Risk Factors Comparison 2024-03-13 to 2023-03-13 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider all information in this Annual Report on Form 10- K prior to investing in our common stock. These risks are discussed more fully in the section titled " Risk Factors. " These risks and uncertainties include, but are not limited to, the following: • ~~General economic~~ **Global and national** conditions ~~can have a material adverse effect on our business, financial conditions~~ and ~~result of operations. • Global and national~~ events, including, but not limited to ~~the COVID- 19 pandemic, increased inflation~~, rising interest rates, **increased inflation,** supply chain disruptions, labor conditions, **pandemics and public health crises** and international conflict, may adversely affect our **business,** revenues, results of operations and financial condition. • Failure to implement strategies to enhance our performance could have a material adverse effect on our business, results of operations and financial conditions. • Our ability to perform depends on keeping and hiring exceptionally talented management and employees, and our failure to do so could have a material adverse effect on our business, revenues, results of operations and financial condition. • Our success depends, in part, on our ability to successfully obtain or retain high- performing third- party performers on commercially acceptable terms, and the failure to do so can have a material adverse effect on our business, financial conditions and results of operations. • Our business is subject to stringent government regulations, it must adhere to numerous complex pieces of legislation, and all of our products face regulatory challenges. • Our business depends on the successful protection of our intellectual property rights and our product candidates becoming approved by regulatory agencies, commercially viable, and accepted by the market. • Our business faces a serious financial risk if generic products that compete with any of our branded pharmaceutical products are approved and sold because sales of our products will be adversely- affected and our business may not recover the capital costs of bringing that product to market. • Our business faces an inherent risk of product liability lawsuits related to the testing of our product candidates and the commercial sale of our products, and if we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. • We may attempt to develop internationally and license our products globally, as well as invest in other businesses or joint ventures, all of which may be unsuccessful, divert our management' s attention and harm our operating results and prospects. The risk factors described below and throughout this report should be carefully considered and could materially affect our business. There are also risks that are not presently known or not presently material, as well as the other information set forth in this report that could materially affect our business. In addition, in our periodic filings with the SEC, press releases and other statements, we discuss estimates and projections regarding our future performance and business outlook. By their nature, such " forward- looking statements " involve known and unknown risks, uncertainties and other factors that in some cases are out of our control. For a further discussion of forward-looking statements, please refer to the section entitled " Special Note Regarding Forward- Looking Statements. " These factors could cause our actual results to differ materially from our historical results or our present expectations and projections. These risk factors and uncertainties include, but are not limited to the following: RISKS RELATED TO OUR BUSINESS ~~Risks related~~ **Global and national economic conditions and events, including, but not limited** to **increased inflation, rising interest rates, supply chain disruptions, labor conditions, pandemics and public health crises and international conflicts, could affect our future access to liquidity and materially adversely affect our results of operations and financial condition. Our business and results of operations could be adversely affected by changes in global or national economic conditions. These conditions include, but are not limited to, increased inflation, high and rising interest rates, supply chain disruptions, labor conditions, the negative impacts from pandemics and public health crises (including any lingering or recurring adverse impacts from** the COVID- 19 pandemic **)** ~~, natural disasters, public health epidemics,~~ and ~~other -- the negative events beyond our control may adversely affect our business. Our business has been adversely impacted by the COVID- 19 pandemic which has affected more than 200 countries and has significantly disrupted the day- to- day activities of both individuals and companies. We rely on individuals and third- party organizations around the world to supply components, manufacture and distribute our products, and execute our clinical trials. We have and may continue to experience revenue loss, supply interruptions, time delays and incur unplanned expenses as a result of the impact~~ **impacts resulting from** ~~of the COVID-19 pandemic. Global and national economic and other --~~ **the ongoing conflicts in Eastern Europe and the Middle East. These** ~~events, including, but not limited to increased inflation, rising interest rates, supply chain disruptions, labor~~ conditions ~~and international conflicts, could affect our future access to liquidity and materially adversely affect our results of operations and financial condition. Ongoing global and national events including, but not limited to increased inflation, rising interest rates, supply chain disruptions, labor conditions and the war between Russia and Ukraine,~~ have had a significant adverse impact on economic and market conditions around the world, including the United States. While the economic impact brought by, and the duration of, such global events is difficult to assess or predict, such events could result in additional disruption of global financial markets, reducing our ability to access capital in the future, which could