

## Risk Factors Comparison 2024-03-14 to 2023-03-03 Form: 10-K

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An investment in our common stock involves a high degree of risk. In deciding whether to invest in our common stock, you should consider carefully the following risk factors, as well as the other information included in this Annual Report on Form 10-K. The materialization of any of these risks could have a material adverse effect on our business, results of operations and financial condition.

**Operational and Competitive Risks** If we are unable to successfully develop or commercialize new products, our operating results will suffer. Developing and commercializing a new product is time consuming, costly and subject to numerous factors that may delay or prevent such development and commercialization. Our future results of operations will depend to a significant extent upon our ability to successfully commercialize new products in a timely manner. We face several challenges when developing and commercializing new products, including:

- our ability to develop products in a timely and cost-efficient manner and in compliance with regulatory requirements, including delays associated with the FDA listing and approval process and our ability to obtain required regulatory approvals in a timely manner, or at all, and maintain such approvals if obtained;
- the success of our clinical testing process to ensure that new products are safe and effective or bioequivalent to the reference listed drug;
- the risk that legal action may be brought against our generic drug products by our branded drug product competitors, including patent infringement claims among others;
- the availability, on commercially reasonable terms, of raw materials, including APIs and other key ingredients necessary to the development of our drug products; and
- Our ability to scale-up manufacturing methods to successfully manufacture commercial quantities of drug product in compliance with regulatory requirements. As a result of these and other difficulties, our products in development may or may not receive necessary regulatory approvals on a timely basis or at all, which may result in unsuccessful development or commercialization of new products.

**For example, on June 30, 2023, we received a CRL from the FDA regarding our NDA for IPX203 for the treatment of Parkinson's disease. We resubmitted our NDA for IPX203 on February 7, 2024 (refer to Note 13. Goodwill and Other Intangible Assets for additional information on the CRL for IPX203). However, we can provide no assurance that the FDA will approve our NDA for IPX203 timely or at all.** Separately, 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 terms such as license scope or termination rights. If any of our products, when acquired or developed and approved, cannot be successfully or timely commercialized, our operating results could be adversely affected. We cannot guarantee that any investment we make in developing, marketing or licensing products will be recouped, even if we are successful in commercializing those products. We face intense competition in the pharmaceutical industry from both brand and generic drug product companies, which could significantly limit our growth and materially adversely affect our financial results. The pharmaceutical industry is highly competitive. The principal competitive factors in the pharmaceutical market include:

- introduction of other generic drug manufacturers' products in direct competition with our generic drug products;
- introduction of authorized generic drug products in direct competition with our products, particularly during exclusivity periods;
- the ability of generic drug product competitors to quickly enter the market after the expiration of patents or exclusivity periods, diminishing the amount and duration of significant profits;
- consolidation among distribution outlets through mergers and acquisitions and the formation of buying groups;
- the willingness of generic drug customers, including wholesale and retail customers, to switch among products of different pharmaceutical manufacturers;
- pricing pressures by competitors and customers, even if similar price savings are not passed on to consumers;
- a company's reputation as a manufacturer and distributor of quality products;
- a company's level of service (including maintaining sufficient inventory levels for timely deliveries);
- **a company's ability to use and integrate artificial intelligence ("AI");**
- product appearance and labeling; and
- a company's breadth of product offerings. Many of our competitors have longer operating histories and greater financial, R & D, marketing and other resources than we do. Consequently, some of our competitors may be able to develop products and / or processes competitive with, or superior to, our products and / or processes. Furthermore, we may not be able to (i) differentiate our products from those of our competitors, (ii) successfully develop or introduce new products, on a timely basis or at all, that are less costly than those of our competitors, ~~or~~ (iii) **integrate new systems or technology, such as AI, as quickly or successfully as our competitors, or (iv)** offer customers payment and other commercial terms as favorable as those offered by our competitors. The markets in which we compete and intend to compete are undergoing, and are expected to continue to undergo, rapid and significant change. We expect competition to intensify as technology advances and consolidation continues. New developments by other manufacturers and distributors could render our products uncompetitive or obsolete.

~~Our~~ **We believe our** principal competitors in the U. S. generic / biosimilar pharmaceutical products market, where we primarily compete, are Teva Pharmaceutical Industries Ltd., Viatris Inc., **Sandoz Group, Pfizer Inc., Fresenius Kabi KGaA, Hikma Pharmaceuticals PLC, Endo International plc, Sandoz International GmbH, Dr. Reddy's Laboratories Ltd., Pfizer Amphastar Pharmaceuticals, Inc., Fresenius Kabi KGaA, Sun Pharmaceutical Industries Ltd., Lupin Pharmaceuticals, Inc., Hikma Zydus Pharmaceuticals USA PLC, Dr. Reddy's Laboratories Ltd., Coherus Biosciences, Inc., Amphastar Pharmaceuticals, Inc., and Aurobindo Pharma Limited.** Our principal competitors in the specialty pharmaceutical products market include Supernus Pharmaceuticals, Inc., Jazz Pharmaceuticals PLC, **Coherus Biosciences, Inc.** and Alkermes PLC. Our competitors in the AvKARE segment are other wholesalers, including Cardinal Health, Inc., ~~AmericourceBergen Corporation~~ **Cencora, Inc., McKesson Drug Co.**, and Golden State Medical Supply. The products produced by these companies, among others, collectively compete with the majority of our products. We also face price competition generally as other generic manufacturers enter the market. Any such price competition may be especially pronounced where our competitors source their

products from jurisdictions where production costs may be lower (sometimes significantly) than our production costs ; ~~especially lower-cost foreign jurisdictions~~. Any of these factors could result in reductions in our sales prices and gross margin. This price competition has led to an increase in demands for downward price adjustments by generic pharmaceutical distributors. Our principal strategy in addressing our competition is to offer customers a consistent supply of our generic drug products, as well as to pursue product opportunities with the potential for limited competition, such as high- barrier- to- entry FTF or FTM products. We cannot provide assurance, however, that this strategy will enable us to compete successfully in the generic drug product industry or that we will be able to develop and implement any new or additional viable strategies. Competition in the generic drug industry has also increased due to the proliferation of authorized generic pharmaceutical products. Authorized generic drug products are generic drug products that are introduced by brand companies, either directly or through third parties, under the brand' s NDA approval. Authorized generics do not face any regulatory barriers to introduction and are not prohibited from sale during the 180- day marketing exclusivity period granted to the FTF ANDA applicant. The sale of authorized generics adversely impacts the market share of a generic drug product that has been granted 180 days of marketing exclusivity. This is a significant source of competition for us, because an authorized generic drug product can materially decrease the profits that we could receive as an otherwise exclusive marketer of a generic drug product. Such actions have the effect of reducing the potential market share and profitability of our generic drug products and may inhibit us from developing and introducing generic pharmaceutical drug products corresponding to certain branded drugs. If we fail to obtain exclusive marketing rights for our products or fail to introduce our products **to the market** on a timely basis, our revenues, gross margin and operating results may decline significantly. The Hatch- Waxman amendments to the FDCA provide for a period of 180 days of generic marketing exclusivity for any applicant that is first to file an ANDA containing a certification of invalidity, non-infringement or unenforceability related to a patent listed with respect to the corresponding branded drug (commonly referred to as a " Paragraph IV certification "). " "First filers " " are often able to price the applicable generic drug to yield relatively high gross margins during this 180- day marketing exclusivity period. With respect to our generic products, ANDAs containing Paragraph IV certifications generally become the subject of patent litigation that can be both lengthy and costly. There is no certainty that we will prevail in any such litigation, that we will be the first to file and thus granted the 180- day marketing exclusivity period, or, if we are granted the 180- day marketing exclusivity period, that we will not forfeit such period. Even where we are awarded marketing exclusivity, we may be required to share our exclusivity period with other first filers. In addition, branded drug product companies often authorize a generic version of the corresponding branded drug product to be sold during any period of marketing exclusivity that is awarded, which reduces gross margins during the marketing exclusivity period. Branded drug product companies may also reduce the price of their branded drug product to compete directly with generic drug products entering the market, which would similarly have the effect of reducing gross margins. Furthermore, timely commencement of the litigation by the patent owner imposes an automatic stay of ANDA approval by the FDA for 30 months, unless the case is decided in the ANDA applicant' s favor during that period. Finally, if the court decision is adverse to the ANDA applicant, the ANDA approval will be delayed until the challenged patent expires, and the applicant forfeits the 180- day marketing exclusivity. Our future profitability depends, to a significant extent, upon our ability to introduce, on a timely basis, new generic drug products that are either the first- to- market (or among the first- to- market) or that otherwise can gain significant market share. The timeliness of our product introductions is dependent upon, among other things, the timing of regulatory approval of our products, which to a large extent is outside of our control, as well as the timing of the introduction of competing products. As additional distributors introduce comparable generic pharmaceutical products, price competition intensifies, market access narrows, and product sales prices and gross margins decline, often significantly and rapidly, regardless of whether consumers ultimately pay less for the drug. Accordingly, our revenues and future profitability are dependent, in large part, upon our ability or the ability of our development partners to file ANDAs with the FDA in a timely and effective manner or, alternatively, to enter into contractual relationships with other parties that have obtained marketing exclusivity. We cannot provide any assurance that we will be able to develop and introduce successful products in the future within the time constraints necessary to be successful. If we or our development partners are unable to continue to timely and effectively file ANDAs with the FDA or to partner with other parties that have obtained marketing exclusivity, our revenues, gross margin and operating results may decline significantly, and our prospects and business may be materially adversely affected. With respect to our branded products, generic equivalents for branded pharmaceutical products are typically sold at lower prices than the branded products. The regulatory approval process in the U. S. and European Union exempts generic products from costly and time- consuming clinical trials to demonstrate their safety and efficacy and relies instead on the safety and efficacy of prior products. After the introduction of a competing generic product, a significant percentage of the prescriptions previously written for the branded product are often written for the generic version. In addition, legislation enacted in most U. S. states allows, or in some instances mandates, a pharmacist to dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Pursuant to the provisions of the Hatch- Waxman Act, manufacturers of branded products often bring lawsuits to enforce their patent rights against generic products released prior to the expiration of branded products' patents, but it is possible for generic manufacturers to offer generic products while such litigation is pending. As a result, branded products typically experience a significant loss in revenues following the introduction of a competing generic product, even if subject to an existing patent. Our branded pharmaceutical products are or may become subject to competition from generic equivalents because there is no proprietary protection for some of the branded pharmaceutical products we sell, because our patent protection expired or because our patent protection is not sufficiently broad or enforceable. If we are unable to execute acquisitions or other strategic transactions, or **successfully integrate such acquisitions or** manage our growth therefrom, it could have a material adverse effect on our business. We may seek to expand our business through complementary or strategic acquisitions of other businesses, products or assets, or through joint ventures, strategic agreements or other arrangements. Any such acquisitions, joint ventures or other

