky and time- consuming.Likewise,product licensing involves inherent risks,including uncertainties due to matters that may affect the achievement of milestones,as well as the possibility of contractual disagreements with regard to the supply of

~~product~~ **17product** 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~~ **licenses** by these third parties.Under these agreements,we pay these third parties a specified percentage of the gross profit earned on sales of the products,and such percentages in certain cases increase as additional gross profit is earned.Any increases in these percentages would impact our future profitability.We may not be successful in commercializing products on a timely basis,if at all,which could adversely affect our business,financial position,and operating results.The FDA must approve any new prescription product before it can be marketed in the U.S.The process of obtaining regulatory approval to manufacture and market branded and generic pharmaceutical products is rigorous,time consuming,costly,and largely unpredictable.We may be unable to obtain requisite approvals on a timely basis for branded or generic products that we may develop,license,or acquire.Moreover,if we obtain regulatory approval for a drug,we may be limited with respect to the indicated uses and delivery methods for which the drug may be marketed,which in turn could restrict the potential market for the drug.Also,for products pending approval,we may obtain raw materials or produce batches of inventory.In the event that regulatory approval is denied or delayed,we could be exposed to the risk of any such inventory becoming obsolete.The timing and cost of obtaining regulatory approvals could adversely affect our product introduction plans,business,financial position,and operating results.The approval process for generic pharmaceutical products often results in the FDA granting simultaneous final approval to a number of generic pharmaceutical products at the time a patent claim for a corresponding branded product or other market exclusivity expires.This often forces a generic firm to face immediate competition when it introduces a generic product into the market.Additionally,further generic approvals often continue to be granted for a given product subsequent to the initial launch of the generic product.These circumstances generally result in significantly lower prices,as well as reduced margins,for generic products compared to branded products.New generic market entrants generally cause continued price and margin erosion over the generic product life cycle.As a result,we could be unable to grow or maintain market share with respect to our generic pharmaceutical products,which could have a material adverse effect on our ability to market that product profitably and on our business,financial position,and operating results.Furthermore,if we are unable to address all regulatory requirements applicable to the development and commercialization of new products in a timely manner,our product introduction plans,business,financial position,and operating results could be materially adversely affected.The FDA regulates and monitors all promotion and advertising of prescription drugs after approval.All promotion must be consistent with the conditions of approval and submitted to the agency.Failure to adhere to FDA promotional requirements can result in enforcement letters,warning letters,changes to existing promotional material,and corrective notices to healthcare professionals.Promotion of a prescription drug for uses not approved by the FDA can have serious consequences and result in lawsuits by private parties,state governments and the federal government,significant civil and criminal penalties,and compliance agreements that require a company to change current practices and prevent unlawful activity **in the future.** . Our branded products may become subject to increased generic competition. Many of our branded products have not been patent- protected for several years and no longer have market exclusivity. As a result, they face competition from lower priced generic products which may reduce and limit the sales of our mature brand products. Additionally, increased focus by the FDA on approval of generic products may accelerate this trend. If generic products are substituted for these branded products, our revenue from these products will decrease, which could have an adverse effect on our business, financial position, and operating results . Future acquisitions and investments could disrupt..... liabilities, and harm our business generally . Our Medicaid rebate accruals have increased and continue to increase due to our acquisitions and subsequent sales of branded products and authorized generics of branded products, and the estimates on which our accruals are based are subject to change. Any such change could have a material adverse effect on our business, financial position, and operating results. Our Medicaid rebate accruals have increased significantly due to our acquisitions and subsequent sales of branded products and authorized generics of branded products. We accrue for these rebates at the time of sale based on our estimates of the amount of our product that will be prescribed to Medicaid beneficiaries. The resulting accruals are significant, and as Medicaid utilization trends change, we may need to change our estimates accordingly. We cannot guarantee that actual results will not differ from our estimates. In addition, the Patient Protection and Affordable Care Act (“ PPACA ”) included a significant expansion of state Medicaid programs. As more individuals become eligible for coverage under these programs, Medicaid utilization of our products could increase, resulting in a corresponding increase in our rebate payments. Increases in Medicaid rebate payments could decrease our revenues from product sales, which in turn could adversely affect our business, financial position, and operating results. Our accruals for the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions. Any such change could have a material adverse effect on our business, financial position, and operating results. Our accruals for the rebates under the Medicare Coverage Gap Discount Program have increased due to growth and acquisitions. We accrue for these rebates at the time of sale based on our estimates of the amount of product that will be prescribed to patients in the Medicare Coverage Gap Discount program, which is primarily for the benefit of persons aged 65 years and over. As we acquire and launch additional products, many of which, are often used by patients in the 65 and older age range, our estimates of these rebates have grown. Increases in Medicare Coverage Gap Discount rebates, and legislative changes to the Medicare Coverage Gap Discount Program, could decrease our revenues from product sales, which in turn could adversely affect our business, financial position, and operating results. ~~21We~~ **We** have entered into distribution agreements under which we market products under ANDAs and NDAs owned by third parties. Any changes to these agreements could have a material adverse effect on our business, financial position, and operating results. We have entered into several distribution agreements to market and distribute products under our own label that are sold under ANDAs and NDAs owned by third parties, over which we have no control. Generally, the responsibility for maintaining the ANDAs and NDAs lies with these third parties. If any regulatory issues were to arise with the underlying ANDA or NDA for one of these products, we could be required to discontinue sales of the product, which could have an adverse effect on our business, financial position, and

operating results. We face vigorous competition from other pharmaceutical manufacturers that may adversely impact commercial acceptance and pricing of our products. If we are unable to successfully compete, such competition could have a material adverse effect on our business, financial position, and operating results. The generic pharmaceutical industry is highly competitive. We face intense competition from U. S. and foreign manufacturers, many of whom are significantly larger than us and operate in lower cost geographies. Our competitors may be able to develop products and processes competitive with or superior to ours for many reasons, including but not limited to the possibility that they may have: • greater financial resources; • proprietary processes or delivery systems; • larger research and development and marketing staffs; • larger production capabilities; • more products; • access to lower cost wages; or • more experience in developing new drugs. Any of our significant competitors, due to one or more of these and other factors, could have a material adverse effect on our business, financial position, and operating results. Our approved products may not achieve commercialization at levels of market acceptance that allow us to achieve profitability, which could have a material adverse effect on our business, financial position, and operating results. We seek to develop, license, or acquire products that we can commercialize at levels of market acceptance that would allow us to recoup our costs, grow market share, and achieve profitability. Even if we are able to obtain regulatory approvals for our pharmaceutical products, if we fail to predict accurately demand for such products, our business, financial position, and operating results could be adversely affected. Levels of market acceptance for our products could be impacted by several factors, including but not limited to: • availability of alternative products from our competitors; • our products' pricing relative to that of our competitors; • our marketing effectiveness relative to that of our competitors; • timing of our market entry; • our ability to market our products effectively to the retail level; and • acceptance of our products by government and private formularies. Some of these factors are outside of our control and, if any arise, our profitability, business, financial position, and operating results could be materially adversely affected. We have entered into several collaborative arrangements that may not result in marketable products. We have entered into several collaborative arrangements to develop generic products for us to market in the U. S. We can offer no assurances that these arrangements will result in additional approved products, or that we will be able to ~~22market --~~ **market** the products at a profit. In addition, any expenses related to clinical trials, or additional studies required by the FDA, that we may incur in connection with these collaborative arrangements may negatively affect our business, financial position, and operating results. Specifically: • clinical trials could be more costly than we anticipate; • formulation development could take longer and be more costly than we expect; • we may be required to obtain specialized equipment in order to manufacture products on a commercial scale; and • we may be subject to milestone payments to collaborative partners, the timing of which we may be unable to predict. Any of these events could have a material adverse effect on our business, financial position, and operating results. We expect to spend a significant amount of resources on research and development efforts, and such efforts may not result in marketable products. Failure to successfully introduce products into the market could have a material adverse effect on our business, financial position, and operating results. We conduct research and development primarily to enable us to manufacture and market approved products in accordance with applicable regulations. Research and development is expensive and time- consuming. As we seek to develop new products, or re- commercialize products that were previously approved, our research expenses will increase, potentially significantly, and we cannot be certain that we will recover our investment in a product, even if that product is commercialized. If we spend significant resources on research and development efforts and are not able to introduce new products, our business, financial position, and operating results may be materially adversely affected. We produce the majority of our products in three manufacturing facilities. Production at any or all of these facilities could be interrupted, which could cause us to fail to deliver sufficient product to customers on a timely basis and have a material adverse effect on our business, financial position, and operating results. Our **internal** manufacturing operations are currently based in ~~four~~ **three** facilities. We have transitioned the ~~majority of~~ products manufactured or packaged in Oakville to one of our three U. S.