negatively affect our liquidity in the future and in ways that cannot be predicted potentially including a prolonged recessionary environment in the United States. In the longer term, there could be significant new regulatory actions and other events that could limit our activities and investment opportunities or change the functioning of the capital markets, and there is the possibility of a severe worldwide economic downturn. ~~Consequently, we may~~ **Inflation rates have increased recently to levels** not ~~be capable of,~~ **seen in decades. If** ~~or~~ **our costs** ~~successful at~~ , **in particular costs related** ~~generating positive investment returns or effectively managing risks. Accordingly, we cannot predict the extent~~ to ~~which~~ **clinical trial expenses and / ~~our~~ or employee- related expenses, were to become subject to significant inflationary pressures, it may adversely impact our business, operating** results **and** ~~of~~

~~operations,~~ financial condition **. In response to inflationary pressures, the Federal Reserve raised interest rates in 2022** and ~~cash flows will be affected~~ **2023, and these increases may continue in 2024 and beyond. Increases in interest rates, especially if coupled with reduced government spending and volatility in financial markets, may further increase economic uncertainty and heighten these risks. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience increases in the near future (especially if inflation rates continue to rise) on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, ongoing effects of the COVID- 19 pandemic, the ongoing conflicts in Eastern Europe and the Middle East and employee availability and wage increases** . An adverse development regarding our products could have a material and adverse impact on our future revenues and profitability. Our product portfolio currently includes ~~eight~~ **seven** brands: Acetadote, Caldolor, Kristalose, Vaprisol, Omeclamox- Pak, Vibativ ~~, RediTrex~~ and Sancuso. A product contamination or other safety or regulatory issues, such as a failure to meet certain FDA reporting requirements involving our products, could negatively impact us and possibly lead to a product recall. In addition, changes impacting any of our products in areas such as competition, lack of market acceptance or demand, government regulation, intellectual property, reimbursement and manufacturing could have an adverse impact on our future revenues and profitability including: • Changes in intellectual property protection available for our products or competing treatments; • Any unfavorable publicity concerning us, our products, or the markets for these products such as information concerning product contamination or other safety issues in any of our product markets, whether or not directly involving our products; • Perception by physicians and other members of the healthcare community of the safety or efficacy of our products or competing products; • Regulatory developments related to our marketing and promotional practices or the manufacture or continued use of our products; • The prices of our products relative to other drugs or competing treatments; • The impact of current or additional generic competitors; • The availability and level of third-party reimbursement for sales of our products; • The continued availability of adequate supplies of our products to meet demand: • Weakened demand for our products; and • Unforeseen or serious adverse effects outside of those specified in current product labeling being attributed to any of our approved products. Acetadote may be used to treat acetaminophen overdoses. The FDA has previously requested prescribers and manufacturers of prescription combination products that contain acetaminophen to limit the amount of acetaminophen to no more than 325 milligrams (mg) in each tablet or capsule. The FDA requested this action to protect consumers from the risk of severe liver damage which can result from excess acetaminophen which may reduce the number of acetaminophen overdoses which could result in a lower demand for Acetadote. If the demand for Acetadote decreases, it could have an adverse impact on our future revenues and profitability. The commercial success of Caldolor is dependent on many third- parties, including physicians, pharmacists, hospital pharmacy and therapeutics committees, or P & T committees, suppliers and distributors, all of whom we have little or no control over. We expect Caldolor to continue to be administered primarily to hospital and surgery center patients who are unable to receive oral therapies for the treatment of pain or fever. Before we can distribute Caldolor to any new hospital customers, Caldolor must be approved for addition to the hospitals' formulary lists by their P & T committees. A hospital' s P & T committee generally governs all matters pertaining to the use of medications within the institution, including review of medication formulary data and recommendations of drugs to the medical staff. We cannot guarantee that we will be successful in getting the approvals we need from enough P & T committees to be able to optimize hospital sales of Caldolor. Even if we obtain hospital approval for Caldolor, we must still convince individual hospital physicians to prescribe Caldolor repeatedly. The commercial success of Caldolor also depends on our ability to coordinate supply, distribution, marketing, sales and education efforts. As with our other products, if Caldolor is not accepted in the marketplace, it could have an adverse impact on our future revenues and profitability. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to review and approve new products and otherwise affect the FDA' s ability to perform routine functions. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and / or approved by necessary government agencies. Such disruptions could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If any manufacturer or partner we rely upon fails to supply our products in the amounts we require on a timely basis, or fails to comply with stringent regulations applicable to pharmaceutical drug manufacturers, we may be unable to meet demand for our products and may lose potential revenues. We do not manufacture any of our products, and we do not currently plan to develop any capacity to do so. Our dependence upon third parties for the manufacture of our products could adversely affect our profit margins or our ability to develop and deliver products on a timely and competitive basis. If for any reason we are unable to obtain or retain third- party manufacturers on commercially acceptable terms, we may not be able to sell our products as planned. Furthermore, if we encounter delays or difficulties with contract manufacturers in producing our products, the distribution, marketing and subsequent sales of these products could be adversely affected. A long- term inability to meet demand for our products could result in impairment of our brands overall future and the carrying value of the assets associated with our brands. Acetadote: We have an agreement with one manufacturer to provide commercial supply of Acetadote. If this manufacturer is unable to produce marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for Acetadote. Caldolor: We have agreements with multiple manufacturers for the supply of Caldolor. If the manufacturers of Caldolor are unable to produce marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for Caldolor. Kristalose: The active pharmaceutical ingredient for Kristalose is manufactured at a single facility through a complex process. It would be particularly difficult to find a new manufacturer of the Kristalose active pharmaceutical ingredient on an expedited basis. We have manufacturing relationship with one packager who provided finished supplies of Kristalose for commercial and sampling purposes during 2022. If the manufacturing or packaging facilities are unable to produce useable or marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for Kristalose. Omeclamox- Pak: Our packager for

Omeclamox- Pak encountered financial difficulties due to the impact of COVID- 19, and their operations are currently suspended. Cumberland is awaiting resumption of those operations while also exploring other alternatives to restart the product' s packaging. In October 2020, we informed the FDA of a shortage of Omeclamox- Pak which continues. If we are unable to obtain marketable inventory in the future, we could **continue to** suffer an inability to meet demand for Omeclamox- Pak **. With uncertain future cash flows, the Board of Directors approved the write- down of the intangible assets related to the product** . Vaprisol: In 2018, the manufacturer of Vaprisol informed us that they would no longer be able to provide the product following the manufacturing of one final batch which is providing us with a multi- year supply. We are currently working with a new manufacturer to provide us with long term supplies of the product. In February 2022, we notified the FDA of a shortage of Vaprisol. If we are unable to produce additional marketable inventory in sufficient quantities, in the required time frame, we could suffer an inability to meet demand for Vaprisol. Vibativ: Through our acquisition of Vibativ, we acquired a multi- year supply of raw material, work in process and finished goods inventory. In 2020, we completed the transfer of Vibativ manufacturing activities to a new supplier. If we are unable to continue to obtain marketable inventory in sufficient quantities, in the agreed upon time period, we could suffer an inability to meet demand for Vibativ. Sancuso: ÷As part of the acquisition of Sancuso in January 2022, we obtained an initial supply of finished goods inventory and work in progress. On December 6, 2022, we received notification from Kyowa Kirin, Inc. that the FDA approved a supplemental new drug application associated with a new site at Kindeva Drug Delivery L. P., for the manufacturing and primary packaging of the Sancuso brand. In addition, all manufacturers of our products and product candidates must comply with current good manufacturing practices, (" GMPs"), enforced by the FDA through its facilities inspection program. These requirements include quality control, quality assurance, and the maintenance of records and documentation. Manufacturers of our products must be unable to comply with GMP requirements and with other FDA, state, and foreign regulatory requirements. We have no control over our manufacturers' compliance with these regulations and standards. If our third- party manufacturers do not comply with these requirements, we could be subject to fines and civil penalties; suspension of production or distribution; suspension or delay in product approval; product seizure or recall; and withdrawal of product approval. We are dependent on a variety of other third parties. If these third parties fail to perform as we expect, our operations could be disrupted and our financial results could suffer. We have a relatively small internal infrastructure. We rely on a variety of third parties, in addition to our manufacturers, to help us operate our business. If these third parties do not continue to provide services to us, or collaborate with us, we might not be able to obtain others who can serve these functions. This could disrupt our business operations, increase our operating expenses or otherwise adversely affect our operating results **. Specifically, we depend and will continue to depend upon independent investigators and collaborators, such as universities, medical institutions, contract research organizations (CROs) and strategic partners to conduct our preclinical and clinical trials. We negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with Good Clinical Practice (GCPs), which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for therapeutic candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. Further, these third parties may have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our therapeutic candidates. As a result, our financial results and the commercial prospects for our therapeutic candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines** . Competitive pressures could reduce our revenues and profits. The pharmaceutical industry is intensely competitive. Our strategy is to target differentiated products in specialized markets. However, this strategy does not relieve us from competitive pressures and can entail distinct competitive risks. Certain of our competitors do not aggressively promote their products in our markets. An increase in promotional activity in our markets could result in large shifts in market share, adversely impacting us. Our competitors may sell or develop drugs