business combinations may involve significant integration challenges, operational complexities and time consumption, adversely affect liquidity and require substantial resources and effort. It may also disrupt our ongoing businesses, which may adversely affect our relationships with customers, employees, regulators and others with whom we conduct business ~~or other dealings~~. Further, if we are unable to realize synergies or other benefits expected to result from any acquisitions, joint ventures or other business combinations, or to generate additional revenue to offset any unanticipated inability to realize these expected synergies or benefits, our growth and ability to compete may be impaired, which would require us to focus additional resources on the integration of operations rather than other profitable areas of our business, and may otherwise cause a material adverse effect on our business, results of operations and financial condition. Acquisitions may also have hidden costs, including unforeseen pre-acquisition liabilities or the impairment of customer relationships or certain acquired assets such as goodwill. We may also incur costs and inefficiencies to the extent an acquisition expands the industries, markets or geographies in which we operate due to our limited exposure to and experience in a given industry, market or region. Finally, acquisitions can also involve litigation and / or post- transaction disputes, including with the counterparty regarding purchase price or other working capital adjustment or liabilities for which we believe we were indemnified under the relevant transaction agreements, among other matters. As our competitors introduce their own generic equivalents of our generic drug products, our revenues and gross margin from such products generally decline, often rapidly. Revenues and gross margin derived from generic pharmaceutical products often follow a pattern based on regulatory and competitive factors that we believe are unique to the generic pharmaceutical industry. As the patent (s) for a brand name product or the statutory marketing exclusivity period (if any) expires, the first generic manufacturer to receive regulatory approval for a generic equivalent of the product is often able to capture a substantial share of the market. However, as other generic manufacturers receive regulatory approvals for their own generic versions, that market share, and the price of that product, will typically decline depending on several factors, including the number of competitors, the price of the branded product and the pricing strategy of the new competitors. **We often** ~~During the year ended December 31, 2022, we experienced~~ **experience** significant competition ~~with for~~ many of our generic products, ~~and which from time to time, as has a result resulted, in a significant decline in~~ our revenue and gross margin ~~from such products declined significantly~~. We cannot provide assurance that we will be able to continue to develop such products or that the number of our competitors for any given product will not increase to such an extent that we may stop marketing a generic drug product for which we previously obtained approval, which may have a material adverse impact on our revenues and gross margin. The illegal distribution and sale by third parties of counterfeit versions of our products or of stolen products could have a negative impact on our reputation and a material adverse effect on our business, results of operations and financial condition. Third parties could illegally distribute and sell counterfeit versions of our products, which do not meet the rigorous manufacturing and testing standards that our products undergo. Counterfeit products are frequently unsafe or ineffective and can be life- threatening. Counterfeit medicines may contain harmful substances, the wrong dose of the API or no API at all. However, to distributors and users, counterfeit products may be visually indistinguishable from the authentic version. Reports of adverse reactions to counterfeit drugs or increased levels of counterfeiting could materially affect patient confidence in the authentic product. It is possible that adverse events caused by unsafe counterfeit products will mistakenly be attributed to the authentic product. In addition, thefts of inventory at warehouses, plants or while in- transit, which are not properly stored and which are sold through unauthorized channels, could adversely impact patient safety, our reputation and our business. Public loss of confidence in the integrity of pharmaceutical products as a result of counterfeiting or theft could have a material adverse effect on our business, results of operations and financial condition. Our business is highly dependent on market perceptions of us and the safety and quality of our products. Our business, products or product pricing could be subject to negative publicity, which could have a material adverse effect on our business, results of operations and financial condition. Market perceptions of our business are very important to us, especially market perceptions of the safety and quality of our products. If any of our products or similar products that other companies distribute are subject to market withdrawal or recall or are proven to be, or are claimed to be, harmful to consumers, then this could have a material adverse effect on our business, results of operations and financial condition. Also, because our business is dependent on market perceptions, negative publicity associated with product quality, illness or other adverse effects resulting from, or perceived to be resulting from, our products could have a material adverse impact on our business, results of operations and financial condition. The generic pharmaceutical industry has also in recent years been the subject of significant publicity regarding the pricing of pharmaceutical products more generally, including publicity and pressure resulting from prices charged by competitors and peer companies for new products as well as price increases by competitors and peer companies on older products that the public has deemed excessive. **This publicity has in the past become more pronounced during U. S. presidential election years, and there may be a heightened risk as the U. S. presidential election progresses in 2024.** Even if we may have reduced the prices we charge our customers for certain products, often consumers do not see similar reductions in the prices they paid. Any downward pricing pressure on the price of certain of our products arising from social or political pressure to lower the cost of pharmaceutical products could have a material adverse impact on our business, results of operations and financial condition. Accompanying the press and media coverage of pharmaceutical pricing practices and public complaints about the same, has been increasing U. S. federal and state legislative and enforcement interest with respect to drug pricing. For instance, the DOJ issued subpoenas to pharmaceutical companies, including ~~us to the Company~~, seeking information about the sales, marketing and pricing of certain generic drugs. See Note 21. Commitments and Contingencies for additional information on the DOJ investigation. In addition to the effects of any investigations or claims brought against us, our business, results of operations and financial condition could also be adversely affected if any such inquiries, of us or of other pharmaceutical companies or the industry more generally, were to result in legislative or regulatory proposals that limit our ability to increase the prices of our products. A substantial portion of our total revenues is expected to be derived from sales of a limited number of products. We expect that we will continue to derive a substantial portion of our revenue from sales of a limited number of products. For the year ended December 31, ~~2022~~ **2023**, our significant product families **(defined as our top five products by**

**annual revenue including both our Generics and Specialty segments**) accounted for 24 % of our consolidated net revenue. The sale of our products may be significantly influenced by market conditions, as well as regulatory actions. We may experience decreases in the sale of our products in the future as a result of actions taken by our competitors, such as price reductions, or as a result of regulatory actions related to our products or to competing products, which could have a material impact on our results of operations. Actions which could be taken by our competitors, which may materially and adversely affect our business, results of operations and financial condition, may include, without limitation, pricing changes and entering or exiting the market for specific products. Our approved products may not achieve expected levels of market acceptance. Even if we are able to obtain regulatory approvals for our new products, the success of those products is dependent upon market acceptance. Levels of market acceptance for our new products could be affected by several factors, including: • the availability of alternative products from our competitors; • the prices of our products relative to those of our competitors; • the timing of our market entry; • the ability to market our products effectively at the retail level; • the perception of patients and the healthcare community, including third-party payers, regarding the safety, efficacy and benefits of our drug products compared to those of competing products; and • the acceptance of our products by government and private formularies. Some of these factors will not be in our control, and our products may not achieve expected levels of market acceptance. Additionally, continuing and increasingly sophisticated studies of the proper utilization, safety and efficacy of pharmaceutical products are being conducted by the industry, government agencies and others which can call into question the utilization, safety and efficacy of products currently or previously marketed by us. In some cases, studies have resulted, and may in the future result, in the discontinuance of product marketing or other risk management programs such as the need for a patient registry. We may discontinue the manufacture and distribution of certain existing products, which may adversely impact our business, results of operations and financial condition. We continually evaluate the performance of our products and may determine that it is in our best interest to discontinue the manufacture and distribution of certain of our products . **For example, in 2023, there was a reduction in the promotional focus on LYVISPAH™, which resulted in an impairment charge of \$ 34. 1 million recorded to cost of goods sold** . We cannot guarantee that we have correctly forecasted, or will correctly forecast in the future, the appropriate products to discontinue or that our decision to discontinue various products is prudent if market conditions change. In addition, we cannot assure you that the discontinuance of products will reduce our operating expenses or will not cause us to incur material charges associated with such a decision. Furthermore, the discontinuance of existing products entails various risks, including, in the event that we decide to sell the discontinued product, the risk that we will not be able to find a purchaser for such products or that the purchase price obtained will not be equal to at least the book value of the net assets for such products. Other risks include managing the expectations of, and maintaining good relations with, our customers who previously purchased products from among our discontinued products, which could prevent us from selling other products to them in the future. Moreover, we may incur other significant liabilities and costs associated with our discontinuance of products, which could have a material adverse effect on our business, results of operations and financial condition. Manufacturing or quality control problems may damage our reputation for quality production, demand costly remedial activities and negatively impact our business, results of operations and financial condition. As a pharmaceutical company, we are subject to substantial regulation by various governmental authorities. For instance, we must comply with requirements of the FDA, DEA and other healthcare regulators with respect to the manufacture, labeling, sale, distribution, marketing, advertising, promotion and development of pharmaceutical products. We must register our facilities, whether located in the U. S. or elsewhere, with the FDA as well as regulators outside the U. S., and our products must be made in a manner consistent with cGMP, or similar standards in each territory in which we manufacture. The failure of one of our facilities, or a facility of one of our third- party suppliers, to comply with applicable laws and regulations may lead to breach of representations made to our customers or to regulatory or government action against us related to products made in that facility. In addition, the FDA, DEA and other agencies periodically inspect our manufacturing facilities. Following an inspection, agencies have in the past issued, and may in the future issue , a notice listing conditions that are believed to violate cGMP or other regulations, or a warning letter for violations of “ regulatory significance ” that may result in enforcement action if not promptly and adequately corrected. We remain committed to continuing to improve our quality control and manufacturing practices; however, we cannot be assured that the FDA will continue to be satisfied with our corrective actions and with our quality control and manufacturing systems and standards. Failure to comply strictly with these regulations and requirements, or our failure to remedy any deficiencies, may damage our reputation and lead to financial penalties, compliance expenditures, the recall or seizure of products, total or partial suspension of production and / or distribution, withdrawal or suspension of the applicable regulator’ s review of our submissions, enforcement actions, injunctions and criminal prosecution. Further, other federal agencies, our customers and partners in our alliance, development, collaboration and other partnership agreements with respect to our products and services may take any such FDA observations or warning letters into account when considering the award of contracts or the continuation or extension of such partnership agreements. Because regulatory approval to manufacture a drug is site- specific, the delay and cost of remedial actions, or obtaining approval to manufacture at a different facility, could negatively impact our business. Any failure by us to comply with applicable laws and regulations and / or any actions by the FDA and other agencies as described above could have a material adverse effect on our business, financial position and results of operations. The majority of our products are produced at a few locations, and a business interruption at one or more of these locations or within our supply chain could have a material adverse effect on our business, financial position and results of operations. We produce the majority of the products that we manufacture at our manufacturing facilities in New York, New Jersey and India, as well as at certain third- party suppliers, one of which is located in Taiwan. Disruptions at these facilities or within our supply chain can occur for many reasons, including events unrelated to us or beyond our control, such as fires and other industrial accidents, floods and other severe weather events, natural disasters, environmental incidents or other catastrophes, utility and transportation infrastructure disruptions, shortages of raw materials, pandemic diseases or viral contagions such as COVID-19, and acts of war or terrorism . **For example, in November 2023, the Houthi movement, which**

**controls parts of Yemen, began attacking merchant ships in the Red Sea disrupting global supply chains. This disruption has resulted in a significant increase in our shipping costs, and a prolonged disruption to the global supply chain could have a material adverse effect on our business, financial position and results of operations.** Natural disasters and adverse weather conditions can be caused or exacerbated by climate change, and the spate of extreme weather events experienced during 2021 **over the past several years** presents an alarming trend. During 2021 **As previously disclosed**, for example, Tropical Storm Ida brought extreme **weather events have compromised our rainfall and flash flooding to New Jersey that caused damage to two of the Company's facilities, compromising the Company's inventory and equipment and resulting in significant costs to repair both facilities the past and may do so in the future.** Furthermore, work stoppages, whether union-organized or not, can also disrupt operations. Business interruption could also be caused by compliance failures. A significant disruption at any of these facilities or otherwise within our supply chain, even on a short-term basis, could impair our ability to produce and ship products to the market on a timely basis or at all, which could have a material adverse effect on our business, financial position and results of operations. Our profitability depends on our major customers. If these relationships do not continue as expected, our business, condition (financial and otherwise), prospects and results of operations could materially suffer. Our four largest customers, **AmerisourceBergen Corporation**, **Cencora, Inc.**, McKesson Drug Co., Cardinal Health, Inc. and CVS Health Corporation, accounted for approximately **70%, 71%, and 75% and 74%** of total net sales of products for the years ended December 31, **2023, 2022, and 2021 and 2020**, respectively. The loss of any one or more of these or any other major customer or the substantial reduction in orders from any one or more of our major customers could have a material impact on our future operating results and financial condition. In total, we currently have over 1, **200-300** customers (including over 1, **000-100** customers specific to our AvKARE segment), some of which are part of large purchasing groups. We may experience declines in the sales volume and prices of our products as a result of the continuing trend of consolidation of certain customer groups, which could have a material adverse effect on our business, financial position and results of operations. Our ability to successfully commercialize any generic or branded pharmaceutical product depends in large part upon the acceptance of the product by third parties, including pharmacies, government formularies, other retailers, physicians and patients. Therefore, our success will depend in large part on market acceptance of our products. We make a significant amount of our sales to a relatively small number of drug wholesalers and retail drug chains. These customers represent an essential part of the distribution chain of our pharmaceutical products. Drug wholesalers and retail drug chains have undergone, and are continuing to undergo, significant consolidation. This consolidation may result in these groups gaining additional purchasing leverage and, consequently, increasing the product pricing pressures facing our business. Additionally, the emergence of large buying groups representing independent retail pharmacies and other drug distributors, and the prevalence and influence of managed care organizations and similar institutions, potentially enable such groups to demand larger price discounts on our products. For example, there has been a recent trend of large wholesalers and retailer customers forming partnerships, such as the alliance between Walgreens and **AmerisourceBergen Corporation**, **Cencora, Inc.**, the alliance between Rite Aid and McKesson Drug Company, and the alliance between CVS Caremark and Cardinal Health. The result of these developments may have a material adverse effect on our business, financial position and results of operations. We depend to a large extent on third-party suppliers and distributors for the raw materials for our products, particularly the chemical compounds comprising the APIs that we use to manufacture our products, as well as for certain finished goods. A prolonged interruption in the supply of such products could have a material adverse effect on our business, financial position and results of operations. We purchase the bulk of the raw materials essential to our manufacturing business from third parties. If we experience supply interruptions or delays, or if a supplier discontinues the sale of certain products, we may have to obtain substitute materials or products, which in turn would require us to obtain amended or additional regulatory approvals, subjecting us to additional expenditures of significant time and resources. In addition, changes in our raw material suppliers could result in significant delays in production, higher raw material costs and loss of sales and customers, because regulatory authorities must generally approve raw material sources for pharmaceutical products, which may be time consuming. For example, we may need as long as 18 months to find and qualify a new sole-source supplier. If we receive less than one year's termination notice from a sole-source supplier that intends to cease supplying raw materials, it could result in disruption of our ability to produce the drug involved. Any significant supply interruption could have a material adverse effect on our business, condition (financial and otherwise), prospects and results of operations. To date, although we have experienced occasional interruptions in supplies, we have experienced no significant difficulties in obtaining raw materials. However, because the federal drug application process requires specification of raw material suppliers, if raw materials from a specified supplier were to become unavailable, FDA approval of a new supplier would be required. The amount of time required for the FDA to qualify a new supplier and confirm that our manufacturing processes meet the necessary standards could cause delays in the manufacturing and marketing of one or more of our products and could, depending on the particular product, have a material adverse effect on our results of operations and financial condition. The time necessary to develop generic drugs may adversely affect whether, and the extent to which, we receive a return on our capital. We generally begin our development activities for a new generic drug product several years in advance of the patent expiration date of the brand-name drug equivalent. The development process, including drug formulation, testing, and FDA review and approval, often takes three or more years. This process requires that we expend considerable capital to pursue activities that do not yield an immediate or near-term return. Also, because of the significant time necessary to develop a product, the actual market for a product at the time it is available for sale may be significantly less than the originally projected market for the product. If this were to occur, our potential return on our investment in developing the product, if approved for marketing by the FDA, would be adversely affected and we may never receive a return on our investment in the product. It is also possible for the manufacturer of the brand-name product for which we are developing a generic drug to obtain approvals from the FDA to switch the brand-name drug from the prescription market to the **over-the-counter ("OTC")** market. If this were to occur, we would be prohibited from marketing our product other than as an OTC drug, in which case revenues could be substantially less