- based manufacturing sites, and we are seeking to find potential buyers for the Oakville site. While these three remaining facilities are sufficient for our current needs, the facilities are highly specialized and any damage to or need for replacement of all or any significant function of our facilities could be very costly and time- consuming and could impair or prohibit production and shipping. A significant disruption at any of the facilities, even on a short- term basis, whether due to a labor strike, adverse quality or compliance observation, vandalism, natural disaster, fire, storm or other environmental damage, or other events could impair our ability to produce and ship products on a timely basis and, among other consequences, could subject us to " failure to supply " claims from our customers, as discussed below. Although we believe we carry commercially reasonable business interruption and liability insurance, we might suffer losses because of business interruptions that exceed the coverage available under our insurance policies or for which we do not have coverage. Any of these events could have a material adverse effect on our business, financial position, and operating results. Virtually all our contracts for the supply of generic products to our customers contain" failure to supply" clauses which require us to reimburse the customer for the difference between our contract price and the price the customer was forced to pay to procure the substitute product in the event we failed to deliver the requested quantity within a specified period of time. This difference can be substantial because of the much higher spot price at which the customer must cover its requirements and can be far in excess of the revenue that we would otherwise have received on the sale of our own product. Therefore, our ability to produce and ship a sufficient quantity of product on a consistent basis is critical. Failure to deliver products could have a material adverse effect on our business, financial position, and operating results. ~~23We~~ **We** rely on third parties to assist with our clinical studies. If these third parties do not perform as required or expected, or if they are not in compliance with FDA rules and regulations, our clinical studies may be extended, delayed or terminated, or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the products being tested in such studies. Further, we may be required to audit or redo previously completed trials or recall already- approved commercial products. We rely on third parties, such as medical institutions, clinical investigators, and contract laboratories, to assist with our clinical studies. We are responsible for confirming that our studies are conducted in accordance with applicable regulations and that each of our clinical studies is conducted in

accordance with our general investigational plan and protocol. The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practices for conducting, monitoring, recording, and reporting the results of clinical studies, to assure that data and reported results are accurate and that the clinical study participants are adequately protected. Our reliance on these third parties does not relieve us of these responsibilities. If the third parties assisting us with our clinical studies do not perform their contractual duties or obligations, do not meet expected deadlines, fail to comply with the FDA' s good clinical practice regulations, do not adhere to our protocols or otherwise fail to generate reliable clinical data, we may need to enter into new arrangements with alternative third parties and our clinical studies may be extended, delayed or terminated or may need to be repeated, and we may not be able to obtain regulatory approval for or commercialize the products being tested in such studies. For our already- approved commercial products, we may be required to audit or redo previously completed trials or recall our products from the market, which could have a material adverse effect on our business, financial position, and operating results. With the exception of **patents or** ~~a license of~~ patent ~~technology for~~ **applications related to** Veregen **, baclofen, and hydrochlorothiazide products,** we do not own or license any material patents associated with our products, and our ability to protect and control unpatented trade secrets, know- how, and other technological innovation is limited. Generally, the branded pharmaceutical business relies upon patent protection to ensure market exclusivity for the life of the patent. Except for ~~a license~~ **licenses** for patent technology for Veregen **, and ownership of patents and patent applications relating to our baclofen and hydrochlorothiazide products,** we do not own or license any material patents associated with our products and therefore do not enjoy the same level of intellectual property protection with respect to such products as would a pharmaceutical manufacturer that markets a patented product. We have limited ability to protect and control trade secrets, know- how, and other technological innovation, all of which are unpatented. Others independently may develop similar or better proprietary information and techniques and disclose them publicly. In addition, others may gain access to our trade secrets, and we may not be able to protect our rights to our unpatented trade secrets. In addition, confidentiality agreements and other measures may not provide protection for our trade secrets in the event of unauthorized use or disclosure of such information. Failure to protect and control such trade secrets, know- how and innovation could harm the value of our trade secrets, know- how and other technological innovation, which could have a material adverse effect on our business, financial position, and operating results. Inability to protect our intellectual property in the U. S. and foreign countries could negatively affect sales of our branded products. We own the trademark names for most of our branded products, including, Apexicon, Cortenema, Purified Cortrophin Gel, Cortrophin- Zinc, Inderal LA, Inderal XL, InnoPran XL, Lithobid, Reglan, Vancocin, and Veregen. We license the trademark names for Atacand, Atacand HCT, Arimidex, Casodex, Oxistat, and Pandel. While we will seek to protect those trademarks through timely renewal in applicable jurisdictions, we may not be able to renew our trademarks in a timely manner or to prevent third parties from using our trademarks, which could have a material adverse effect on our business, financial position, and operating results. **Our success is largely** ~~We have very limited staffing and are~~ dependent upon **certain** key employees **, including members of our senior management team** , the loss of whom could adversely affect our operations. Competition for talent is intense, especially in northern Minnesota, where the population is small. If we cannot attract and retain qualified personnel, the growth and success of our business could be adversely affected. Our success is dependent upon the efforts of ~~a relatively small~~ **certain key employees, including members of our senior** management team ~~and staff~~. We have employment arrangements in place with our executive and other officers, but none of these executive and other officers are bound legally to remain employed with ANI for any specific term. We do not have key person life insurance policies covering our executive and other officers or any of our other employees. If key individuals were to leave ANI, our business could ~~24be~~ **be** affected adversely if suitable replacement personnel are not recruited quickly. ~~The population~~ **Competition for personnel is intense** in **certain localities in which we operate, specifically** northern Minnesota, where two of our ~~four~~ **three** current manufacturing facilities are located, is small, and as a result, there is a limited number of qualified personnel available in all functional areas, which could make it difficult to retain and attract the qualified personnel necessary for the development and growth of our business. If we were unable to attract and retain qualified personnel, our business, financial position, and operating results could be materially adversely affected. We rely significantly on information technology and any failure, inadequacy, interruption, or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate the business effectively. We rely significantly on our information technology and manufacturing infrastructure to effectively manage and maintain inventory and financial reports, manufacture and ship products, and invoice customers in a timely manner. While we have invested in the protection of data and information technology, any failure, accidents, inadequacy, or interruption of that infrastructure or security lapse of that technology, including cybersecurity incidents, could harm our ability to operate our business effectively. Our ability to manage and maintain inventory and financial reports, manufacture and ship products, and invoice customers timely depends significantly on our general ledger, our contracted electronic data interface system, and other information systems. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of confidential or otherwise protected information and corruption of data. Cybersecurity incidents resulting in the failure of our information systems to operate effectively or to integrate with other systems, or a breach in security or other unauthorized access of these systems, may affect our ability to manage and maintain inventory and financial reports, and result in delays in product fulfillment and reduced efficiency of operations. A breach in security, unauthorized access resulting in misappropriation, theft, or sabotage with respect to proprietary and confidential information, including research or clinical data, could require significant capital investments to remediate any such failure, problem or breach, all of which could adversely affect our business, financial position, and operating results. We are currently involved in and may from time to time become involved in legal proceedings, some of which may result in substantial losses, government enforcement actions, damage to our business and reputation, and place a strain on our internal resources. We are currently involved in and in the future may become involved in legal proceedings in the ordinary course of our business, as a