that are more effective and useful or less costly than ours, and they may be more successful in manufacturing and marketing their products. Many of our competitors have significantly greater financial and marketing resources than we do. Additional competitors may enter our markets. The pharmaceutical industry is characterized by constant and significant investment in new product development, which can result in rapid technological change. The introduction of new products could substantially reduce our market share or render our products obsolete. The selling prices of pharmaceutical products tend to decline as competition increases, through new product introduction or otherwise, which could reduce our revenues and profitability. If generic products that compete with any of our branded pharmaceutical products are approved and sold, sales of our products will be adversely affected. Generic equivalents for branded pharmaceutical products are typically sold at lower costs than the branded products. The regulatory approval process in the United States exempts generic products from costly and time-consuming clinical trials to demonstrate their safety and efficacy and rely instead on the safety and efficacy of prior products, manufacturers of generic products can invest far less in research and development. 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, that a pharmacist dispense an available generic equivalent when filling a prescription for a branded product, in the absence of specific instructions from the prescribing physician. Governmental and private healthcare payors also emphasize substitution of branded pharmaceuticals with less expensive generic equivalents. 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 expires or because our patent protection is not sufficiently broad or enforceable. In addition, we may not be successful in our efforts to extend the proprietary protection afforded our branded products through the development and commercialization of proprietary product improvements. Competition from generic equivalents could result in a decrease in revenues of our branded pharmaceuticals or result in a material impairment of our intangible assets or the acceleration of amortization on our non- impaired intangible assets and may have a material adverse impact on our revenues, financial condition, results of operations and cash flows. Any attempt by us to expand the potential market for any of our products is subject to limitations. Expansion of the market for our products may be subject to certain limitations. In the past, these limitations have included FDA required Phase IV commitments. We may also experience delays associated with future required Phase IV clinical studies potentially resulting from, among other factors, difficulty enrolling patients. ~~Such~~ **We may not be able to initiate or continue clinical trials for our product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. Subject enrollment, a significant factor in the timeline of clinical trials, is affected by many factors including the size and characteristics of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, our ability to obtain and maintain patient consents, patient referral practices of physicians, ability to monitor patients adequately during and after treatment, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development. We will be required to identify and enroll a sufficient number of subjects for each of our clinical trials.** ~~delays~~ **Delays that may result from difficulty enrolling patients** could impact our ability to explore opportunities for label expansion and limit our ability to bring our products to new patient populations. In addition, we have largely obtained regulatory approval to market our products in the United States. Not all foreign jurisdictions may represent attractive opportunities for our products due to pricing, competitive, regulatory or other factors. In certain foreign jurisdictions, we have licensed the right to market some of our products to third parties. These third parties are responsible for seeking and maintaining regulatory approval for the products in their respective jurisdictions. We have no control over these third parties and cannot be sure that marketing approval for our products will be obtained outside the United States. Our future growth depends on our ability to identify, acquire rights and successfully integrate new brands into our operations. If we do not successfully identify and acquire rights to products or if we do not successfully integrate acquired product brands into our operations, our growth opportunities may be limited. We have added six products to our portfolio of brands through acquisitions. Our business strategy is to continue to acquire rights to FDA- approved products as well as pharmaceutical product candidates in the late stages of development. We do not plan to conduct basic research or preclinical product development, except to the extent of our investment in CET. As compared to large multi- national pharmaceutical companies, we have limited resources to acquire third- party products, businesses and technologies and integrate them into our current infrastructure. Many acquisition opportunities involve competition among several potential purchasers including large multi- national pharmaceutical companies and other competitors that have access to greater financial resources than we do. With future acquisitions, we may face financial and operational risks and uncertainties. We may not be able to engage in future product acquisitions, and those we do complete may not be beneficial to us in the long term. Furthermore, other products in development may encounter unforeseen issues during their clinical trials. Any unforeseen issues or lack of FDA approval will negatively affect marketing and development plans for those products. If we are unable to successfully integrate the marketing, sale and distribution of any other potential products into our current infrastructure or if they require significantly greater resources than originally anticipated, we may face financial and operational risks and uncertainties. If we are unable to successfully integrate any acquired brands, both current and future, these product acquisitions may not be beneficial to us in the long term. Our ~~ifetoban~~ **ifetroban** product candidates have