than we anticipated. The use of legal, regulatory and legislative strategies by brand competitors, including authorized generics and citizen's petitions, as well as the potential impact of proposed legislation, may have an adverse effect on our business. Brand drug companies often pursue strategies that may serve to prevent or delay competition from our generic alternatives to their branded products. These strategies **may** include, but are not limited to: • ~~marketing an authorized generic version of a branded product~~, **using certain tactics** directly or through agreement with **our regulators** a generic competitor, at the same time that **could** we introduce a generic equivalent of that product; • filing "citizen's petitions" with the FDA to thwart generic competition by causing delays— **delay** of our product approvals; • using risk evaluation and mitigation strategies ("REMS"), related distribution restrictions— **restricting** or **our** other means of limiting access to their branded products, to prevent us from obtaining product samples needed **for our** to conduct bioequivalence testing required for— **or using the legal system** ANDA approval, thereby delaying or preventing us from obtaining FDA approval of a generic version of such branded products; • seeking to secure patent protection of certain "Elements to Assure Safe Use" of a REMS program, which are required medical interventions or other **IP-related** actions healthcare professionals need to execute prior to prescribing or dispensing the drug to the patient, in an attempt to thwart our— **or** ability to avoid infringement of the patents in question or secure approval; • seeking to establish regulatory **mechanisms** and legal obstacles that would make it more difficult for us to **severely** demonstrate a generic product's bioequivalence or "sameness" to the related branded product; • initiating legislative and administrative efforts in various states to limit the substitution of generic versions of branded pharmaceutical products for the corresponding branded products; • filing suits for patent infringement that automatically delay FDA approval of our— **or disrupt** generic products; • introducing "next-generation" products prior to the expiration of market exclusivity for their branded product, which often materially reduces the demand for the generic product for which we may be seeking FDA approval; • obtaining extensions of market exclusivity by conducting clinical trials of branded drugs in pediatric populations or **our process** by other methods as discussed below; • persuading the FDA to withdraw the approval of branded drugs for which the associated patents are about to expire, thus allowing the brand company to develop and launch new patented products serving as substitutes for the withdrawn products; • seeking to obtain new patents on drugs for which patent protection is about to expire; • filing patent applications that are more complex and costly to challenge; • seeking temporary restraining orders and injunctions against selling a generic equivalent of their branded product based on alleged misappropriation of trade secrets or breach of confidentiality obligations; • seeking temporary restraining orders and injunctions against us after we have received final FDA approval for a product for which we are attempting to launch at risk prior to resolution of related patent litigation; • reducing the marketing of the branded product to healthcare providers, thereby reducing the branded drug's commercial exposure and market size, which in turn adversely affects the market potential of the equivalent generic product; and • ~~converting branded prescription drugs that are facing potential generic competition to over-the-counter products, thereby significantly impeding the growth of the generic prescription market for such drugs~~. These and other strategies by brand competitors, as well as the potential impact of proposed legislation, may increase our costs associated with the introduction or marketing of our generic products, delay or prevent such introduction and / or significantly reduce the profit potential of our products. The risks and uncertainties inherent in conducting clinical trials could delay or prevent the development and commercialization of our own branded products, which could have a material adverse effect on our business, results of operations and financial condition. With respect to our branded products which do not qualify for the FDA's abbreviated application procedures, we must demonstrate through clinical trials that these products are safe and effective for use. We have only limited experience in conducting and supervising clinical trials. The process of completing clinical trials and preparing **a an** NDA may take several years and requires substantial resources. Our studies and filings may not result in FDA approval to market our new drug products and, if the FDA grants approval, we cannot predict the timing of any approval. There are substantial filing fees for NDAs that are not refundable if FDA approval is not obtained. There are a number of risks and uncertainties associated with clinical trials. The results of clinical trials may not be indicative of results that would be obtained from large scale testing. Clinical trials are often conducted with patients having advanced stages of disease and, as a result, during the course of treatment these patients can die or suffer adverse medical effects for reasons that may not be related to the pharmaceutical agents being tested, but which nevertheless affect the clinical trial results. In addition, side effects experienced by the patients may cause delay of approval or limit the profile of an approved product. Moreover, our clinical trials may not demonstrate sufficient safety and efficacy to obtain approval from the FDA or foreign regulatory authorities. The FDA or foreign regulatory authorities may not agree with our assessment of the clinical data or they may interpret it differently. Such regulatory authorities may require additional or expanded clinical trials. Even if the FDA or foreign regulatory authorities approve certain products developed by us, we cannot provide assurance that such regulatory authorities will not subject marketing of such products to certain limits on indicated use. Developing and commercializing branded pharmaceutical products is generally more costly than developing and commercializing generic products. **To in order to** grow and achieve success in our branded product business, we must continually identify, develop, acquire and license new products that we can ultimately market. There are many difficulties and uncertainties inherent in pharmaceutical R & D, and there is a high rate of failure inherent in new drug discovery and development. Failure can occur at any point in the process, including late in the process after substantial investment. New product candidates that appear promising in development may fail to reach the market or may have only limited commercial success because of efficacy or safety concerns, inability to obtain necessary regulatory approvals and payer reimbursement, limited scope of approved uses, difficulty or excessive costs to manufacture, or infringement of the patents or **IP intellectual property** rights of others. Products that do reach the market may ultimately be subject to recalls or other suspensions in sales. Delays and uncertainties in the FDA approval process and the approval processes in other countries can result in delays in product launches and lost market opportunity. Because there is a high rate of failure inherent in the R & D process of new products, there is a significant risk that funds invested in R & D will not generate financial returns. We cannot be certain when or whether any of our products currently under development will be approved or launched or whether, once launched, such

products will be commercially successful. We may be required to spend several years and incur substantial expense in completing certain clinical trials. The length of time, number of trial sites and patients required for clinical trials vary substantially, and we may have difficulty finding a sufficient number of sites and subjects to participate in our trials. Delays in planned clinical trials can result in increased development costs, delays in regulatory approvals and delays in product candidates reaching the market. We rely on independent third- party clinical investigators to recruit subjects and conduct clinical trials in accordance with applicable study protocols and laws and regulations. If regulatory authorities determine that we have not complied with regulations in the development of a product candidate, they may refuse to accept trial data from the site and / or not approve the product candidate, and we would not be able to market and sell that product. If we are not able to market and sell our products after significant expenditures to develop and test them, our business and results of operations could be materially and adversely affected. **The Failure can occur at any time during the clinical trial process; in addition, the** results from early clinical trials may not be predictive of results obtained in later and larger clinical trials, and product candidates in later clinical trials may fail to show the desired safety or efficacy despite having progressed successfully through earlier clinical testing. A number of companies in the pharmaceutical industry, including us, have suffered significant setbacks in clinical trials, even in advanced clinical trials after showing positive results in earlier clinical trials. The completion of clinical trials for our product candidates may be delayed or halted for **a variety of reasons in addition to** the reasons noted above **in addition to many other reasons, including:** • delays in patient enrollment, and variability in the number and types of patients available for clinical trials; • regulators or institutional review boards may not allow us to commence or continue a clinical trial; • our inability, or the inability of our partners, to manufacture or obtain from third parties materials sufficient to complete our clinical trials; • delays or failure in reaching agreement on acceptable clinical trial contracts or clinical trial protocols with prospective clinical trial sites; • risks associated with trial design, which may result in a failure of the trial to show statistically significant results even if the product candidate is effective; • difficulty in maintaining contact with patients after treatment commences, resulting in incomplete data; • poor effectiveness of product candidates during clinical trials; • safety issues, including adverse events associated with product candidates; • the failure of patients to complete clinical trials due to adverse side effects, dissatisfaction with the product candidate, or other reasons; • governmental or regulatory delays or changes in regulatory requirements, policy and guidelines; and • varying interpretation of data by the FDA or foreign regulatory authorities. In addition, our product candidates could be subject to competition for clinical study sites and patients from other therapies under development which may delay the enrollment in or initiation of our clinical trials. The FDA or foreign regulatory authorities may require us to conduct unanticipated additional clinical trials, which could result in additional expense and delays in bringing our product candidates to market. Any failure or delay in completing clinical trials for our product candidates would prevent or delay the commercialization of our product candidates. We cannot assure you that our expenses related to clinical trials will lead to the development of brand- name drugs that will generate revenues in the near future. Delays or failure in the development and commercialization of our own branded products could have a material adverse effect on our business, results of operations and financial condition. We are increasingly dependent on information technology, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks. Significant disruptions to our **IT information technology** systems or breaches of information security could adversely affect our business. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such information. Additionally, our **IT information technology** systems are critical to our ability to store electronic and financial information and to manage a variety of business processes and activities, including manufacturing, financial, logistics, sales, marketing and administrative functions. We depend on our **IT information technology** infrastructure to communicate internally and externally with employees, customers, suppliers and others. We also use **IT information technology** networks and systems to comply with regulatory, legal and tax requirements. We have outsourced significant elements of our **IT information technology** infrastructure; as a result we manage independent vendor relationships with third- parties who are responsible for maintaining significant elements of our **IT information technology** systems and infrastructure and who may or could have access to our confidential information. The size and complexity of our **IT information technology** systems, and those of our third- party vendors, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors. These systems are also vulnerable to attacks by malicious third parties, such as phishing or ransomware attacks, and may be susceptible to intentional or accidental physical damage to the infrastructure maintained by us or by third parties, including as a result of extreme weather events, such as fires, floods, hurricanes, or tornadoes **or as the result of the use of AI or other new technologies**. For example, **from mid- in 2023, certain third - party file transfer services** December 2021 to late January 2022, our operations were **attacked and compromised** affected by the shutdown of the UKG, Inc.'s Kronos cloud- based employee work time keeping system, which **impacted** certain of our operations **vendors** and corporate functions use to record **ultimately certain of our information including personally identifiable information of enrolled employee-employees** hours worked and **dependents in certain cases** manage paid time off. Our human resources and operations management teams quickly implemented alternate procedures until the Kronos system was restored. We do not believe that we have incurred a material loss due to the outage. UKG, Inc. reported their forensic investigation found no evidence that Amneal employee data was compromised. Maintaining the secrecy of confidential, proprietary, and / or trade secret information is important to our competitive business position. We continually assess these threats and make investments to increase internal protection, detection, and response capabilities, as well as ensure our third- party providers have required capabilities and controls, to address these risks. Like other public companies, our computer systems and those of our third- party vendors and service providers are regularly subject to, and will continue to be the target of, computer viruses, malware or other malicious **codes- code** (including ransomware), unauthorized access, cyber- attacks or other computer- related penetrations, which have caused, and may continue to cause, disruptions to our operations. For example, we have been the victim of phishing attempts, some of which have been successful **in evading**