party or non- party witness, with both private parties and certain government agencies. We may incur substantial time and expenses participating in these types of lawsuits and investigations, which could also divert management' s attention from ongoing business concerns and normal operations. In addition, these matters and any other substantial litigation may result in verdicts against us or government enforcement actions, which may include significant monetary awards, and preventing the manufacture, marketing and sale of our products. Any dispute resolved unfavorably, could have a material adverse effect on our business, financial position, and operating results. For a description of legal proceedings which are currently pending, see Note ~~13~~ **15** . Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10- K. We are susceptible to product liability claims that may not be covered by insurance, which, if successful, could require us to pay substantial sums. Like all pharmaceutical companies, we face ~~of~~ the risk of loss resulting from, and the adverse publicity associated with, product liability lawsuits, whether or not such claims are valid. We likely cannot avoid such claims. Unanticipated side effects or unfavorable publicity concerning any of our products or product candidates would likely have an adverse effect on our ability to achieve acceptance by prescribing physicians, managed care providers, pharmacies and other retailers, customers, patients and clinical trial participants. Even unsuccessful product liability claims could require us to spend money on litigation, divert management' s time, damage our reputation and impair the marketability of our products. In addition, although we believe that we have adequate product liability insurance coverage, we cannot be certain that our insurance will, in fact, be sufficient to cover such claims or that we will be able to obtain or maintain adequate insurance coverage in the future at acceptable prices. A successful product liability claim that is excluded from coverage or exceeds our policy limits could require us to pay substantial sums. Additionally, insurance coverage for product liability may become prohibitively expensive in the future or may not be available at all, and as a result, we may ~~25not~~ -- **not** be able to maintain adequate product liability insurance coverage to mitigate the risk of large claims, or we may be required to maintain a larger self- insured retention that we would otherwise choose. Currency fluctuations and changes in exchange rates could have a material adverse effect on our business, financial position, and operating results. A portion of our transactions are denominated in a foreign currency, the ~~Canadian dollar and the~~ Indian rupee. Because we engage in certain transactions in a foreign currency, we are subject to the effects of exchange rate fluctuations. If the U. S. dollar depreciates against the ~~Canadian dollar and the~~ Indian rupee, the expenses we recognize from ~~Canadian- denominated and~~ Indian- denominated transactions made by our ~~Canadian and~~ Indian ~~subsidiaries~~ **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. ~~Our~~ Risks Related to our ~~IndustryThe~~ --- **Industry Public health outbreaks, epidemics, or pandemics (such as the** COVID- 19 pandemic **)** ~~is ongoing and its impact on the global economy and our operations remains uncertain. A continuation of the pandemic could~~ have ~~a material adverse~~ **adversely** ~~impact on~~ **affected and may in the future adversely affect** our business ~~, results of operations and financial condition and on the market price of our common stock~~ . **The** ~~On March 12, 2020, the World Health Organization declared COVID- 19 to be a pandemic. In an effort to contain and mitigate the spread of COVID- 19, many countries, including the United States and Canada, imposed unprecedented restrictions on travel, and there were business closures and a substantial reduction in economic activity in countries that have had significant outbreaks of COVID- 19. While restrictions and impacts eased in 2021, significant uncertainty remains as to the continued potential impact of the~~ COVID- 19 pandemic **previously adversely affected us in** ~~on our operations and on the global economy as a whole. Demand for the products we sell was negatively impacted by COVID- 19 during~~ the years ended December 31, 2021 and 2020, ~~as fewer patients visited physicians for conditions treated by our products, fewer elective surgeries occurred~~ and ~~visits to pharmacies declined due to government orders and closures of or restrictions~~

~~placed on visits to medical offices and facilities. Additionally, we have experienced disruptions to our supply chain, including increased lead times on the procurement of materials. While most government orders, closures and restrictions have now lapsed, this situation could continue or worsen depending on the duration and severity of~~ the COVID- 19 pandemic ~~, the level of success in implementing mitigation measures, such as vaccines, the continued emergence of new variants of COVID- 19, the length of time it takes for~~ **or** ~~normal~~ **other actual or threatened public health outbreaks, epidemics, or pandemics may in the future adversely affect, among other things, the** economic and ~~operating conditions to resume, the impact of the pandemic on inflation, additional governmental actions that may be taken, and numerous other uncertainties. It is currently not possible to predict how long the pandemic will continue, whether new government restrictions will be reinstituted, the effectiveness of mitigation efforts such as vaccines, the emergence of new variants of the virus, and the related impact on economic activity, including inflation. A disruption in the~~ financial markets and ~~volatility, as seen~~ **labor resources of the countries** in **which we operate; our manufacturing** ~~2020, 2021, and 2022, could have an~~ **and** ~~adverse effect on our ability to access capital, our pharmaceutical~~ supply chain **operations** , ~~our~~ **research and development efforts, commercial operations and sales force, administrative personnel, third- party service providers, and** business **partners and customers; and the demand for our products. Such disruptions in our operations could materially adversely impact our business** , **prospects, operating** results **,** ~~of operations~~ and financial condition ~~, and~~ **. To** the ~~market price of~~ **extent a public health outbreak, epidemic,** ~~our~~ **or** ~~common stock~~ **pandemic adversely affects our business, prospects, operating results, or financial condition, it may also have the effect of heightening many of the other risks described in this" Risk Factors" section** . The continuing trend toward consolidation of customer groups could result in declines in the sales volume and prices of our products, and increased fees charged by customers, each of which could have a material adverse effect on our business, financial position, and operating results. Consolidation and the formation of strategic partnerships among and between wholesale distributors, chain drug stores, and group purchasing organizations has resulted in a smaller number of companies, each controlling a larger share of pharmaceutical distribution channels. For example, our net revenues are concentrated among ~~three~~ **four** customers representing ~~26~~ **31** %, ~~18~~ **13** %, **13 %,** and ~~15~~ **12** % of net revenues, respectively, during the year ended December 31, ~~2022~~ **2023** . As of December 31, ~~2022~~ **2023** , accounts receivable from these ~~three~~ **four** customers was approximately ~~82~~ **81** % of our accounts receivable, net. Drug wholesalers and retail pharmacy chains, which represent an essential part of the distribution chain for generic pharmaceutical products, have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in declines in our sales volumes if a customer is consolidated into another company that purchases products ~~26from~~ -- **from** a competitor. In addition, the consolidation of drug wholesalers and retail pharmacy chains could result in these groups gaining additional purchasing leverage and consequently increasing the product pricing pressures facing our business and enabling those groups to charge us increased fees. Additionally, the emergence of large buying groups representing independent retail pharmacies and the prevalence and influence of managed care organizations and similar institutions potentially enable those groups to extract price discounts on our products. The result of these developments or the loss of our relationship with one or more of these wholesalers, may have a material adverse effect on our business, financial position, and operating results. Our reporting and payment obligations under the Medicaid rebate program and other governmental purchasing and rebate programs are complex and may involve subjective decisions. Any determination that we have failed to comply with those obligations could subject us to penalties and sanctions, which could adversely affect our business, financial position, and operating results. The regulations regarding reporting and payment obligations with respect to Medicaid rebates and other governmental programs are complex. Because our processes for these calculations and the judgments involved in making these calculations involve subjective decisions and complex methodologies, these calculations are subject to the risk of errors. Our calculations and methodologies are subject to review and challenge by governmental agencies, and it is possible that such reviews could result in changes. Any determination by governmental agencies that we have failed to comply with our reporting and payment obligations could subject us to penalties and sanctions, which could have a material adverse effect on our business, financial position, and operating results. **Three** ~~Two of our~~ products, which together comprised less than 10 % of our total revenue in ~~2022~~ **2023** , are marketed without approved NDAs or Abbreviated New Drug Applications (" ANDAs ") and we can offer no assurances that the U. S. Food and Drug Administration (" FDA ") will not require us to either seek approval for these products or withdraw them from the market. In either case, our business, financial position, and operating results could be materially adversely affected. **Three** ~~Two of our~~ products, Esterified Estrogen with Methyltestosterone (" EEMT ") ~~and~~ **,** Opium Tincture, **and Thyroid Tablets** are marketed without approved NDAs or ANDAs **. The Company obtained the rights to Hyoscyamine, a product without approved NDAs or ANDAs, on of December 27, 2023. During 2023 the Company recorded only contract manufacturing revenues for Hyoscyamine (see further discussion in Note 15. Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10- K). We plan to launch Hyoscyamine commercially in early 2024** . The FDA' s policy with respect to the continued marketing of unapproved products appears in the FDA' s September 2011 Compliance Policy Guide Sec. 440. 100 titled " Marketed New Drugs without Approved NDAs or ANDAs. " Under this policy, the FDA has stated that it will follow a risk- based approach with regard to enforcement against marketing of unapproved products. The FDA evaluates whether to initiate enforcement action on a case- by- case basis, but gives higher priority to enforcement action against products in certain categories, such as those with potential safety risks or that lack evidence of effectiveness. We continue to believe that, so long as we comply with applicable manufacturing standards, the FDA will continue to operate on a risk- based approach and will not take action against us. However, we can offer no assurance that the FDA will continue to follow this approach or that it will not take a contrary position with any individual product or group of products. Additionally, our EEMT products are related to an outstanding Notice of Opportunity for Hearing on estrogen- androgen products. The hearing relates to the FDA' s intent to reclassify certain estrogen- androgen combination drugs as lacking substantial evidence of their effectiveness for the treatment of moderate to severe vasomotor symptoms associated with the menopause in those patients not improved by estrogen alone. If the FDA were

to move away from the risk- based approach to enforcement against marketing of unapproved products, we may be required to seek FDA approval for these products or withdraw such products from the market. If we decide to withdraw the products from the market, our net revenues for generic pharmaceutical products would decline materially, and if we decide to seek FDA approval, we would face increased expenses and might need to suspend sales of the products until such approval was obtained, and there are no assurances that we would receive such approval. ~~27Imported~~ -- **Imported** API are subject to inspection by the FDA and the FDA can refuse to permit the importation of API for use in products that are marketed without approved NDAs or ANDAs. We are dependent on imported API to make certain of our products. If the FDA detained or refused to allow the importation of such API, our revenues from certain of our products would be reduced or eliminated and our business, financial position, and operating results could be materially adversely affected. We source some of the API for our products, including those that are marketed without approved NDAs or ANDAs, from international suppliers. From time to time, due to FDA inspections, we have experienced temporary disruptions in the supply of imported API. Any prolonged disruption in the supply of imported API could materially affect our ability to manufacture and distribute our products, reduce or eliminate our revenues, and have a material adverse effect on our business, financial position, and operating results. In addition, as regulatory fees and compliance oversight of API manufacturers increase, this could result in certain companies discontinuing their supply of API to us, which would materially affect our ability to manufacture our products. The FDA does not provide guidance on safety labeling for products that are marketed without approved NDAs or ANDAs. As a result, we are dependent on our internal post- approval drug safety surveillance program to identify necessary safety- related changes to the labels for EEMT ~~and~~ **,** Opium Tincture **, and Thyroid Tablets, and Hyoscyamine** . Pharmaceutical product labels contain important safety information including Black Box warnings, contraindications, dosing and administration, adverse reactions, drug interactions, use in specific populations such as pregnant women, pediatric, and geriatric patients, and other warnings and precautions. Pharmaceutical manufacturers may change product labels when post- approval drug safety surveillance programs identify previously unknown side- effects, drug interactions, and other risks. Manufacturers may also change product labels after conducting post- approval clinical studies and may receive or seek guidance from the FDA regarding updating safety labeling information. However, the FDA does not provide guidance on labeling for products that are marketed without approved NDAs or ANDAs. As a result, we are dependent on our internal post- approval drug safety surveillance program to identify necessary safety- related changes to the labels for EEMT ~~and~~ **,** Opium Tincture **, Thyroid Tablets, and Hyoscyamine** . Additionally, because the FDA does not review and approve labeling for the products without approved NDAs or ANDAs, it would be difficult to make a claim for preemption due to the FDA' s approval of the labeling and this could increase our potential liability with respect to failure- to- warn claims for these products. Such claims, even if successfully defended, could have an adverse impact on our business, financial position, and operating results. We are entirely dependent on periodic approval by the DEA for the supply of the API needed to manufacture our controlled substances. An inability to obtain such approvals would reduce or eliminate our revenues for our controlled substances, and could have a material adverse effect on our business, financial position, and operating results. In addition, we are subject to strict regulation by the DEA and are subject to sanctions if we are unable to comply with related regulatory requirements. The DEA regulates products containing controlled substances, such as opiates, pursuant to the U. S. Controlled Substances Act (" CSA "). The CSA and DEA regulations impose specific requirements on manufacturers and other entities that handle these substances including registration, recordkeeping, reporting, storage, security, and distribution. Recordkeeping requirements include accounting for the amount of product received, manufactured, stored, and distributed. Companies handling controlled substances also are required to maintain adequate security and to report suspicious orders, thefts and significant losses. The DEA periodically inspects facilities for compliance with the CSA and its regulations. Failure to comply with current and future regulations of the DEA could lead to a variety of sanctions, including revocation or denial of renewal of DEA registrations, injunctions, or civil or criminal penalties. In addition, each year, we must submit a request to the DEA for a procurement quota in order to purchase the amount of API needed to manufacture our Schedule II controlled substances. Without approved procurement quotas from the DEA, we would not be able to purchase these ingredients from our suppliers. As a result, we are entirely dependent upon the DEA to approve, on an annual basis, a quota of API that is sufficiently large to support our plans for the continued manufacture of our controlled substances at commercial levels. In 2017, the DEA announced that the administration would decrease the total quotas approved for Schedule II opioid painkillers. In 2018, the DEA decreased quotas approved for Schedule II opioid painkillers. The DEA continues to closely monitor quotas of certain opioids and as a result there may be a reduction from what was requested; however, firms may file an application for a quota ~~28adjustment~~ -- **adjustment** at any time during the calendar year. If the DEA does not approve our requested procurement quotas, we may be unable to obtain sufficient API to manufacture these products at levels required by our customers, which could have an adverse impact on our business, financial position, and operating results. ~~Pharmaceutical~~ **Our** ~~product~~ **products are subject to regulatory and** quality standards ~~are steadily increasing~~ and ~~all~~ **guidelines set forth by FDA and other governmental agencies. Changes or developments in such standards and guidelines may affect the ability of our** products **to meet such standards** , including ~~those~~ **with respect to** already approved **products** ~~, may need to meet current standards or enhanced standards in the future~~ . If our products are not able to meet these standards, we may be required to discontinue marketing and / or recall such products from the market. ~~Steadily increasing~~ **Changes or developments in regulatory and** quality standards ~~are applicable to pharmaceutical products still under development~~ and **guidelines set forth** ~~those already approved and on the market. These standards result from product quality initiatives implemented~~ by ~~the~~ FDA, such as criteria for residual solvents, periodic guidance from the FDA regarding testing for impurities, such as nitrosamines, in our products, and updated U. S. Pharmacopeial Convention (" USP ") Reference Standards **may impact our ability to sell certain drug products** . The USP is a scientific nonprofit organization that sets standards for the identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide. Pharmaceutical products approved prior to the implementation of new or revised quality standards, including those produced or sold by us, may