not been approved for sale and may never be successfully commercialized. We anticipate that a portion of our future revenue growth may come from sales of our ifetroban product candidates. However, none of these products have been approved by the FDA for marketing, and these product candidates are still subject to risks associated with their development. Drug development is a long, expensive and inherently uncertain process with a high risk of failure at every stage of development, and results of earlier studies and trials may not be predictive of future trial results The FDA has cleared our IND' s for the ifetroban product candidates as we evaluate them as treatments for these conditions. Delays in the enrollment and completion of the clinical studies could significantly delay commercial launch and affect our product development costs. Moreover, results from the clinical studies may not be favorable. Even if they are eventually developed and approved by the FDA, they may never gain significant acceptance in the marketplace and therefore never generate substantial revenue or profits for us. Physicians may determine that existing drugs are adequate to address patients ' needs. The extent to which these product candidates will be reimbursed by the U. S. government or third- party payors is also currently unknown. As a result of the foregoing and other factors, we do not know the extent to which our product candidates will contribute to our future growth. If we are unable to maintain, train and build an effective sales and marketing infrastructure, we will not be able to commercialize and grow our products and product candidates successfully. As we grow, we may not be able to secure sales personnel or organizations that are adequate in number or expertise to successfully market and sell our products. This risk would be accentuated if we acquire products in areas outside of our current focus areas since our sales forces specialize in our existing areas. If we are unable to expand our sales and marketing capability, train our sales force effectively or provide any other capabilities necessary to commercialize our products and product candidates, we will need to contract with third parties to market and sell our products. We must train our employees on proper regulatory compliance, including, but not limited to, " fair balance " promotion of our products and anti- kickback laws. If we are unable to establish and maintain compliant and adequate sales and marketing capabilities, we may not be able to increase our product revenue, may generate increased expenses and may experience regulatory compliance issues. If governmental or third- party payors do not provide adequate reimbursement for our products, our revenue and prospects for profitability may be limited. Our financial success depends, in part, on the availability of adequate reimbursement from third- party healthcare payors. Such third- party payors include governmental health programs such as Medicare and Medicaid, managed care providers and private health insurers. Third- party payors are increasingly challenging the pricing of medical products and services, while governments continue to propose and pass legislation designed to reduce the cost of healthcare. Adoption of such legislation could further limit reimbursement for pharmaceuticals. In addition, as part of the Inflation Reduction Act legislation, provisions intended to lower the price of prescription drugs, including permitting Medicare to negotiate the price of prescription drugs once they have been on the market for a fixed number of years, and imposing a tax penalty on drug manufacturers if the price of their drugs increase faster than the rate of inflation. At this time no assurances can be given that these measures, or subsequent legislative proposals, will not have an adverse effect on our revenues in the future. Future cost control initiatives, legislation, and regulations could decrease the price that we receive for our products, which would limit our revenue and profitability. Also, reimbursement practices of third- party payors might preclude us from achieving market acceptance for our products or maintaining price levels sufficient to realize an appropriate return on our investment in product acquisition and development. If we cannot obtain adequate reimbursement levels, our business, financial condition and results of operations would be materially and adversely affected. Our employees have been trained to submit accurate and correct pricing information to payors. If, despite the training, our employees provide incorrect or fraudulent information, then we will be subject to various administrative and judicial investigations and litigation. " Formulary " practices of third- party payors could adversely affect our competitive position. Many managed healthcare organizations control the pharmaceutical products included on their formulary lists. Having products listed on these formulary lists creates competition among pharmaceutical companies which, in turn, has created a trend of downward pricing pressure in our industry. In addition, many managed care organizations are pursuing various ways to reduce pharmaceutical costs and are considering formulary contracts primarily with those pharmaceutical companies that can offer a full line of products for a given therapy sector or disease state. Our products might not be included on the formulary lists of managed care organizations, and downward pricing pressure in our industry generally could negatively impact our operations. Continued consolidation of distributor networks in the pharmaceutical industry as well as increases in retailer concentration may limit our ability to profitably