**detection and blocking**. While we have experienced threats to our data and systems, to date, we are not aware that we have experienced a material cyber- security breach. Over time, however, the sophistication of these threats continues to increase. **Our reliance on unsupported and vulnerable operating systems and other software in certain cases may increase both the likelihood and potential severity of cyber incidents.** The preventative actions we take to reduce the risk of cyber incidents and protect our information may be insufficient. Our efforts may not prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other cause, could enable others to produce competing products, use our proprietary technology or information, and / or adversely affect our business position. Further, any such interruption, security breach, loss or disclosure of confidential information could result in financial, legal, business, and reputational harm to us and could have a material adverse effect on our business, financial position, results of operations and / or cash flow. **Artificial intelligence- based platforms may present new risks and challenges to our business. AI technologies may exacerbate existing risks, including risks associated with data privacy, cybersecurity, IP, healthcare fraud and abuse, drug development and manufacturing, and risks to patients or human subjects in clinical trials. AI also introduces new risks, due to the autonomous nature of the technology, which, in some cases, may be deployed to perform tasks, inform decisions, automate decisions, and make predictions. AI may amplify biased and discriminatory decision making, perform unreliably and malfunction, generate insights which are difficult to interpret and explain, and cause direct harm to individuals or groups. Regulators are proposing, adopting, and implementing new AI laws and regulations. We may be required to change our business practices and policies as a result of such laws and regulations and may incur substantial compliance- related costs. Regulators are also using existing laws and regulations to take enforcement actions related to the deployment of AI in ways that result in non- compliance with current laws and regulations. If we fail to comply with AI laws and regulations, we may be subject to sanctions, fines, and reputational damage, orders to stop certain processing of personal data, orders to delete certain data or destroy AI algorithms derived from data collects, legal action on behalf of impacted individuals or other enforcement or other actions. If we fail to take steps to protect our confidential data, trade secrets, IP and personal data, we may be subject to legal, regulatory, financial, and reputational risks. AI technologies present significant opportunities and risks to our business. Harnessing AI' s transformative potential may enable us to speed up the discovery and development of new drugs, optimize our manufacturing processes, and drive efficiencies. Our failure to use AI technologies in a way that maintains trust, quality and control in our business activities and to capitalize on opportunities presented by AI may also place us at a competitive disadvantage. Failure to address AI risks will reduce our ability to deliver strategic objectives. Also, investments in AI may not realize the benefits that were anticipated**. Our future success depends on our ability to attract and retain talented employees and consultants. Our future success depends, to a substantial degree, upon the continued service of the members of our management team. The loss of the services of members of our management team, or their inability to perform services on our behalf, could have a material adverse effect on our business, condition (financial and otherwise), prospects and results of operations. Our success also depends, to a large extent, upon the contributions of our sales, marketing, scientific and quality assurance staff. We compete with brand and generic pharmaceutical manufacturers for qualified personnel, and our competitors may offer more favorable employment opportunities than we do. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we could experience constraints that would adversely affect our ability to sell and market our products effectively, to meet the demands of our strategic partners in a timely fashion, and to support our R & D programs. In particular, our sales and marketing efforts depend on the ability to attract and retain skilled and experienced sales, marketing and quality assurance representatives. Although we believe that we have been successful in attracting and retaining skilled personnel in all areas of our business, we cannot provide assurance that we can continue to attract, train and retain such personnel. Any failure in this regard could limit the rates at which we generate sales and develop or acquire new products. Catastrophic events, including severe weather events, **war** and **terrorist attacks** global pandemics such as the COVID-19 pandemic, may negatively affect our business and results of operations. We rely on our network infrastructure and enterprise applications, internal technology systems and websites to run our business as well as our or our third- party partners' physical facilities, such as our R & D or manufacturing premises. In addition, we rely on third- party hosted services. A disruption, infiltration or failure of these systems, facilities or third- party hosted services in the event of a hurricane, tsunami, tornado, earthquake, wildfire or flooding or other weather event, power loss, telecommunications failure, software or hardware malfunctions, pandemics (including the COVID-19 pandemic), cyber- attack, war, terrorist attack or other catastrophic event that our disaster recovery plans do not adequately address, could cause system interruptions, reputational harm, loss of **IP intellectual property**, delays in our product development, lengthy interruptions in our services, breaches of data security and loss of critical data. Any of these events could prevent us from conducting our day- to- day activities and could disrupt the operation of our supply chain. For example, **we source some of our APIs from the Middle East region, and the armed conflicts that have escalated in the area since October 2023 could threaten our ability to obtain these important inputs. Also, recent attacks by the Houthis movement, which controls parts of Yemen, on merchant ships in the Red Sea has resulted in a significant increase in shipping costs**. September 1, 2021, Tropical Storm Ida brought extreme rainfall and flash flooding to New Jersey that caused damage to two of our facilities **shipping costs**. **Separately**, certain of our products utilize a contract manufacturing company in Taiwan, and an escalation of tensions between China and Taiwan could impair or prevent altogether our ability to source these products. A catastrophic event that results in the destruction or disruption of any of our or our third- party partners' business centers, manufacturing facilities, data centers, R & D or manufacturing facilities, or our critical business or **IT information technology** systems could severely



affect our ability to conduct normal business operations and, as a result, our future operating results could be adversely affected. The adverse effects of any such catastrophic event would be exacerbated if experienced at the same time as another unexpected and adverse event, such as the COVID-19 pandemic. Additionally, the impacts of the changing weather on water resources may result in water scarcity, limiting our ability to access sufficient high-quality water in certain locations, which may increase operational costs. Our business interruption plans may be insufficient to mitigate these, and any other, catastrophic events. ~~The occurrence of regional epidemics or a global pandemic, such as the COVID-19 pandemic, have had and may continue to have an adverse effect on how we and our customers are operating our businesses and our operating results. Our operations have also been and may in the future be negatively affected by a range of external factors related to the pandemic that are not within our control, including the emergence and spread of more transmissible variants. The extent to which global pandemics, such as the COVID-19 pandemic, impact our financial condition or results of operations will depend on factors such as the duration and scope of the pandemic, as well as whether there is a material impact on the businesses or productivity of our customers, partners, employee, suppliers and other partners. To the extent that the pandemic harms our business and results of operations, many of the other risks described in this Part I, Item 1A of this report may be heightened.~~ Our business is subject to evolving corporate governance and public disclosure regulations and expectations, including with respect to environmental, social and governance matters, that could expose us to numerous risks. We are subject to changing rules and regulations promulgated by a number of governmental and self-regulatory organizations, including the SEC, **Nasdaq** ~~the New York Stock Exchange~~ and the Financial Accounting Standards Board. These rules and regulations continue to evolve in scope and complexity and many new requirements have been created in response to laws enacted by Congress, making compliance more difficult and uncertain. In addition, increasingly regulators, customers, investors, employees and other stakeholders are focusing on ESG matters and related disclosures. Concern over severe weather may also result in new or additional legal or regulatory requirements designed to mitigate the effects of severe weather on the environment **and businesses**. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with sourcing, manufacturing and distribution of our products, **as well as an increase in costs associated with monitoring, tracking and reporting ESG related information to regulatory bodies**, which may adversely affect our business, results of operations or financial condition. These changing rules, regulations and stakeholder expectations have resulted in, and are likely to continue to result in, increased general and administrative expenses and increased management time and attention spent complying with or meeting such regulations and expectations. For example, **the State of California recently passed the Climate Corporate Data Accountability Act and the Climate-Related Financial Risk Act that, if implemented, will impose broad climate-related disclosure obligations on certain companies doing business in California, including us. Other U. S. states' legislatures are considering enactment of similar rules and regulations. In addition, the European Union ("EU") enacted the Corporate Sustainability Reporting Directive ("CSRD") legislation in January 2023 which requires certain reporting and disclosure relating to ESG matters for companies whose business and assets exceed certain thresholds within EU countries. Due to our subsidiaries in Ireland, the CSRD requirements will apply to us for 2025 reporting, which will require significant preparatory work to comply with the reporting rules.** ~~developing~~ **Developing** and acting on initiatives within the scope of ESG, and collecting, measuring and reporting ESG related information and metrics can be costly, difficult and time consuming and is subject to evolving reporting standards, including the SEC's ~~recently~~ proposed climate-related reporting requirements, and similar proposals by other international regulatory bodies. We may also communicate certain initiatives and goals, regarding environmental matters, diversity, responsible sourcing and social investments and other ESG related matters, in our SEC filings or in other public disclosures. These initiatives and goals within the scope of ESG could be difficult and expensive to implement, the technologies needed to implement them may not be cost effective and may not advance at a sufficient pace, and we could be criticized for the accuracy, adequacy or completeness of the disclosure. Further, statements about our ESG ~~related~~ initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve, and assumptions that are subject to change in the future. In addition, we could be criticized for the scope or nature of such initiatives or goals, or for any revisions to these goals. If our ESG-related data, processes and reporting are incomplete or inaccurate, or if we fail to achieve progress with respect to our goals within the scope of ESG on a timely basis, or at all, our reputation, business, financial performance and growth could be adversely affected. **IP Risks Relating to Our Indebtedness** We have..... accordance with our strategy. **Intellectual Property** and Licensing Risks Federal regulation of arrangements between manufacturers of branded and generic products could adversely affect our business. We are involved in numerous patent litigations in which we challenge the validity or enforceability of innovator companies' listed patents and / or their applicability to our generic and / or biosimilar pharmaceutical products, as well as patent infringement litigation in which other generic / biosimilar companies challenge the validity or enforceability of our patents and / or their applicability to their generic / biosimilar pharmaceutical products, and therefore settling patent litigations has been and is likely to continue to be an important part of our business. As part of the Medicare Prescription Drug and Modernization Act of 2003, companies, including us, are required to file with the FTC and the DOJ agreements entered into between branded and generic and / or biosimilar pharmaceutical companies related to the manufacture, marketing and sale of generic / biosimilar versions of branded drugs for their review. In June 2013, the U. S. Supreme Court in its decision in *FTC v. Actavis* determined that "reverse payment" patent settlement agreements between brand and generic / biosimilar companies could violate the antitrust laws. The Supreme Court held that such settlement agreements are neither immune from antitrust attack nor presumptively illegal but rather should be analyzed under the "Rule of Reason" test to determine whether they violate the federal antitrust laws. This holding has resulted in heightened scrutiny of such settlement agreements by the FTC and state and local authorities, and has increased the risk of liability in pending antitrust litigation brought by private plaintiffs. The FTC has brought actions against parties to such settlement agreements, including us, and we have become subject to increased FTC investigations or enforcement actions arising from such settlement agreements.

Further, private plaintiffs, including direct and indirect purchasers of our products, have also become more active in bringing private litigation claims against us and other brand and generic / biosimilar pharmaceutical companies alleging that such settlement agreements violate the antitrust laws. Accordingly, we have in the past received and may receive formal or informal requests from the FTC for information about a particular settlement agreement, and there is a risk that the FTC, state and local authorities, or private plaintiffs, may commence an action against us alleging violations of the antitrust laws. We have been and are currently involved in private antitrust actions involving certain settlement agreements as described in Note 21. Commitments and Contingencies- Other Litigation Related to the Company' s Business. Antitrust investigations and claims are generally expensive and time consuming, and we can give no assurance as to the timing or outcome of such investigations or claims or of any future private litigation or government action alleging that one of our settlement agreements violates antitrust laws. The impact of federal regulation of arrangements between manufacturers of brand and generic / biosimilar products, further legislation and the potential for private- party lawsuits associated with such arrangements could adversely affect our business. From time to time we may need to rely on licenses to proprietary technologies, which may be difficult or expensive to obtain. We may need to obtain licenses to patents and other proprietary rights held by third parties to develop, manufacture and market products. If we are unable to timely obtain these licenses on commercially reasonable terms, our ability to commercially market our products may be inhibited or prevented, which could have a material adverse effect on our business, results of operations and financial condition. Our competitors or other third parties may allege that we are infringing upon their **IP intellectual property**, forcing us to expend substantial resources in litigation, the outcome of which is uncertain. Any unfavorable outcome of such litigation, including losses related to " at- risk" product launches, could have a material adverse effect on our business, financial position and results of operations. Companies that produce branded pharmaceutical products routinely bring litigation against ANDA filers or similar applicants that seek regulatory approval to manufacture and market generic forms of their branded products alleging patent infringement or other violations of **IP intellectual property** rights. Patent holders may also bring patent infringement suits against companies that are currently marketing and selling approved generic products. Similarly, companies that produce biologics may bring litigation against abbreviated Biologics License Application (" aBLA ") filers that seek regulatory approval to manufacture and market biosimilars. Litigation often involves significant expense and can delay or prevent introduction or sale of our generic and / or biosimilar products. If valid and enforceable patents are infringed by our products, we would need to delay selling the infringing generic product unless we could obtain a license from the patent holder, and, if we were already selling the infringing product, cease selling and potentially destroy existing product stock. There may be situations in which we may make business and legal judgments to market and sell products that are subject to claims of alleged patent infringement prior to final resolution of those claims by the courts, based upon our belief that such patents are invalid, unenforceable, or are not infringed by our marketing and sale of such products. This is referred to in the pharmaceutical industry as an " at- risk " launch. The risk involved in an at- risk launch can be substantial because, if a patent holder ultimately prevails against us, the remedies available to such holder may include, among other things, damages measured by the profits lost by the patent holder or treble damages, which can be significantly higher than the profits we make from selling the generic or biosimilar version of the product. We may also be harmed by the loss of any value of such inventory that we are unable to market or sell. We expend a significant amount of resources on research and development, including milestones on in- licensed products, which may not lead to successful product introductions. Much of our development effort is focused on technically difficult- to- formulate products and / or products that require advanced manufacturing technology. We expend significant resources on R & D primarily to enable us to manufacture and market FDA- approved pharmaceuticals in accordance with FDA regulations. We have entered into, and may in the future enter into, agreements that require us to make significant milestone payments upon achievement of various R & D events and regulatory approvals. As we continue to develop and in- license new products, we will likely incur increased research and licensing expenses. Because of the inherent risk associated with R & D efforts in the industry, particularly with respect to new drugs, our R & D expenditures may not result in the successful introduction of FDA- approved pharmaceutical products. Additionally, after we or our development partners submit an ANDA or aBLA, the FDA may request that additional studies be conducted. As a result, we may be unable to reasonably determine the total R & D costs required to develop a particular product. Finally, we cannot be certain that any investment made in developing products will be recovered, even if we are successful in commercialization. To the extent that we expend significant resources on R & D efforts and are not ultimately able to successfully introduce new products as a result of those efforts, our business, financial position and results of operations may be materially adversely affected. We depend on our ability to protect our **IP intellectual property** and proprietary rights. Our success depends on our ability to protect and defend the **IP intellectual property** rights associated with our current and future products. If we fail to protect our **IP intellectual property** adequately, competitors may manufacture and market products similar to, or that may be confused with, our products, and our generic competitors may obtain regulatory approval to make and distribute generic versions of our branded products. Some patent applications in the **United States U. S.** are maintained in secrecy or are not published until the resulting patents issue. We also cannot be certain that patents will be issued with respect to any of our patent applications or that any existing or future patents issued to or licensed by us will provide competitive advantages for our products or will not be challenged, invalidated, circumvented or held unenforceable in proceedings commenced by our competitors or other third parties. Furthermore, our patent rights may not prevent or limit our present and future competitors from developing, making, importing, using or commercializing products that are functionally similar to our products. We rely particularly on trade secrets, trademarks, unpatented proprietary expertise and continuing innovation that we seek to protect, in part, by registering and using marks; and by entering into confidentiality agreements with licensees, suppliers, employees, consultants and other parties. We use this approach to protecting our **IP intellectual property** in large part because few of our products are protected by patents. We cannot provide assurance that these agreements will not be breached or circumvented. We also cannot be certain that we will have recourse to adequate remedies in the event of a breach of such agreements. Disputes may arise concerning the ownership of **IP intellectual property** or the