not meet these standards, which could require us to discontinue marketing and / or recall such products from the market, either of which could adversely affect our business, financial position, and operating results. In addition, results of periodic testing we conduct on our products may indicate the presence of substances at levels greater than those deemed acceptable under FDA or other standards, which ~~will~~ **could potentially** require a recall of the product. For example, during the fourth quarter of 2019, testing of the API used in our ranitidine drug product, as well as testing of the drug product itself, indicated a level of a nitrosamine impurity called N- nitrosdimethylamine (" NDMA ") above acceptable thresholds. NDMA is classified as a probable human carcinogen. Appco Pharma, LLC, with whom we had partnered to develop and market the product, initiated a voluntary recall, and we elected to exit the market for Ranitidine in 2019. For a description of legal proceedings which are currently pending relating to ranitidine, see Note ~~13~~ **15** . Commitments and Contingencies, in the notes to the consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10- K. **In** ~~Another example of evolving standards occurred in~~ December of 2021, ~~when~~ the FDA issued an information request to **all** manufacturers of propranolol products, including Inderal LA (Propranolol ER) currently being marketed **by ANI** in the United States to evaluate their product for the presence and level of a nitrosamine impurity known as N- nitroso- propranolol (" NNP "), which is distinct from NDMA. **We undertook a review** ~~Pfizer, Inc. and its affiliates (" Pfizer "), our contract manufacturer for both our Inderal LA brand~~ -- **and** ~~product and our authorized generic product, Propranolol ER, initiated that evaluation and shared its~~ analysis ~~and test results with the Company in February 2022. Pfizer also manufactures and markets Inderal LA in Canada. On March 1, 2022, Pfizer announced that it was recalling all lots and strengths (60 mg, 80 mg, 120 mg, and 160 mg)~~ of **NNP** ~~Inderal LA in the Canadian market after engagement with Health Canada. We are currently undertaking our own review and analysis of the nitrosamine impurity at issue~~ , working with testing and toxicology experts, and ~~are in active communication~~ **communicated** with the FDA on the **scientific bases for establishing** appropriate acceptable daily intake for NNP and the appropriate approach for ~~the~~ **propranolol** ~~product~~ **products** in the U. S. ~~The~~ **On August 4, 2023, the** FDA **issued** ~~has not provided public notification for a~~ final ~~NNP~~ **guidance on** acceptable intake **limits for nitrosamine drug substance- related impurities (NDSRIs), with recommended limits for propranolol products of 1500 mg / day** . ~~After briefly halting and then resuming further~~ **Based on this guidance, we were able to continue** sales of the product to ~~our trade customers, there has been no recall in the United States of Inderal LA and Propranolol ER, and the necessity for any recall has not been determined. The discussion above illustrates the potential risk of a recall of a product due to enhanced standards, at the initiation of the Company and / or the FDA. The loss of sales of this product would have an adverse effect on our results of operations, as revenues from Inderal LA and Propranolol ER are anticipated to contribute approximately 4 % of our forecasted total 2023 ex- Cortrophin Net Revenues. In addition, Pfizer' s decision to withdraw the product in Canada creates uncertainties as to the future supply of our product from Pfizer which could have an adverse effect on our operating results if we are unable to supply the product pursuant to existing contracts with~~ our customers. We may become subject to federal and state false claims litigation brought by private individuals and the government. We are subject to state and federal laws that govern the submission of claims for reimbursement. The Federal False Claims Act (" FFCA "), also known as Qui Tam, imposes civil liability and criminal fines on individuals or entities that ~~29knowingly~~ -- **knowingly** submit, or cause to be submitted, false or fraudulent claims for payment to the government. Violations of the FFCA and other similar laws may result in criminal fines, imprisonment, and civil penalties for each false claim submitted and exclusion from federally funded health care programs, including Medicare and Medicaid. The FFCA also allows private individuals to bring a suit on behalf of the government against an individual or entity for violations of the FFCA. These suits, also known as Qui Tam actions, may be brought, with only a few exceptions, by any private citizen who has material information of a false claim that has not yet been previously disclosed. These suits have increased significantly in recent years because the FFCA allows an individual to share in any amounts paid to the federal government from a successful Qui Tam action. If our past or present operations are found to be in violation of any of such laws or other applicable governmental regulations, we may be subject to civil and criminal penalties, damages, fines, exclusion from federal health care programs, and / or the curtailment or restructuring of our operations, any of which could materially adversely affect our business, financial position, and operating results. Actions brought against ANI for violations of these laws, even if successfully defended, could also have a material adverse effect on our business, financial position, and operating results. The use of legal, regulatory, and legislative strategies by competitors, both branded and generic, including" authorized generics," citizen' s petitions, and legislative proposals, may increase the costs to develop and market our generic products, could delay or prevent new product introductions, and could significantly reduce our profit potential. These factors could have a material adverse effect on our business, financial position, and operating results. Our competitors, both branded and generic, often pursue legal, regulatory, and / or legislative strategies to prevent or delay competition from generic alternatives to branded products. These strategies include, but are not limited to: ●-● entering into agreements whereby other generic companies will begin to market an authorized generic, a generic equivalent of a branded product, at the same time generic competition initially enters the market; ●-● launching a generic version of their own branded product at the same time generic competition initially enters the market; ●-● filing citizen petitions with the FDA or other regulatory bodies, including timing the filings so as to thwart generic competition by causing delays of generic product approvals; ●-● seeking to establish regulatory and legal obstacles that would make it more difficult to demonstrate bioequivalence or meet other approval requirements; ●-● initiating legislative and regulatory efforts to limit the substitution of generic versions of branded pharmaceuticals; ●-● filing suits for patent infringement that may delay regulatory approval of generic products; ●-● introducing" next- generation" products prior to the expiration of market exclusivity for the reference product, which often materially reduces the demand for the first generic product; ●-● obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or by other potential methods; ●-● persuading regulatory bodies to withdraw the approval of branded name drugs for which the patents are about to expire, thus allowing the branded company to obtain new patented products serving as substitutes for the products withdrawn; and ●-● seeking to obtain new patents on drugs for which patent protection is about to expire. If we cannot compete with such strategies, our business,

financial position, and operating results could be adversely impacted. If third- party payers deny coverage, substitute another company' s product for our product, or offer inadequate levels of reimbursement, we may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated. Third- party payers are increasingly challenging the prices charged for medical products and services. For example, third- party payers may deny coverage, choose to provide coverage for a competitor' s bioequivalent product rather than our product, or offer limited reimbursement if they determine that a prescribed product has not received appropriate ~~30clearances~~ -- **clearances** from the FDA, is not used in accordance with cost- effective treatment methods as determined by the third- party payer, or is experimental, unnecessary, or inappropriate. Prices also could be driven down by health maintenance organizations that control or significantly influence purchases of healthcare services and products. If third- party payers deny coverage or limit reimbursement, we may not be able to market our products effectively or we may be required to offer our products at prices lower than anticipated. We are subject to federal, state, and local laws and regulations, and complying with these may cause us to incur significant additional costs. The pharmaceutical industry is subject to regulation by various federal authorities, including the FDA, the DEA, and state governmental authorities. Federal and state statutes and regulations govern or influence the testing, manufacturing, packing, labeling, storing, record keeping, safety, approval, advertising, promotion, sale, and distribution of our products. Noncompliance with applicable legal and regulatory requirements can have a broad range of consequences, including warning letters, fines, seizure of products, product recalls, total or partial suspension of production and distribution, refusal to approve NDAs or other applications or revocation of approvals previously granted, withdrawal of product from marketing, injunctions, withdrawal of licenses or registrations necessary to conduct business, disqualification from supply contracts with the government, civil penalties, debarment, and criminal prosecution. All U. S. facilities where prescription drugs are manufactured, tested, packaged, stored, or distributed must comply with FDA current good manufacturing practices (" cGMPs "). All of our products are manufactured, tested, packaged, stored, and distributed according to cGMP regulations. The FDA performs periodic audits to ensure that our facilities remain in compliance with all applicable regulations. If it finds violations of cGMP, the FDA could make its concerns public and could impose sanctions including, among others, fines, product recalls, total or partial suspension of production and / or distribution, suspension of the FDA' s review of product applications, injunctions, and civil or criminal prosecution. If imposed, enforcement actions could have a material adverse effect on our business, financial position, and operating results. Under certain circumstances, the FDA also has the authority to revoke previously granted drug approvals. Although we have internal compliance programs in place that we believe are adequate, the FDA may conclude that these programs do not meet regulatory standards. If compliance is deemed deficient in any significant way, it could have a material adverse effect on our business. The U. S. government has enacted the Federal Drug Supply Chain Security Act (" DSCSA") that requires development of an electronic pedigree to track and trace each prescription drug at the salable unit level through the distribution system, which will be effective incrementally over a 10- year period. All prescription pharmaceutical products distributed in the U. S. must be serialized with unique product identifiers. ANI started manufacturing serialization- compliant products in November 2018. The ~~final~~ **DSCSA establishes national traceability standards requiring drugs to be labeled and tracked at the bottle level, preempts state drug pedigree** ~~requirement~~ **requirements** ~~for~~ **, and requires all supply- chain stakeholders to participate in an electronic, interoperable prescription drug traceability system by November 2023. In August 2023, however, the FDA established a one- year stabilization period to allow** ~~tracking~~ **trading partners to implement, troubleshoot and mature** ~~the~~ **their** ~~products will commence~~ **electronic interoperable systems. The FDA expects trading partners to use this stabilization period, which expires** on November 27, ~~2023~~ **2024 , to build and validate interoperable systems and processes, manage products and data, and ensure continuity of the supply chain and product availability to patients. Additionally, certain of our largest customer are requiring earlier compliance with the DSCSA, despite the stabilization period enacted by the FDA** . Compliance with DSCSA and future U. S. federal or state electronic pedigree requirements may increase the Company' s operational expenses and impose significant administrative burdens. In addition, if we are unable to comply with DSCSA as of the required dates, we could face penalties or be unable to sell our products. Our research, product development, and manufacturing activities involve the controlled use of hazardous materials, and we may incur significant costs in complying with numerous laws and regulations. We are subject to laws and regulations enforced by the FDA, the DEA, and other regulatory statutes including the Occupational Safety and Health Act (" OSHA "), the Environmental Protection Act, the Toxic Substances Control Act, the Resource Conservation and Recovery Act, and other current and potential federal, state, local, and foreign laws and regulations governing the use, manufacture, storage, handling, and disposal of our products, materials used to develop and manufacture such products, and resulting waste products. We cannot completely eliminate the risk of contamination or injury, by accident or as the result of intentional acts, from these materials. In the event of an accident, we could be held liable for any damages that result, and any resulting liability could exceed our resources. We may also incur significant costs in complying with environmental laws and regulations in the future. We are also subject to laws generally applicable to businesses, including but not limited to, federal, state, and local regulations relating to wage and hour matters, employee classification, mandatory healthcare benefits, unlawful workplace discrimination, and whistle-blowing. Any actual or alleged failure to comply with any regulation applicable to our business or any whistle- blowing claim, even if without merit, could result in costly litigation, regulatory action or otherwise harm our business, financial position, and operating results. ~~31Our~~ -- **Our** operations in an international market subject us to additional regulatory oversight both in the international market and in the U. S., as well as, social, and political uncertainties, which could cause a material adverse effect on our business, financial position, and operating results. We are subject to certain risks associated with having assets and operations located in a foreign jurisdiction, including our operations in ~~Canada and~~ India ~~. Our Canadian operations are subject to regulation by Health Canada and other federal, provincial, and local regulatory authorities. Health Canada regulates the testing, manufacture, labeling, marketing, and sale of pharmaceutical products manufactured and distributed in Canada~~ . Our operations in ~~Canada and~~ India may be adversely affected by general economic conditions and economic and fiscal policy,

including changes in exchange rates and controls, interest rates and taxation policies, and increased government regulation, which could have a material adverse effect on our business, financial position, and operating results. Additionally, involvement in a war or other military action or international acts of terrorism may cause significant disruption to commerce throughout the world. To the extent that such disruptions result in (i) delays or cancellations of customer orders, (ii) a general decrease in consumer spending on healthcare technology, (iii) our inability to effectively market and distribute our products ~~globally~~ **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** ~~rapidly developing~~ conflict between Russia and Ukraine, the United States has imposed and may further impose, and other countries may additionally impose, broad sanctions or other restrictive actions against governmental and other entities in Russia. Additionally, further escalation of geopolitical tensions **, such as the conflict in Israel and Gaza and the surrounding areas, and conflicts related to the attacks on cargo ships in the Red Sea,** could have a broader impact that extends into other markets where we do business. We are unable to predict whether acts of international terrorism or the involvement in a war or other military actions by the United States and / or the countries in which we sell or distribute our products will result in any long- term commercial disruptions or if such involvement or responses will have any long- term material adverse effect on our business, results of operations, or financial condition. Continuing studies of our products could produce negative results, which could require us to implement risk management programs, or discontinue product marketing. In addition, ongoing post- approval drug safety surveillance of our products could result in the submission of adverse event reports to the FDA. Studies of the proper utilization, safety, and efficacy of pharmaceutical products are being conducted by the industry, government agencies, and others on a continuous basis. Such studies, which increasingly employ sophisticated methods and techniques, can call into question the utilization, safety, and efficacy of current and previously marketed products, including those that we produce. In addition, we are required by the FDA to submit reports of adverse events involving the use of our products. In some cases, studies and safety surveillance programs have resulted, and in the future may result, in the one or more of the following: ~~•~~ product label changes including FDA- mandated Black Box warnings; ~~•~~ risk management programs such as patient registries; ~~•~~ reduced product sales due to concerns among patients and physicians; and ~~•~~ discontinuance of product marketing. These situations, should they occur with respect to any of our products, could have a material adverse effect on our business, financial position, and operating results. Healthcare reform and changes in pharmaceutical pricing, reimbursement and coverage, by governmental authorities and third- party payors may materially affect our business, financial position and operating results. In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of, and reimbursement for healthcare services in the U. S. generally and prescription drug coverage, reimbursement and pricing specifically, and it is likely that federal and state legislatures will continue to advocate change to the healthcare system generally and to prescription drug coverage, reimbursement and pricing specifically. ~~32At~~ **At** the federal level, the American Rescue Plan Act eliminated the cap on Medicaid Drug Rebate Program rebates beginning January 1, ~~2023~~ **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** ~~Significant developments that may adversely affect pricing in~~ the ~~United States include proposed drug pricing and~~ **Inflation Reduction Act (" IRA") has brought sweeping change to** Medicare **coverage of** ~~reforms by Congress~~ and **reimbursement for prescription** ~~regulatory changes to Medicare Part B (physician administered~~ drugs ~~) and~~ **. Most notably, CMS is able to directly negotiate the reimbursement for certain prescription drugs reimbursed under** Medicare Part D **or B to be effective for the 2026 plan year. If a manufacturer' s drug is selected for negotiation, the manufacturer must negotiate a Maximum Fair Price with CMS or be liable for an excise tax of 65 to 95 percent of Medicare utilization based on the prior year. While no ANI drugs have currently been selected for negotiation, ANI continues to evaluate the implications of direct negotiation on its products in the future and potential repercussions of competitive products being selected for direct negotiation. In addition, as previously noted, there are numerous legal challenges to the direct negotiation provisions of the IRA. If any of those challenges are successful, this could change the current competitive landscape for manufacturers generally and may change the dynamics of the Medicare Part D marketplace potentially resulting in increased premiums, fewer Part D plans and sponsors and increased pressure on manufacturers to offer formulary placement rebates and additional price concessions. In addition, under the IRA the Part D benefit design with be altered and the coverage gap discount program replaced by a new manufacturer discount program pursuant to which manufacturers will provide a 10 percent discount off the negotiated price for applicable drugs** (~~prescription~~ **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** ~~benefit) could financially impact us~~ . **Lastly** ~~On November 19~~ , ~~2021, the U. S. House of Representatives passed the Build Back Better Act, which includes several provisions aimed at lowering prescription drug costs and reducing spending by the federal government and private payers by, among other~~ -- **the IRA imposed additional** ~~things, allowing the U. S. federal government to negotiate prices for certain high- cost drugs covered under Medicare, imposing~~ rebates on manufacturers **including ANI to the extent certain** ~~of single- source drugs and biologics~~