applicability of confidentiality agreements. We cannot be sure that our trade secrets and proprietary technology will not be independently developed or otherwise become known by our competitors or, if patents are not issued with respect to our internally developed products, that we will be able to maintain the confidentiality of information relating to these products. In addition, efforts to ensure our ~~IP intellectual property~~ rights may be costly, time-consuming and / or ultimately unsuccessful. We cannot be sure that we will have the resources to protect our own rights against infringement by third parties. Our inability to protect our ~~IP intellectual property~~ and proprietary rights could have a material adverse effect on our business, results of operations, financial condition and cash flows.

**Legal and Regulatory Risks** We are involved in various legal proceedings and may be involved in future legal proceedings, all of which are uncertain, and existing and future proceedings may require us to incur substantial expense to defend and / or expose us to substantial liability. The development, manufacture and sale of our drug products involves an inherent risk of product liability and other claims and the associated adverse publicity, and insurance against such potential claims is expensive and may be difficult to obtain. Litigation is inherently subject to uncertainties and we may be required to expend substantial amounts in the defense or resolution of this and similar matters. We regularly monitor the use of our products for trends or increases in reports of adverse events or product complaints, and regularly report such matters to the FDA. In some cases, an increase in adverse event reports may be an indication that there has been a change in a product's specifications or efficacy. Such changes could lead to a recall of the product in question or, in some cases, increases in product liability claims related to the product in question. If the coverage limits for product liability and other insurance policies are not adequate, or if certain of our products are excluded from coverage, a claim brought against us, whether covered by insurance or not, could have a material adverse effect on our business, results of operations, financial condition and cash flows. ~~We also rely on self-insurance to cover product liability and other claims, and these claims may exceed the amounts we have reserved under our self-insurance program.~~

In the ordinary course of our business, we may also be subject to a variety of other types of claims, proceedings, investigations and litigation initiated by government agencies or third parties. These matters may include compliance matters, product regulation or safety, taxes, employee benefit plans, employment discrimination, health and safety, environmental, antitrust, securities law, customs, import / export, government contract compliance, financial controls or reporting, ~~IP intellectual property~~, allegations of misrepresentation, false claims or false statements, commercial claims, claims regarding promotion of our products and services, or other similar matters. In addition, government investigations related to the use of our generic drug products may cause reputational harm to us. Negative publicity, whether accurate or inaccurate, about the efficacy, safety or side effects of our generic drug products or product categories, whether involving us or a competitor, could materially reduce market acceptance of our products, cause consumers to seek alternatives to our products, result in product withdrawals and cause our stock price to decline. Negative publicity could also result in an increased number of product liability claims, whether or not these claims have a basis in scientific fact. Any such claims, proceedings, investigations or litigation, regardless of the merits, might result in substantial costs to defend or settle, restrictions on product use or sales, or otherwise injure our business. We manufacture and derive a portion of our revenue from the sale of pharmaceutical products in the opioid class of drugs. The U. S. Department of Health and Human Services has declared the ~~wide spread~~ **widespread** addiction to and abuse of such products a public health emergency, and ~~in recent months,~~ the federal government has also announced plans to increase federal oversight on opioid sale and consumption. These plans, along with changing public and clinical perceptions of opioid products and the risks relating to their use may result in the imposition of even stricter regulation of such products and further restrictions on their sale and use. For instance, the DEA has recently increased its scrutiny and regulation over the manufacture, distribution and sale of opioid products, which may require us to incur significant expenses to comply with such regulations. We derive substantial revenues from the sale of certain controlled drug substances that are subject to specific aggregate production quotas established and administered by the DEA in accordance with governing laws and regulations. Our inability to secure our quota allocation, the DEA's decision to allocate quota in an amount less than the amount we requested, or a delay by the government in the issuance of the quota for these substances can result in a substantial impact to our revenues. State governments have also taken steps to impose surcharges or taxes on opioid manufacturers or distributors. Any new or stricter regulations imposed by governmental authorities such as the DEA related to opioid products, as well as a potential increase in opioid-related litigation involving us, could result in material adverse effects on our business and results of operations. Refer to Note 21. Commitments and Contingencies- Prescription Opioid Litigation for more information regarding opioid-related litigation involving ~~us the Company~~.

We are subject to United States federal and state laws related to healthcare fraud and abuse and health information privacy and security, and the failure to comply with such laws may adversely affect our business. In the ~~United States~~ **U. S.**, many of our products are eligible for reimbursement under federal and state health care programs such as Medicaid, Medicare, TRICARE, and / or state pharmaceutical assistance programs, and as a result, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are, and will be, applicable to our business. We could be subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. The domestic and foreign laws that may affect our ability to operate include, but are not limited to: (i) the U. S. Anti-Kickback Statute, which applies to our marketing and research practices, educational programs, pricing policies and relationships with healthcare providers or other entities, by prohibiting, among other things, soliciting, receiving, offering or paying remuneration, directly or indirectly, as a means of inducing, or in exchange for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; (ii) U. S. federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent; (iii) the U. S. Health Insurance Portability and Accountability Act of 1996, ("~~the HIPAA~~"), which among other things created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters, and HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of

2009, and our implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information and place restrictions on the use of such information for marketing communications; (iv) the U. S. Physician Payments Sunshine Act, which among other things, requires manufacturers of drugs, devices, biologics and medical supplies for which payment is available under a federal healthcare program to report annually information related to " payments or other transfers of value " made to physicians, physician assistants, advanced practice nurses and teaching hospitals, and ownership and investment interests held by certain healthcare professionals and their immediate family members, and similar state laws; (v) the government pricing rules applicable to the Medicaid, Medicare Part B, 340B Drug Pricing Program, the U. S. Department of Veterans Affairs program, the TRICARE program, and state price reporting laws; and (vi) state and foreign law equivalents of each of the above U. S. laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health and other sensitive information in certain circumstances, such as the requirements under the European Union' s General Data Protection Regulation and certain U. S. state privacy laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Violations of certain of these laws, including the fraud and abuse laws may result in severe penalties against us and / or our responsible employees, including jail sentences, large fines, and the exclusion of our products from reimbursement under federal and state programs. Additionally, these risks may be compounded by our rapid international expansion. Defense of litigation claims and government investigations can be costly, time- consuming, and distract management, and it is possible that we could incur judgments or enter into settlements that would require us to change the way we operate our business. We are committed to conducting the sales and marketing of our products in compliance with the healthcare fraud and abuse laws, but certain applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity, a governmental authority may take a position contrary to a position we have taken, or should an employee violate these laws without our knowledge, a governmental authority may impose civil and / or criminal sanctions. Any adverse outcome in these types of actions, or the imposition of penalties or sanctions for failing to comply with fraud and abuse laws, could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Some of the statutes and regulations that govern our activities, such as federal and state anti- kickback and false claims laws, are broad in scope, and while exemptions and safe harbors protecting certain common activities exist, they are often narrowly drawn. While we manage our business activities to comply with these statutory provisions, due to their breadth, complexity and, in certain cases, uncertainty of application, it is possible that our activities could be subject to challenge by various government agencies. In particular, the FDA, the DOJ and other agencies have increased their enforcement activities with respect to the sales, marketing, research and similar activities of pharmaceutical companies in recent years, and many pharmaceutical companies have been subject to government investigations related to these practices. A determination that we are in violation of these and / or other government regulations and legal requirements may result in civil damages and penalties, criminal fines and prosecution, administrative remedies, the recall of products, the total or partial suspension of manufacturing and / or distribution activities, seizure of products, injunctions, whistleblower lawsuits, failure to obtain approval of pending product applications, withdrawal of existing product approvals, exclusion from participation in government healthcare programs and other sanctions. Any of these types of investigations or enforcement actions could affect our ability to commercially distribute our products and could materially and adversely affect our business, financial condition, results of operations and cash flows. Approvals for our new generic drug products may be delayed or become more difficult to obtain if the FDA institutes changes to its approval requirements. **Similarly, the FDA could change the approval or post- approval regulatory requirements for new drug applications.** The FDA may institute changes to its **ANDA approval requirements user fee structure**, such as implementing new or additional fees similar to the fees imposed by the GDUFA and its **second-third iteration (GDUFA H-III)**, which may make it more difficult or expensive for us to obtain approval for our new generic products. The FDA may also implement **other changes to the ANDA approval or post- approval regulatory requirements** that may directly affect some of our ANDA filings pending approval from the FDA **or our already- approved products**, such as changes to guidance from the FDA regarding bioequivalency requirements for particular drugs. Such changes may cause our development of such generic drugs to be significantly more difficult or result in delays in FDA approval or result in our decision to abandon or terminate certain projects **or the marketing of certain approved products**. Any changes in FDA requirements may make it more difficult for us to file ANDAs or obtain approval of our ANDAs and generate revenues and thus have a material adverse effect on our business, results of operations and financial condition. Healthcare reform and a reduction in the coverage and reimbursement levels by governmental authorities, HMOs, MCOs or other third- party payers may adversely affect our business. As part of commercializing our products, we have obtained authorization to receive reimbursement at varying levels for the cost of certain products and related treatments from governmental authorities and private health insurers and other organizations, such as **health maintenance organizations ("HMOs ") and managed care organizations ("MCOs ")**. **The drug pricing reforms in the IRA have impacted, and may impact in the future, the prices of certain of our products. For example, rebates related to the IRA reduced our net revenue for the year ended December 31, 2023 by \$ 7. 9 million**. The trend toward managed healthcare in the **United States-U. S.**, the growth of organizations such as HMOs and MCOs, and legislative proposals to reform healthcare and government insurance programs could significantly influence the purchase of pharmaceutical products, resulting in lower prices and a reduction in product demand. The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010 were signed into law on March 23, 2010 and March 30, 2010, respectively. These laws are referred to herein as " healthcare reform. " " A number of provisions of the healthcare reform laws continue to have a negative impact on the price of our products sold to U. S. government entities. For example, the legislation includes measures that (i) significantly increase Medicaid rebates through **both** the expansion of the program; (ii) substantially expand the Public Health System (340B) program to allow other entities to purchase prescription drugs at substantial discounts; (iii) extend the

Medicaid rebate rate to a significant portion of Managed Medicaid enrollees; (iv) apply a 75 % discount to Medicare Part D beneficiary spending in the coverage gap for branded and authorized generic prescription drugs; and (v) levy a significant excise tax on the industry to fund healthcare reform. Such cost containment measures and healthcare reform affect our ability to sell our products and have a material adverse effect on our business, results of operations and financial condition. Additionally, the Medicare Part D Prescription Drug Benefit established a voluntary outpatient prescription drug benefit for Medicare beneficiaries (primarily the elderly over 65 and the disabled). These beneficiaries may enroll in private drug plans. There are multiple types of Part D plans and numerous plan sponsors, each with its own formulary and product access requirements. The plans have considerable discretion in establishing formularies and tiered co-pay structures and in placing prior authorization and other restrictions on the utilization of specific products. In addition, Part D plan sponsors are permitted and encouraged to negotiate rebates with manufacturers. The Medicare Part D program, which went into effect January 1, 2006, is administered by the CMS within the Department of Health and Human Services. The CMS has issued extensive regulations and other sub-regulatory guidance documents implementing the Medicare Part D benefit, and the OIG has issued regulations and other guidance in connection with the Medicare Part D program. The federal government can be expected to continue to issue guidance and regulations regarding the obligations of Part D sponsors and their subcontractors. Participating drug plans may establish drug formularies that exclude coverage of specific drugs and payment levels for drugs negotiated with Part D drug plans may be lower than reimbursement levels available through private health plans or other payers. Moreover, beneficiary co-insurance requirements could influence which products are recommended by physicians and selected by patients. There is no guarantee that any drug that we market will be offered by drug plans participating under the Medicare Part D program or of the terms of any such coverage, or that covered drugs will be reimbursed at amounts that reflect current or historical levels. Additionally, any reimbursement granted may not be maintained, or limits on reimbursement available from third-party payers may reduce the demand for, or negatively affect the price of those products, which could significantly harm our business, results of operations, financial condition and cash flows. We may also be subject to lawsuits relating to reimbursement programs that could be costly to defend, divert management's attention and adversely affect our operating results. Most state Medicaid programs have established preferred drug lists, and the process, criteria and timeframe for obtaining placement on the preferred drug list varies from state to state. Under the Medicaid drug rebate program, a manufacturer must pay a rebate for Medicaid utilization of a product. The rebate for single source products (including authorized generics) is based on the greater of (i) a specified percentage of the product's average manufacturer price or (ii) the difference between the product's average manufacturer price and the best price offered by the manufacturer. The rebate for multiple source products is a specified percentage of the product's average manufacturer price. In addition, many states have established supplemental rebate programs as a condition for including a drug product on a preferred drug list. The profitability of our products may depend on the extent to which they appear on the preferred drug lists of a significant number of state Medicaid programs and the amount of the rebates that must be paid to such states. ~~The IRA may also impact prices of certain of our pharmaceuticals and the return on investment of biosimilars.~~ In addition, there is significant fiscal pressure on the Medicaid program, and amendments to lower the pharmaceutical costs of the program are possible. Such amendments could materially adversely affect our anticipated revenues and results of operations. Due to the uncertainties regarding the outcome of future healthcare reform initiatives and their enactment and implementation, we cannot predict which, if any, of the future reform proposals will be adopted or the effect such adoption may have on our business. Future rulemaking and reform, including repeal of existing ~~law~~ **laws, including healthcare reform laws**, with respect to the healthcare and pharmaceutical industries, could increase rebates, reduce prices or the rate of price increases for healthcare products and services, or require additional reporting and disclosure. We cannot predict the timing or impact of any future rule making, reform or repeal of healthcare laws. We depend on third-party agreements for a portion of our product offerings and any failure to maintain these arrangements or enter into similar arrangements with new partners could result in a material adverse effect. We have broadened our product offering by entering into a variety of third-party agreements covering any combination of joint development, supply, marketing and / or distribution of products. We cannot provide assurance that the development, supply, marketing and / or distribution efforts of our contractual partners will continue to be successful, that we will be able to renew such agreements or that we will be able to enter into new agreements **with favorable terms** for additional products. Any alteration to, or termination of, our current distribution and marketing agreements, failure to enter into new and similar agreements, or interruption of our product supply under ~~the~~ such agreements, could have a material adverse effect on our business, condition (financial and otherwise), prospects or results of operations. The testing required for the regulatory approval of our products is conducted primarily by independent third parties. Any failure by any of these third parties to perform this testing properly and in a timely manner may have an adverse effect upon our ability to obtain regulatory approvals. Our applications for regulatory approval of our products, including both internally developed and in-licensed products, incorporate the results of testing and other information that is conducted or gathered primarily by independent third parties (including, for example, manufacturers of raw materials, testing laboratories, contract research organizations or independent research facilities). Our ability to obtain and maintain regulatory approval of the products being tested is dependent upon the quality of the work performed by these third parties, the quality of the third parties' facilities, and the accuracy of the information provided by third parties. We have little or no control over any of these factors. If this testing is not performed properly, our ability to obtain or maintain regulatory approvals, and to launch or continue selling products, could be restricted or delayed. 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 have a material adverse effect on our business. The regulations applicable to us regarding reporting and payment obligations with respect to Medicaid reimbursement and rebates and other governmental programs are complex. Our calculations and methodologies are subject to review and challenge by the applicable governmental agencies, and it is possible that such reviews could adversely affect us and our business. In addition,

because our processes for these calculations and the judgments involved in making these calculations involve, and will continue to involve, subjective decisions and complex methodologies, these calculations are subject to the risk of error and misjudgment. Any governmental agencies that have commenced (or that may commence) an investigation of us could impose, based on a claim of violation of anti-fraud and false claims laws or otherwise, civil and / or criminal sanctions, including fines, penalties and possible exclusion from federal health care programs (including Medicaid and Medicare). Some of the applicable laws may impose liability even in the absence of specific intent to defraud. Furthermore, should there be ambiguity with respect to how to properly calculate and report payments, and even in the absence of any such ambiguity, a governmental authority may take a position contrary to a position that we have taken and may impose civil and / or criminal sanctions on us. Any such penalties, sanctions, or exclusion from federal health care programs could have a material adverse effect on our business, financial position and results of operations. From time to time we conduct routine reviews of our government pricing calculations. These reviews may have an impact on government price reporting and rebate calculations used to comply with various government regulations regarding reporting and payment obligations. Investigations and litigation concerning the calculation of average wholesale prices may adversely affect our business. Many government and third-party payers, including Medicare, Medicaid, HMOs and others, reimburse doctors and others for the purchase of certain prescription drugs based on a drug's average wholesale price ("AWP"). In the past several years, state and federal government agencies have conducted ongoing investigations of manufacturers' reporting practices with respect to AWP, as a result of which certain agencies have suggested that reporting of inflated AWP by manufacturers has led to excessive payments for prescription drugs. Numerous pharmaceutical companies have been named as defendants in actions brought by various State Attorneys General and have faced state law qui tam actions brought on behalf of various states, alleging generally that the defendants defrauded state Medicaid systems by purportedly reporting or causing the reporting of AWP and / or "Wholesale Acquisition Costs" that exceeded the actual selling price of the defendants' prescription drugs. These cases generally seek some combination of actual damages, and / or double damages, treble damages, compensatory damages, statutory damages, civil penalties, disgorgement of excessive profits, restitution, disbursements, counsel fees and costs, litigation expenses, investigative costs, injunctive relief, punitive damages, imposition of a constructive trust, accounting of profits or gains derived through the alleged conduct, expert fees, interest and other relief that the court may have deemed proper. We can give no assurance that we will be able to settle current or future actions on terms that we deem reasonable, or that such settlements or adverse judgments, if entered, will not exceed the amount of any **reserve liability we have recorded**. Accordingly, such actions could adversely affect us and may have a material adverse effect on our business, results of operations, financial condition and cash flows. Failure to comply with our government contracting regulations could adversely affect our business and results of operations. **Our** In January 2020, we completed the acquisition of AvKARE **segment**, Inc. and Dixon Shane, LLC d/b/a R & S Northeast LLC. For further details, refer to Note 3. Acquisitions. AvKARE generates a substantial amount of its net revenue from government contracts. Contracts with federal, state, and local governmental customers are subject to various procurement regulations, contract provisions and other requirements relating to their formation, administration and performance, and are subject to regular audits and investigations. Any failure by us to comply with the government contracting regulations could result in the imposition of various civil and criminal penalties, which may include termination of contracts, forfeiture of profits, suspension of payments, fines and suspension or debarment from future government business. Such failures could also cause reputational damage to our business. In addition, some of AvKARE's contracts provide for termination by the government, without cause. If one or more of our government contracts is suspended or terminated or if we are suspended, debarred or otherwise restricted from future government work, our business, results of operations and financial condition could suffer. **Risks Relating to Our Indebtedness We have a substantial amount** Overnight Financing Rate ("SOFR"). The phase-out of LIBOR is underway and will conclude by July 1 **indebtedness, which could adversely affect our financial health. As of December 31, 2023** when LIBOR rates and quotations are scheduled to be discontinued. In response to the phasing out of LIBOR, on March 15, 2022, President Biden signed the Adjustable Interest Rate (LIBOR) Act (the "LIBOR Act"), pursuant to which certain contracts that rely on LIBOR and do not contain procedures for determining an alternative base rate in the event that LIBOR is discontinued will transition from LIBOR to SOFR, effective July 1, 2023. While the LIBOR Act effectively established SOFR as the default replacement rate for LIBOR, there can be no assurances that SOFR will become a widely-accepted benchmark, or that SOFR or other alternative base rates will be more or less favorable than LIBOR. The discontinuance of LIBOR and the adoption of SOFR and / or other alternative based rates could create volatility and instability in the financial markets and within banking and financial institutions. Regardless, we **had \$ 2** will continue to monitor to take steps to assess LIBOR exposure and mitigate potential impacts of the transition. The consequences **7 billion** of these developments cannot be entirely predicted but could include **total indebtedness, comprised of \$ 2.4 billion, \$ 192.0 million and increase \$ 179.0 million** in the cost of our borrowings under outstanding on the Term Loan Due 2028, Term Loan Due 2025 and Amended New Revolving Credit Facility, respectively. As of December 31, 2023, we had an ability to borrow up to an additional \$ 253.2 million under our revolving credit facilities, comprised of \$ 225.2 million and \$ 28.0 million of available capacity under the Amended New Revolving Credit Facility and the Amended Rondo Revolving Credit Facility, respectively. Our substantial level of indebtedness could have important consequences. For example, it could: • increase our vulnerability to adverse economic and industry conditions; • limit our ability to obtain additional financing for future working capital, capital expenditures, raw materials, strategic acquisitions and other general corporate requirements; • expose us to unhedged interest rate fluctuations (such as recent increases in interest rates from 2022 through 2023, which may continue into 2024 and potentially beyond) because the interest on certain debt under the credit facilities is imposed at variable rates; • require us to dedicate a material adverse effect substantial portion of our cash flow from operations to payments on our debt, thereby reducing the availability of cash flow for operations and other purposes; • make it more difficult for us to satisfy our obligations to our lenders, resulting in possible defaults on and acceleration of such indebtedness; • limit our ability to refinance indebtedness our or Term Loan on

**increase the associated costs; require us to sell assets to reduce debt or influence the decision about whether to do so; limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate or prevent us from carrying out capital spending that is necessary or important to our growth strategy and efforts to improve operating margins or our business; and place us at a competitive disadvantage compared to any competitors that have less debt or comparable debt at more favorable terms—interest rates and that, as a result, may be better positioned to withstand economic downturn.** We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful. Our ability to make scheduled payments on or refinance our debt obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors which may be beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our indebtedness. As of December 31, 2022-2023, we had approximately \$ 2.7 billion of total indebtedness. **During 2024, we expect to make \$ 58.8 million in principal payments on the Term Loan Due 2028.** We expect to make \$ 27.0 million in principal payments and make interest payments totaling \$ 209-274.5-6 million, excluding the impact of our interest rate swap **and borrowings under our Amended New Revolving Credit Facility**, during 2023-2024 related to ~~our the~~ Term Loan ~~Related to Due 2028 and the term loan we entered into in connection with the Rondo Acquisition (the “Rondo Term Loan Due ”);~~ we expect to make \$ 9.0 million in principal payments and make interest payments totaling \$ 4.1 million during 2023-2025. Refer to Note 16, Debt and “ Commitments and Contractual Obligations ” under Part II, Item 7, Management’ s Discussion and Analysis of Financial Condition and Results of Operations for additional information. If our cash flows and capital resources are insufficient to fund our debt service obligations, we could face substantial liquidity problems and could be forced to reduce or delay investments and capital expenditures or to dispose of material assets or operations, seek additional debt or equity capital or restructure or refinance our indebtedness. We may not be able to effect any such alternative measures on commercially reasonable terms or at all and, even if successful, those alternative actions may not allow us to meet our scheduled debt service obligations. Our credit agreements restrict our ability to dispose of assets and use the proceeds from those dispositions and also restrict our ability to raise debt or equity capital to be used to repay other indebtedness when it becomes due. We may not be able to consummate those dispositions or obtain proceeds in an amount sufficient to meet any debt service obligations when due. **Any of these circumstances** ~~Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all,~~ would materially and adversely affect our financial position and results of operations and our ability to satisfy our obligations, including our indebtedness. If we cannot make scheduled payments on our debt, we will be in default and, as a result:
 

- our debt holders could declare all outstanding principal and interest to be due and payable;
- the lenders under our credit agreements could terminate their commitments to lend us capital; and
- we could be forced into bankruptcy or liquidation.