~~covered by Medicare Part B and nearly all drugs covered under Part D, if~~ drug ~~prices increase~~ **pricing metrics are rising** faster than ~~the rate of~~ inflation ~~, based~~ **. These new inflation rebates are similar to those imposed** on ~~the Consumer Price Index for All Urban Consumers (" CPI- U "). Build Back Better would also re- structure the Part D benefit and replace the existing Coverage Gap Discount Program with another manufacturer~~ **manufacturers under Medicaid and** ~~- imposed rebate or discount program, which~~ could result in additional rebates ~~to~~ **due from us on** Medicare **utilization of** ~~Part D plans in order to obtain Medicare Part D coverage. These concepts were included in the Inflation Reduction Act, which was signed into law on August 16, 2022. We are actively evaluating how this legislation will impact~~ our **products** ~~business and operations.~~ Certain U. S. states have implemented statutes aimed at prescription drug price transparency and some of those laws would permit state run boards or agencies to cap reimbursement for certain prescription drugs in the states. Such laws could negatively impact our financial performance and could result in us terminating distribution of certain products in certain states or regions. Inflation could have a material adverse effect on our business, financial position, and operating results. Inflationary pressures are currently being experienced and may continue to exist in the U. S. and key worldwide markets. The rate of inflation may significantly increase input costs for our products and, given the competitive nature of the generic **and rare disease** markets in which we compete, we may not be able to pass those costs on to our ~~generic~~ customers. Risks Related to Accounting, Tax, and SEC Rules and ~~RegulationsWe~~ -- **Regulations We** have increased exposure to tax liabilities, including foreign tax liabilities. **We** ~~As a company based in the U. S. with subsidiaries in Canada and India, we~~ are subject to, or potentially subject to, income taxes as well as non-income based taxes in ~~these~~ **various U. S.** jurisdictions **, Canada, and India** ~~as well as the U. S~~. Significant judgment is required in determining our international provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significantly adverse impact on our effective tax rate. In addition, we have potential tax exposures resulting from the varying application of statutes, regulations, and interpretations, which include exposures on intercompany terms of cross- border arrangements between our U. S. operations and our ~~Canadian and~~ Indian ~~subsidiaries~~ **subsidiary** in relation to various aspects of our business, including research and development services, tech transfers, and contract manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions; such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and which could have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations. Our expanded international operations from the Novitium acquisition increased our exposure to potential liability under anti- corruption, trade protection, tax, and other laws and regulations. ~~33The~~ -- **The** Foreign Corrupt Practices Act and other anti- corruption laws and regulations (" Anti- Corruption Laws ") prohibit corrupt payments by our employees, vendors, or agents. From time to time, we receive inquiries from authorities in the U. S. and elsewhere about our business activities outside of the U. S. and our compliance with Anti- Corruption Laws. While we devote substantial resources to our ~~global~~ compliance programs and have implemented policies, training, and internal controls designed to reduce the risk of corrupt payments, our employees, vendors or agents may violate our policies and with the acquisition of Novitium, our expanded international operations would significantly increase our exposure to potential liability. Our failure to comply with Anti- Corruption Laws could result in significant fines and penalties, criminal sanctions against us, our officers or our employees, prohibitions on the conduct of our business, and damage to our reputation. Operations outside of the U. S. may be affected by changes in trade production laws, policies, and measures, and other regulatory requirements affecting trade and investment. We are also subject to Indian foreign tax regulations. Such regulations may not be clear, not consistently applied and subject to sudden change, particularly with regard to international transfer pricing. Our earnings could be reduced by **changes to** ~~the uncertain and changing nature of~~ such tax regulations **or changing interpretation of such tax regulations** . The ~~global~~ **international** nature of Novitium' s operations (including those of its Indian subsidiary Novitium Labs Private Limited) will subject us to political and economic risks that could adversely affect our business, results of operations, or financial condition. The risks presented by ~~global~~ **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 ~~evolving~~ 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 ~~; and • the severity and duration of the COVID- 19 pandemic and its impacts where we operate globally~~ . If we are unable to successfully manage these and other risks associated with managing the expansion of our business to the jurisdictions in which Novitium operates, including India, the risks could have a material adverse effect on our business, results of operations, or financial condition. Failure to comply with applicable transfer pricing and similar regulations could have a material adverse effect on our financial position and operating results. We are subject to complex transfer pricing and other tax regulations in the United States ~~, Canada,~~ and India designed to ensure that appropriate levels of income are reported as earned and are taxed in the appropriate taxing jurisdictions. Although we believe that we are in substantial compliance with all applicable regulations and restrictions, we are subject to the risk that governmental authorities could audit our transfer pricing and related practices and assert that additional taxes are owed. In the event that ~~the~~ **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. ~~34Changes~~ -- **Changes** in estimates regarding the fair value of goodwill or intangible assets may result in an adverse impact to our business, financial position, and operating results. We test goodwill for impairment annually, or more frequently if changes in circumstances indicate that the carrying amount of goodwill might not be recoverable. Judgment is used in determining when these events and circumstances arise. We perform our ~~review~~ **annual assessment** of goodwill based on our ~~one~~ **two** reporting ~~unit~~ **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 ~~2022~~ **2023** did not result in an impairment charge related to goodwill, there can be no assurances that our goodwill will not be impaired in the future. Our material definite- lived intangible assets consist of ANDAs for previously marketed generic products, NDAs and product rights for our branded products, product rights related to certain generic products, and a non- compete agreement. These assets are being amortized over their useful lives of seven to 10 years. For these definite-lived intangible assets, we perform an impairment analysis when events or circumstances indicate that the carrying value of the assets may not be recoverable. An impairment loss is recognized if, based on our impairment analysis, the carrying amount of the asset is not recoverable and its carrying amount exceeds its fair value. Any significant change in market conditions, estimates or judgments used to determine expected future cash flows that indicate a reduction in carrying value may give rise to impairment in the period that the change becomes known. An impairment charge could have a material negative impact on our business, financial position, and operating results. ~~We~~ **No impairment losses were** recognized ~~an impairment of $ 0. 1 million~~ in the year ended December 31, ~~2022~~ **2023** ~~, in relation to an ANDA asset, and there can be no assurances that our remaining intangible assets will not be impaired in the future~~. Our management is required to devote substantial time to comply with public company regulations. If we are unable to comply with these regulations, investors could lose confidence in us, which could have a material adverse effect on our stock price, business, financial position, and operating results. As a public company, we are required to comply with significant legal, accounting, and other requirements, and as a result, we incur significant regulatory compliance- related expenses. The Sarbanes- Oxley Act of 2002, the Dodd- Frank Wall Street Reform and Consumer Protection Act as well as rules implemented by the SEC and The Nasdaq Stock Market, impose various requirements on public companies, including those related to corporate governance practices. Our management and other personnel devote a substantial amount of time to these requirements. Some members of management do not have significant experience in addressing these requirements. Moreover, these rules and regulations have increased our legal and financial compliance costs relative to those of previous years and make some activities more time consuming and costly. The Sarbanes- Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures. In particular, we must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes- Oxley Act. The Committee of Sponsoring Organizations of the Treadway Commission (" COSO ") provides a framework for companies to assess and improve their internal control systems. Our compliance with these requirements has required that we incur substantial accounting and related expenses and expend significant management efforts. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act, are unable to assert that our internal controls over financial reporting are effective, or identify deficiencies that are deemed to be material weaknesses, investors could lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline and we could be subject to sanctions or investigations by The Nasdaq Stock Market, the SEC, or other regulatory authorities, which would require additional financial and management resources and could damage our reputation. Further, if we identify any material weaknesses or deficiencies that aggregate to a material weakness in our internal controls, we will have to implement appropriate changes to these controls, which may require specific compliance training for our directors, officers and employees, require the hiring of additional finance, accounting, legal and other personnel, entail substantial costs to modify our existing accounting systems and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, ~~35could~~ -- **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** . ~~If we do~~ **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** ~~effectively~~ -- **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** ~~remediate~~ **remediated as of December 31, 2023. For a detailed summary of** these material weaknesses **, including** ~~or~~ **our** ~~if~~ **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 ~~otherwise fail~~ **are unable** to maintain effective internal control over financial reporting **or disclosure controls and procedures** , ~~we may not~~ **our ability to record, process, and report financial information accurately and to prepare financial statements within required time periods could** be ~~able~~ **adversely affected, which could subject us** to ~~accurately~~ **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** ~~report~~ **reports ,** ~~our~~ - **or** ~~financial results~~ **investor confidence in** ~~or~~ **our** ~~prevent fraud. Management identified material weaknesses in our internal control over~~ financial reporting ~~as of December 31~~ , **any of which may divert management resources** ~~2022. See Item 9A, " Controls and Procedures, " in this Annual Report on Form 10- K for~~ - **or** ~~information regarding the identified~~ **cause our stock price to**