 The terms of our credit agreements restrict our operations, particularly our ability to respond to changes or to take certain actions. Our credit agreements contain a number of restrictive covenants that impose operating and financial restrictions on us and may limit our ability to ~~engage in acts that may be in our long-term best interest.~~ **among including restrictions on the other things** ability to:
 

- incur additional indebtedness;
- pay dividends or make other distributions or repurchase or redeem capital stock;
- prepay, redeem or repurchase certain debt;
- make loans and investments **or**;
- sell assets;
- incur liens;
- enter into transactions with affiliates;
- alter the businesses conducted by us;
- enter into agreements restricting subsidiaries’ ability to pay dividends; and
- consolidate, merge or sell all or substantially all of our assets.

 A breach of the covenants under such credit agreements could result in an event of default under the applicable indebtedness. Such a default may allow the creditors to accelerate the related debt and may result in the acceleration of any other debt to which a cross-acceleration or cross-default provision applies which could have a material adverse effect on our business, operations and financial results. **Furthermore, if we were unable to repay the amounts due and payable under our credit agreements, those lenders could proceed against the collateral granted to them to secure that indebtedness which could force us into bankruptcy or liquidation.** In the event our lenders accelerated the repayment of the borrowings, we and our subsidiaries may not have sufficient assets to repay that indebtedness. Any acceleration of amounts due under the credit agreements would likely have a material adverse effect on us. As a result of these restrictions, we may be:
 

- limited in how we conduct business;
- unable to raise additional debt or equity financing **and** to operate during general economic or business downturns; or
- unable to compete effectively or to take advantage of new business opportunities.

 These restrictions may affect our ability to grow in accordance with our strategy. **Economic, Political and Financial Risks** Our current operations in, and potential expansion into additional, international markets subjects us to increased regulatory oversight both in those international markets and domestically as well as regulatory, economic, social and political uncertainties, which could cause a material adverse effect on our business, financial position and results of operations. We are subject to certain risks associated with having substantial assets and operations located in foreign jurisdictions, including our operations in India and Ireland, as well as related to our **licensed distribution** activities ~~expected to be rolled out across parts of Europe, Australia~~ **being initiated in new geographies outside the U. S. and India New Zealand.** Over the past several years, we have significantly expanded our Indian operations, and we may in the future expand our international business and operations in these jurisdictions or into jurisdictions in which we have limited operating experience, including with respect to seeking regulatory approvals, marketing or selling products. Our international operations may be adversely affected by general economic conditions (including inflation, expropriation and other government actions), economic and fiscal policy (including changes in exchange rates and controls, interest rates and taxation policies), changes in **IP intellectual property** protections and remedies, trade regulations, tax laws, and increased government regulation (including those affecting approval, production, pricing, and marketing of, reimbursement for and access to our products). With respect to India, our operations could also be adversely affected by any reversal of India’ s recent economic liberalization and deregulation policies, as well as social instability and other political, economic or diplomatic developments in the future. Certain jurisdictions

have, from time to time, experienced instances of civil unrest and hostilities, both internally and with neighboring countries. Rioting, military activity, terrorist attacks, armed hostilities or unstable government and legal systems could cause our operations in such jurisdictions to be adversely affected or suspended. We generally do not have insurance for losses and interruptions caused by terrorist attacks, military conflicts and wars. In addition, our international operations may subject us to heightened scrutiny under the Foreign Corrupt Practices Act or similar anti-bribery laws, and could subject us to liability under such laws despite our efforts to comply. Some emerging market countries may be particularly vulnerable to periods of financial or political instability or significant currency fluctuations or may have limited resources for healthcare spending. As a result of these and other factors, our strategy to grow in emerging markets may not be successful, and growth rates in these markets may not be sustainable. Government financing and economic pressures can lead to negative pricing pressure in various markets where governments take an active role in setting prices, access criteria (e. g., through health technology assessments) or other means of cost control. Further, notwithstanding our compliance programs, there can be no assurances that our policies will prevent our employees or agents from violating any applicable laws or protect us from any such violations. Additionally, we cannot predict the nature, scope or impact of any future regulatory requirements that may apply to our expanding international operations or how foreign governments will interpret existing or new laws. We may make acquisitions of, or investments in, complementary businesses or products, which may be on terms that may not turn out to be commercially advantageous, or may require additional debt or equity financing, which could increase our leverage and /or dilute equity holders. While we regularly review the potential acquisition of technologies, products, product rights and complementary businesses and are currently evaluating, and intend to continue to evaluate, potential product and / or company acquisitions and other business development opportunities, we may not be able to identify suitable acquisition or investment candidates. In addition, to the extent that we do identify candidates that we believe to be suitable, we cannot provide any assurance that we will be able to reach an agreement with the selling party or parties or consummate the transaction on terms that are commercially advantageous to us or at all. If we make any acquisitions or investments, we may finance such acquisitions or investments through our cash reserves, debt financing, which may increase our leverage, or by issuing additional equity interests, which could dilute the holdings of our then-existing shareholders. If, due to capital constraints, we require financing, we cannot provide any assurance that we will be able to obtain such financing when needed on acceptable terms or at all. Global economic conditions could harm us. Global efforts to contain health care costs continue to exert pressure on product pricing and market access to pharmaceutical products. In many international markets, government-mandated pricing actions have reduced prices of patented drugs, and it is possible that the U. S. may adopt similar measures to reduce drug prices to consumers. Some countries may be subject to periods of financial instability, may have reduced resources to spend on healthcare or may be subject to economic sanctions, and our business in these countries may be disproportionately affected by these changes. Continued concerns about the systemic impact of potential geopolitical issues and economic policy uncertainty, particularly in areas in which we operate, could potentially cause economic and market instability in the future and could adversely affect our business, including our financial performance.

**These conditions may also result in decreased consumer spending, including spending on our products.** Challenging economic conditions could also have resulted, and may continue to result, in tighter credit conditions. The cost and availability of credit may be adversely affected by illiquid credit markets and wider credit spreads, which could adversely affect the ability of our third-party distributors, partners, manufacturers and suppliers to buy inventory or raw materials and to perform their obligations under agreements with us, which could disrupt our operations and adversely affect our financial performance. We have increased exposure to tax liabilities, including foreign tax liabilities. As a U. S. company with subsidiaries in, among other countries, India, Switzerland, Ireland and the ~~United Kingdom U. K.~~, we are subject to, or potentially subject to, income and other taxes in these jurisdictions as well as the ~~United States U. S.~~. Significant judgment is required in determining our worldwide provision for income taxes and other tax liabilities. Changes in tax laws or tax rulings may have a significant 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 among foreign subsidiaries in relation to various aspects of our business, including R & D activities and manufacturing. Tax authorities in various jurisdictions may disagree with, and subsequently challenge, the amount of profits taxed in such jurisdictions. Any such challenges may result in increased tax liability, including accrued interest and penalties, which would cause our tax expense to increase and may have a material adverse effect on our business, financial position and results of operations and our ability to satisfy our debt obligations. In **addition, many countries are implementing legislation and other guidance to align their international tax rules with the Organization for Economic Co-operation and Development's ("OECD") Base Erosion and Profit Shifting recommendations and action plan that aim to standardize and modernize global corporate tax policy, including changes to cross-border tax, transfer pricing documentation rules, and nexus-based tax incentive practices. The OECD has issued a two-pillar approach to global taxation, focusing on global profit allocation and a global minimum tax rate. The "Pillar One" global profit allocation proposal would not apply to us, since it generally applies to companies with global revenues exceeding € 20 billion (approximately \$ 22 billion using the exchange rate as of December 31, 2023). We have begun to evaluate the "Pillar Two" proposal which focuses on a global minimum tax of at least 15 %. Legislation for the "Pillar Two" proposal has been enacted or substantively enacted in certain jurisdictions in which we operate. The legislation will be effective with the financial year beginning on January 1, 2024. While the Pillar Two effective tax rates in most of the jurisdictions in which we operate exceeds 15 %, our provision for income taxes, net income and cash flows may be adversely impacted by the Pillar Two proposal.** In certain circumstances, we issue price adjustments and other sales allowances to our customers. Although we may establish ~~reserves~~ **liabilities** based on our estimates of these amounts, if estimates are incorrect and the ~~reserves~~ **liabilities** are inadequate, it may result in adjustments to these ~~reserves~~ **liabilities** that may have a material adverse effect on our financial position and results of operations. As described above, the first company to file an ANDA containing a Paragraph IV



certification that successfully challenges the patent (s) on a branded product may be granted 180 days of generic market exclusivity by the FDA for such generic product. At the expiration of such exclusivity period, other generic distributors may enter the market, resulting in a significant price decline for the drug (in some instances, price declines have exceeded 90 %). When we experience price declines following a period of generic marketing exclusivity, or at any time when a competitor enters the market or offers a lower price with respect to a product we are selling, we may, at our discretion, decide to lower the price of our product to retain market share and provide price adjustments to our customers for the difference between our new (lower) price and the price at which we previously sold the product which is still held in inventory by such customers. We accrue for these adjustments when the expected value of an adjustment is greater than zero, based on contractual pricing, actual net sales, accrual rates based on historical average rates, and estimates of the level of inventory of its products in the distribution channel that remain subject to these adjustments. There are also circumstances under which we may decide not to provide price adjustments to certain customers, and consequently, as a matter of business strategy, we may risk a greater level of sale returns of products in a customer's existing inventory and lose future sales volume to competitors rather than reduce our pricing. Based on estimates, we establish reserves liabilities for sales allowances including, but not limited to: sales discounts and returns, chargebacks, sales volume rebates, shelf stocks, re-procurement charges, cash discounts, and Medicaid rebate obligations at the time of sale. Although we believe our reserves liabilities are adequate as of the date of this report, we cannot provide assurances that our reserves will ultimately prove to be adequate. Increases in sales allowances may exceed our estimates for a variety of reasons, including unanticipated competition or an unexpected change in one or more of our contractual relationships. We will continue to evaluate the effects of competition and will record a price adjustment reserve liability if and when we deem it necessary. Any failure to establish adequate reserves liabilities with respect to sales allowances may result in a material adverse effect on our financial position and results of operations. If we determine that our goodwill and other intangible assets have become impaired, we may record significant impairment charges, which would adversely affect our results of operations. Goodwill and other intangible assets represent a significant portion of our assets. Goodwill is the excess of cost over the fair market value of net assets acquired in business combinations. In the future, goodwill and intangible assets may increase as a result of future acquisitions. We review our goodwill and indefinite lived intangible assets at least annually for impairment. We review our intangible assets with finite lives for recoverability whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. Impairment may result from, among other things, deterioration in the performance of acquired businesses, adverse market conditions and adverse changes in applicable laws or regulations, including changes that restrict the activities of an acquired business. Generic pharmaceuticals have faced regular and increasing price erosion each year, placing even greater importance on our ability to continually introduce new products. If these trends continue or worsen, or if we experience further difficulty in this market or the specialty market, our revenues and profits in our Generics and Specialty segments may continue to be affected adversely. A decline in our market capitalization, even if otherwise due to macroeconomic or industry-wide factors, could put pressure on the carrying value of our goodwill in both our Generics and Specialty segments and cause us the Company to conduct an interim impairment test. A determination that all or a portion of our goodwill or other intangible assets is impaired, although a non-cash charge against earnings, could have a material adverse effect on our results of operations and financial condition.

**Risks Related to Our Tax Receivable Agreement** We are required under a tax receivable agreement to make cash payments in respect of certain tax benefits to which we may become entitled, and we expect that the payments we will be required to make will be substantial. We are a party to a tax receivable agreement ("TRA") with each of the members of the group, together with their affiliates and certain assignees, who owned Amneal when it was a private company ("Members" or the "Amneal Group"), dated May 4, 2018. **On November 7, 2023, the TRA was amended as part of the Reorganization, and it may be further amended or supplemented from time to time. Under the November 7, 2023 amendment, the parties agreed to reduce our future obligation to pay 85 % of the realized tax benefits subject to the TRA to 75 % of such realized tax benefits. Therefore, under the TRA, we will be required to make cash payments to the Members and their permitted transferees equal to 85-75 % of certain attributed tax benefits, if any, that we actually realize, or in certain circumstances are deemed to realize, as a result of redemptions or exchanges of Amneal common units and the corresponding number of shares of Class B Common Stock for Class A Common Stock by the Members and their permitted transferees as set forth in the agreement.** The amount of the cash payments that we will be required to make under the TRA could be significant. **Any payments made by us to the Members and their permitted transferees under the TRA will generally reduce the amount of overall cash flow that might have otherwise been available to us.** As discussed in Note 7, Income Taxes, we have determined it is more-likely-than-not we will be unable to utilize all of our deferred tax assets ("DTAs") subject to the TRA and, therefore, reversed the substantially all of the liability under the TRA related to the tax savings we may realize from **Amneal common Common units Units** sold or exchanged through December 31, 2019. **For We reversed the accrued TRA liability of \$ 192.8 million, which resulted in a gain recorded in other--- the (expense) income, net for the year years ended December 31, 2023 and 2019. For the year ended December 31, 2022, we recorded an expense associated with the TRA in other income, net of \$ 3.1 million and \$ 0.6 million of which all of that amount is a liability as of, respectively. We did not record an expense associated with the TRA for the year ended December 31, 2021. As of December 31, 2023 and 2022, we had a TRA liability of \$ 3.7 million and \$ 0.6 million, respectively.** If utilization of these DTAs becomes more-likely-than-not in the future, at such time, we could incur obligations incremental to and substantially larger than the approximately approximating the \$ 202-185.7-2 million unrecorded contingent TRA liability as of December 31, 2022-2023. **Should we determine that a DTA with a valuation allowance is realizable in a subsequent period, the related valuation allowance will be released and if a resulting TRA payment is determined to be probable, a corresponding liability will be recorded. As a result, our future results of operations and earnings could be significantly impacted by these matters.**

However, if the tax attributes are not utilized in future years, it is reasonably possible no amounts would be paid under the TRA. **Should we determine that a DTA with a valuation allowance is realizable in a subsequent period, the related valuation allowance**

will be released and if a resulting TRA payment is determined to be probable, a corresponding liability will be recorded. As a result, our future results of operations and earnings could be significantly impacted as results of these matters. The timing and amount of any payments under the TRA may vary, depending upon a number of factors including the timing and number of Amneal common units sold or exchanged for our Class A Common stock, the price of our Class A Common Stock on the date of sale or exchange, the timing and amount of our taxable income, and the tax rate in effect at the time of realization of the taxable income (the TRA liability is determined based on a percentage of the corporate tax savings from the use of the TRA's attributes). Further sales **Because the Amneal Group has sold or exchanges-exchanged** occurring subsequent to December 31 **all of their common units**, 2022 could result in **as of the Reorganization**, future Amneal tax deductions and obligations **are no longer an associated risk** to pay 85% of such benefits to the holders of Amneal common units. In certain cases, payments under the TRA to the Members or their permitted transferees may be accelerated or significantly exceed the actual benefits we realize in respect of the tax attributes subject to the TRA. The TRA **continues to provides- provide** that upon certain mergers, asset sales, other forms of business combinations or other changes of control or if, at any time, we elect an early termination of the TRA, then our obligations under the TRA to make payments would be based on certain assumptions, including an assumption that we would have sufficient taxable income to fully utilize all potential future tax benefits that are subject to the TRA. **The parties agree that there was no change of control from the Reorganization**. As a result of the foregoing, we could be required to make payments under the TRA that (i) are greater than the actual benefits we ultimately realize in respect of the tax benefits that are subject to the TRA and (ii) are based on the present value of the anticipated future tax benefits that are the subject of the TRA, which payment may be required to be made significantly in advance of the actual realization, if any, of such future tax benefits. In these situations, our obligations under the TRA could have a substantial negative impact on our liquidity and could have the effect of delaying or preventing certain mergers, asset sales, other forms of business combinations or other changes of control. There can be no assurance that we will be able to fund or finance our obligations under the TRA. We will not be reimbursed for any payments made to the Members or their permitted transferees under the TRA in the event that any tax benefits are disallowed. Payments under the TRA will be based on the tax reporting positions that we determine, and the Internal Revenue Service or another tax authority may challenge all or part of the tax benefits we claim, as well as other related tax positions we take, and a court could sustain such challenge. If the outcome of any such challenge would reasonably be expected to materially adversely affect a recipient's rights or obligations (including the amount or timing of payments) under the TRA, then we will not be permitted to settle or fail to contest such challenge without the consent of the Members. We will not be reimbursed for any cash payments previously made to the Members or their permitted transferees under the TRA in the event that any tax benefits initially claimed by us and for which payment has been made to the Members or their permitted transferees are subsequently challenged by a taxing authority and are ultimately disallowed. Instead, any excess cash payments made by us to the Members or their permitted transferees will be netted against any future cash payments that we might otherwise be required to make to **Holdings-Members** or **its-their** permitted transferees under the terms of the TRA. However, we might not determine that we have effectively made an excess cash payment to the Members or their permitted transferees for a number of years following the initial time of such payment. As a result, payments could be made under the TRA in excess of the tax savings that we ultimately realize in respect of the tax attributes with respect to the Members or their permitted transferees. Risks Related to Our Class A Common Stock **The We are controlled by the-Amneal Group owns a majority of our outstanding Class A Common Stock**. The interests of the Amneal Group may differ from the interests of our other stockholders. As of December 31, **2022-2023**, the Amneal Group controlled the majority of the voting power of all of our outstanding shares of common stock. Accordingly, the Amneal Group has substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation, or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of the Company, even if such a change of control would benefit our other stockholders. This concentrated control could discourage a potential investor from seeking to acquire Class A **Common-common Stock-stock** and, as a result, might harm the market price of that Class A **Common-common Stock-stock**. Through its control of a majority of our voting power and the provisions set forth in our charter, bylaws and **our Third the Company's Second** Amended and Restated Stockholders Agreement, dated **December 16-November 7, 2017-2023** (as amended to date, the "Stockholders Agreement"), the Amneal Group has the ability to designate and elect a majority of our board of directors. As of December 31, **2022-2023**, six out of eleven members of our board of directors (**the "Board of Directors"**), have been designated by the Amneal Group. The Amneal Group has control over all matters submitted to our stockholders for approval, including changes in capital structure, transactions requiring stockholder approval under Delaware law and corporate governance, subject to the terms of the Stockholders Agreement relating to the Amneal Group's agreement to vote in favor of directors not designated by the Amneal Group and such other matters that are set forth in the Stockholders Agreement. The Amneal Group may have different interests than our other stockholders and may make decisions adverse to such interests. In the ordinary course of their business activities, the Amneal Group may engage in activities where their interests conflict with our interests or those of our other stockholders. Our certificate of incorporation provides that the Amneal Group have no duty to refrain from engaging in the same business activities or similar business activities or lines of business in which we operate. The Amneal Group also may pursue business opportunities with any of our clients, customers or vendors -that may be complementary to our business and, as a result, those acquisition opportunities may not be available to us. The Amneal Group could also transfer control of us to a third-party by transferring its shares. In addition, **the Company believes-** members of the Amneal Group have pledged **Amneal Common Units and the corresponding-** shares of **our Class B-A Common-common Stock-stock** to secure borrowings, and other members of the Amneal Group could enter into similar arrangements. In connection with these arrangements, we have entered into agreements with certain Amneal Group members and the lending institutions to whom their securities may be pledged. The voluntary or forced sale of some or all of these **units or** shares pursuant to a margin call or otherwise could cause our stock price to decline

and negatively impact our business. Similarly, a voluntary or forced sale could cause us to lose our “controlled company” status under the **Nasdaq New York Stock Exchange** listing requirements, which would require us to comply over a transition period with certain corporate governance requirements from which we are currently exempt, including having a fully independent compensation committee. If all of **our the Amneal Common Units and corresponding shares of Class B-A common** stock were pledged to secure borrowings **by members of the Amneal Group**, a complete foreclosure could result in a change of control. Future sales of shares by the Amneal Group could cause our Class A Common Stock price to decline. The majority of our **Class A Common common Stock stock** is held by the Amneal Group and is eligible for sale or transfer (subject to certain continuing restrictions). The Amneal Group may elect to sell their shares. If some or all of these shares are sold, or if it is perceived that they will be sold, the trading price of our Class A **Common common Stock stock** could decline. We are a holding company with nominal net worth and depend on dividends and distributions from our subsidiaries. We are a holding company with nominal net worth and will not have any material assets or conduct any business operations other than our investments in our subsidiaries. Our business operations are conducted primarily out of our direct operating subsidiary, Amneal, and its subsidiaries. As a result, our ability to satisfy our financial obligations and, notwithstanding any restrictions on payment of dividends under our existing indebtedness, our ability to pay dividends, if any, is dependent upon cash dividends and distributions or other transfers from our subsidiaries, including from Amneal. ~~Our charter provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders, which could limit the ability of our stockholders to obtain a favorable judicial forum for disputes with us or our current or former directors, officers or employees. Our charter provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if such court does not have jurisdiction, the Superior Court of the State of Delaware or the federal district court for the District of Delaware) will be the sole and exclusive forum for any derivative action or proceeding brought on behalf of the Company, any action asserting a claim of breach of fiduciary duty owed by any of our current or former director or officer to us or our stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporate Law (“DGCL”), our charter or bylaws or any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder’s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our current or former directors, officers or other employees, which may discourage such lawsuits against us and our current or former directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. The choice of forum provision in our charter will not preclude or contract the scope of exclusive federal or concurrent jurisdiction for actions brought under the federal securities laws, including the Securities Exchange Act of 1934, as amended, or the Securities Act of 1933, as amended, or the respective rules and regulations promulgated thereunder. Anti-takeover provisions under Delaware law could make an acquisition of the Company more difficult and may prevent attempts by our stockholders to replace or remove our management. Because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15 % of the outstanding voting stock of the Company from merging or combining with us unless certain conditions are met. Although we believe these provisions collectively will provide for an opportunity to receive higher bids by requiring potential acquirers to negotiate with our board of directors, they would apply even if the offer may be considered beneficial by some stockholders. In addition, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove then current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of management.~~ We do not anticipate that we will pay any cash dividends in the foreseeable future. We expect that we will retain our future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our Class A **Common common Stock stock** will be the sole source of gain for our stockholders for the foreseeable future. The payment of future cash dividends, if any, will be at the discretion of our Board of Directors and will be dependent upon our earnings, financial condition, capital requirements and other factors as our Board of Directors may deem relevant. **General Risk Factors** We may need to raise additional funds in the future which may not be available on acceptable terms or at all. We may consider issuing additional debt or equity securities in the future to fund potential acquisitions or investments, to refinance existing debt, or for general corporate purposes. If we issue equity, convertible preferred equity or convertible debt securities to raise additional funds, our stockholders may experience dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our stockholders. If we incur additional debt, we may increase our leverage relative to our earnings or to our equity capitalization, requiring us to pay additional interest expenses and potentially lowering our credit ratings. We may not be able to market such issuances on favorable terms, or at all, in which case, we may not be able to develop or enhance our products, execute our business plan, take advantage of future opportunities, or respond to competitive pressures or unanticipated customer requirements. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results, timely file our periodic reports, maintain our reporting status or prevent fraud. We are required to comply with Section 404 of the Sarbanes-Oxley Act, which requires public companies to conduct an annual review and evaluation of their internal controls and attestations of the effectiveness of such internal controls by independent auditors. Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that will need to be evaluated frequently. Our failure to maintain the effectiveness of our internal controls in accordance with the requirements of the Sarbanes-Oxley Act or the inability of our independent registered public accounting firm to express an opinion as to the effectiveness of our internal control over financial reporting could have a material adverse effect on our business. We could lose investor confidence in the accuracy and completeness of our financial reports, which could have an adverse effect on the price of our common stock. In addition, if our efforts to comply with new or changed laws, regulations, and standards differ from the

activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Our management or our independent registered public accounting firm may also identify material weaknesses in our internal control over financial reporting in the future. The existence of material weaknesses in internal control may result in current and potential stockholders and alliance and collaboration agreement partners losing confidence in our financial reporting, which could harm our business, the market price of our common stock, and our ability to retain our current, or obtain new, alliance and collaboration agreement partners. In addition, our internal controls over financial reporting may not prevent or detect misstatements because of their inherent limitations, including the possibility of human error, the circumvention or overriding of controls or fraud. Even effective internal controls can provide only reasonable assurance with respect to the preparation and fair presentation of financial statements. If we fail to maintain adequate internal controls, including any failure to implement required new or improved controls, or if we experience difficulties in their implementation, we could fail to meet our financial reporting obligations and our business, financial results and reputation could be harmed.