decline. Further, remediation of a material ~~weaknesses~~ -- **weakness does** ~~and our actions to date to remediate the material weaknesses. If we do~~ not **provide assurance that** ~~effectively remediate these material weaknesses or~~ **our remediation or other** ~~if we otherwise fail to maintain effective internal control~~ **controls will continue** ~~over financial reporting, we may not be able~~ to ~~accurately report~~ **operate properly** ~~our~~ - **or remain adequate** ~~financial results or prevent fraud~~ . Our policies regarding returns, allowances and chargebacks, and marketing programs adopted by wholesalers may reduce revenues in future fiscal periods. We, like other generic drug manufacturers, have agreements with customers allowing chargebacks, product returns, administrative fees, and other rebates. Under many of these arrangements, we may match lower prices offered to customers by competitors. If we choose to lower our prices, we generally give the customer a credit on the products that the customer is holding in inventory, which could reduce sales revenue for the period the credit is provided. Like our competitors, we also give credits for chargebacks to wholesalers with whom we have contracts for their sales to hospitals, group purchasing organizations, pharmacies, or other customers. A chargeback is the difference between the price at which we invoice the wholesaler and the price that the wholesaler' s end- customer pays for a product. Although we establish reserves based on prior experience and our best estimates of the impact that these policies may have in subsequent periods, we cannot ensure that our reserves are adequate or that actual product returns, allowances, and chargebacks will not exceed our estimates. Risks Related to our **Debt** ~~DebtMaking~~ ---- **Making** interest and principal payments under our Credit Facility consisting of $ 300. 0 million term loan and a $ 40. 0 million revolving credit facility, requires a significant amount of cash. In connection with the completion of the Novitium acquisition, we entered into a ~~new~~ $ 300. 0 million term loan and a $ 40. 0 million revolving credit facility. The Credit Facility, which is secured by all our assets and the assets of our subsidiaries, was used to finance the cash consideration of the acquisition of Novitium and terminate and repay our previous senior credit facilities. In order to service the debt we incur under this facility, we will require a significant amount of cash. Our ability to make scheduled payments of principal and interest depends on our future performance, which is subject to economic, financial, competitive, and other factors beyond our control. Our business may not continue to generate cash flow from operations in the future sufficient to service our debt. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt, or obtaining additional debt or equity financing on terms that may not be favorable to us or available to us at all. Our ability to refinance any such debt will depend on the capital markets and our financial condition at that time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default under our current or future indebtedness. Any event of default or inability to otherwise satisfy our obligations could have a material adverse effect on our future operating results and financial condition. Our Credit Agreement contains restrictive and financial covenants and if we are not in compliance with these covenants, our outstanding indebtedness under this facility could be accelerated and the lenders could terminate their commitments under the facility. The Credit Agreement contains customary covenants that require maintenance of a leverage ratio at or below specified thresholds and restricts our ability to make certain distributions with respect to our capital stock, prepay other debt, make certain investments, encumber our assets, incur additional indebtedness, make capital expenditures, engage in certain business combinations, transfer, lease or dispose of our assets, alter the character of our business in any material ~~36respect~~ -- **respect** or undertake various other corporate activities. Therefore, as a practical matter, these covenants restrict our ability to engage in or benefit from such activities. In addition, we pledged our assets in order to secure our repayment obligations under the Credit Agreement. This pledge may reduce our operating flexibility because it restricts our ability to dispose of our assets or engage in other transactions that may be beneficial to us. If we are unable to comply with the covenants in the Credit Agreement, we will be in default, which could result in the acceleration of our outstanding indebtedness and termination of funding commitments by the lenders. If such an acceleration occurs, we may not be able to repay our debt and we may not be able to borrow sufficient additional funds to refinance our debt, which would have a material adverse effect on our business, financial position, and operating results. Changes in the method of determining London Interbank Offered Rate (" LIBOR"), or the replacement of LIBOR with an alternative reference rate, **such as SOFR,** may adversely affect interest expense related to outstanding debt. ~~Amounts drawn under~~ **In July 2023, we amended our Credit Agreement to transition from LIBOR to SOFR due to** the ~~New~~ **cessation of LIBOR pursuant to the terms of Amendment No. 1 to the Credit Agreement. SOFR will be applied to the** Credit Facility ~~may bear~~ **for the** interest ~~rates~~ **period (as defined** in ~~relation to~~ **the Credit Agreement) beginning on August 1, 2023 and will replace all** LIBOR **terms** ~~, depending on our selection~~ . **We have no** ~~On July 27, 2017, the~~ **other material financing agreements** ~~Financial Conduct Authority (" FCA ") in the United Kingdom announced~~ that **use** ~~it would phase out~~ LIBOR as **an interest index** ~~a benchmark by the end of 2021~~ . **There is no guarantee that** ~~Subsequently, recent actions taken by~~ the **transition from** ~~U. K. Financial Conduct Authority, which regulates~~ LIBOR **to SOFR** ~~, indicate that the continuation of LIBOR on the current basis cannot and~~ 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 ~~guaranteed after June 30, 2023. Moreover, it is possible that the U. S. LIBOR will be discontinued or modified prior to June 30, 2023. The U. S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, a steering committee comprised of large U. S. financial institutions, is recommending replacing U. S.- dollar LIBOR with the Secured Overnight Financing Rate (" SOFR "), a new index calculated by short- term repurchase agreements, backed by Treasury securities. At this time, it is not possible to predict the effect any discontinuance, modification, or other reforms to LIBOR, or the establishment~~ - **established , or the use** of alternative reference rates **. These consequences are not entirely predictable and could have an adverse impact on our financing costs and our results of operations. As** such ~~as~~ **, the future of** SOFR **at** ~~, or any other reference rate, will have on the Company or its borrowing costs. Our credit agreement allows for a change to an alternate benchmark rate, including SOFR, as defined in the Credit Agreement, but no change has been made yet. In December 2022, the Financial Accounting Standards Board issued ASU 2022- 06, which extended the sunset date of the reference rate reform in ASU 848 from December 31, 2022, to December 31, 2024. We have not adopted the guidance and are~~

~~currently evaluating the impact, if any, that the adoption of~~ this **time remains uncertain** ~~guidance will have on our consolidated financial statements~~. Risks Related to our Common ~~StockOur~~ --- **Stock Our** principal stockholders, directors, and executive officers own a significant percentage of our stock and will be able to exercise meaningful influence over our business. Our current principal stockholders, directors, and executive officers beneficially own approximately ~~28~~ **13** % of our outstanding capital stock entitled to vote as of December 31, ~~2022~~ **2023**. As a result, these stockholders, if acting together, would be able to influence or control matters requiring approval by our stockholders, including the election of directors and the approval of mergers, acquisitions, or other extraordinary transactions. They may also have interests that differ from stockholders generally and may vote in a way with which other stockholders disagree and which may be adverse to their interests. This concentration of ownership may have the effect of delaying, preventing, or deterring a change of control of ANI, could deprive stockholders of an opportunity to receive a premium for their common stock as part of a sale of ANI, and might ultimately affect the market price of our common stock. Raising additional funds by issuing additional equity securities may cause dilution to our current stockholders. Raising additional funds by entering into additional credit or other borrowing facilities or issuing debt may subject us to covenants and other requirements that may restrict our operations. We may seek to raise additional funds through the issuance of equity or equity- linked securities. If we were to raise funds through the issuance of equity or equity- linked securities, the percentage ownership of our stockholders could be diluted, potentially significantly, and these newly issued securities may have rights, preferences, or privileges senior to those of our existing stockholders. In addition, the issuance of any equity securities could be at a discount to the then- prevailing market price of our common stock. ~~37If~~ **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 ~~FactorsWe~~ -- **Factors We** use a variety of estimates, judgments, and assumptions in preparing our consolidated financial statements. Estimates, judgments, and assumptions are inherently subject to change, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses, and income. Any such changes could have a material adverse effect on our business, financial position, and operating results. The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America (" U. S. GAAP ") requires us to make estimates, judgments, and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amount of revenues and expenses during the period. There are inherent uncertainties involved in estimates, judgments and assumptions, and any changes in estimates, judgments and assumptions used could have a material adverse effect on our business, financial position, and operating results. In the consolidated financial statements included in the periodic reports filed with the SEC, estimates, judgments, and assumptions are used for, but not limited to, revenue recognition, allowance for credit losses, accruals for chargebacks, rebates, returns and other allowances, allowance for inventory obsolescence, stock- based compensation, valuation of financial instruments and intangible assets, allowances for contingencies and litigation, deferred tax assets and liabilities, deferred tax valuation allowance, contingent consideration, and the depreciable lives of fixed and intangible assets. Actual results could differ from those estimates. Estimates, judgments, and assumptions are inherently subject to change in the future, and any such changes could result in corresponding changes to the amounts of assets, liabilities, revenues, expenses, and income. Any such changes could have a material adverse effect on our business, financial position, and operating results. ~~38~~ **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.