sell our products. We sell most of our products to large pharmaceutical wholesalers, who in turn sell to hospitals, surgery centers and retail pharmacies. The distribution network for pharmaceutical products has become increasingly consolidated in recent years. Further consolidation or financial difficulties could also cause our customers to reduce the amounts of our products that they purchase, adversely impacting our business, financial condition and results of operations. Our CET joint initiative may not result in our gaining access to commercially viable products. Our CET joint initiative with Vanderbilt University, WinHealth and Tennessee Technology Development Corporation is designed to help us investigate, in a cost- effective manner, early- stage products and technologies. However, we may never gain access to commercially viable products from CET for a variety of reasons, including: • CET investigates early- stage products, which have risk of failure prior to FDA approval and commercialization; • In some programs, we do not have pre- set rights to product candidates developed by CET. We would need to agree with CET and its collaborators on the terms of any product licensed or acquired by us; • We rely principally on government grants to fund CET' s research and development programs. If these grants were no longer available, we or our co- owners might be unable or unwilling to fund CET operations at current levels or at all; • We may become involved in disputes with our co- owners regarding CET policy or operations, such as how best to deploy CET assets or which product opportunities to pursue. Disagreement could disrupt or halt product development; and • CET may disagree with one of the various universities with which CET is collaborating on research. A disagreement could disrupt or halt product development. We depend on our key personnel, the loss of whom would adversely affect our operations. If we fail to attract and retain the talent required for our business, our business will be materially harmed. We are a relatively small company, and we depend to a great extent on

principal members of our management, scientific staff, and sales representatives and managers. If we lose the services of any key personnel, in particular, A. J. Kazimi, our Chief Executive Officer, or other members of senior management it could have a material adverse effect on our business prospects. Mr. Kazimi, plays a key role in several operational and strategic decisions such that any loss of his services due to death or disability would adversely impact our day- to- day operations. We have a life insurance policy covering the life of Mr. Kazimi. We have entered into agreements with each of our employees that contain restrictive covenants relating to non- competition and non- solicitation of our customers and suppliers for one year after termination of employment. Nevertheless, each of our officers and key employees may terminate his or her employment at any time without notice and without cause or good reason, and so as a practical matter these agreements do not guarantee the continued service of these employees. Our success depends on our ability to attract and retain highly qualified scientific, technical, sales and managerial personnel and research partners. Competition among pharmaceutical companies for qualified employees is intense, and we may not be able to retain existing personnel or attract and retain qualified staff in the future. If we experience difficulties in hiring and retaining personnel in key positions, we could suffer from delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect operating results. In addition, we have recently observed an overall tightening and increasingly competitive labor market. Our business could be adversely affected by an inability to retain personnel or upward pressure on wages as a result of the competitive labor market. The size of our organization and our potential growth may lead to difficulties in managing operations. As of December 31, ~~2022~~ **2023**, we had ~~85~~ **91** employees. We may need to continue to expand our managerial, operational, financial and other resources in order to increase our marketing efforts with regard to our currently marketed products, continue our business development and product development activities and commercialize our product candidates. We have experienced, and may continue to experience, growth and increased expenses in the scope of our operations in connection with the continued marketing and development of our products. Our financial performance will depend, in part, on our ability to manage any such growth and expenses of the current organization effectively. We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product or product candidate and may have to limit its commercialization. We face an inherent risk of product liability lawsuits related to the testing of our product candidates and the commercial sale of our products. An individual may bring a liability claim against us if one of our product candidates or products causes, or appears to have caused, an injury. If we cannot successfully defend ourselves against the product liability claim, we may incur substantial liabilities. Liability claims may result in decreased demand for our products; injury to our reputation; withdrawal of clinical trial participants; significant litigation costs; substantial monetary awards to or costly settlement with patients; product recalls; loss of revenue; and the inability to commercialize our product candidates. We have product liability insurance that covers our clinical trials, the marketing and sale of our products up to a $ 10 million annual aggregate limit, subject to specified deductibles. Our current or future insurance coverage may prove insufficient to cover any liability claims brought against us. Because of the increasing costs of insurance coverage, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated. Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected. Our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or payment of fines, or could result in disgorgement of money, operating restrictions, injunctions or criminal prosecution, any of which could harm our business. Our business and operations would suffer in the event of system failures, security breaches, including any cybersecurity incidents, adverse events or other disruptions within our information technology infrastructure at our corporate headquarters; or in the event of intellectual property infringement. Our business depends on effective, secure and operational information systems which include systems provided by external contractors and other service providers. Despite the implementation of security measures, our computer systems and information technology infrastructure, including those resources at our corporate headquarters, are vulnerable to damage from cyber- attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Our business is at risk from and may be impacted by information security incidents, including ransomware, malware, phishing, social engineering, and other security events. Such incidents can range from individual attempts to gain unauthorized access to information technology systems to more sophisticated security threats. These events can also result from internal compromises, such as human error or malicious acts. These events can occur on our systems or on the systems of our partners and subcontractors. In the ordinary course of our business, we store sensitive data, including intellectual property, our proprietary business information and that of our customers. We also maintain personally identifiable information of our employees in our data centers and on our networks. The secure processing and maintenance of this information is critical to our operations. Problems with, or the failure of, our technology and systems or any system upgrades or programming changes associated with such technology and systems would have a substantial and material negative effect on our operations. Furthermore, any system failure, accident or security breach that causes interruptions in our operations could result in a material disruption of our drug development programs. While we continue to invest in data protection and information technology, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, lost or stolen. If we are subject to cyber- attacks or security breaches, this could result in business interruptions and delays; the loss, misappropriation, corruption or unauthorized access of data; litigation and potential liability under privacy, security and consumer protection laws or other applicable laws; reputational damage and federal and state

governmental inquiries. Any such problems or failures and the costs incurred in correcting any such problems or failures, could have a material adverse effect on our business and financial condition, results of operations and cash flows. To the extent that any disruption or security breach results in a loss or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we may incur liability and the further development of our products or product candidates may be delayed. A failure to restore our information systems after the occurrence of any of these events could have a material adverse effect on our business and financial condition, results of operations and cash flows. Our information systems and applications also require maintenance, upgrading and enhancement to meet our operational needs. We regularly upgrade and expand our information systems' capabilities. If we experience difficulties with the transition and integration of information systems or are unable to implement, maintain, or expand our systems properly, we could suffer from, among other things, operational disruptions, regulatory problems and increases in administrative expenses. As cyber threats continue to evolve, we may be required to expend significant capital and other resources to protect against the threat of security breaches or to mitigate and alleviate problems caused by breaches, including unauthorized access to proprietary information and personally identifiable information stored in our information systems, and the introduction of computer viruses or other malicious software programs to our systems. Our security measures may be inadequate to prevent security breaches and our business operations could be materially adversely affected by federal and state fines and penalties, legal claims or proceedings, cancellation of contracts and loss of customers if security breaches are not prevented. We believe that our subcontractors and vendors take precautionary measures to prevent problems that could affect our business operations as a result of failure or disruption to their information systems. However, there is no guarantee such efforts will be successful in preventing a disruption, and it is possible that we may be impacted by information system failures. The occurrence of any information system failures could result in interruptions, delays, loss or corruption of data and cessations or interruptions in the availability of these systems. All of these events or circumstances, among others, could have an adverse effect on our business, results of operations, financial position and cash flows, and they could harm our business reputation. We believe we have all the necessary licenses from third parties to use technology and software that we do not own. A third party could, however, allege that we are infringing its rights, which may deter our ability to obtain licenses on commercially reasonable terms from the third party, if at all, or cause the third party to commence litigation against us. In addition, we may find it necessary to initiate litigation to protect our trade secrets, to enforce our intellectual property rights and to determine the scope and validity of any proprietary rights of others. Any such litigation, or the failure to obtain any necessary licenses or other rights, could materially and adversely affect our business. We license our products globally; therefore, we may have exposure to foreign regulatory requirements and fluctuations in foreign currency exchange rates. Continued foreign licensure inherently subjects us to a number of risks and uncertainties, including: • longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems; • political and economic instability or sanctions in areas in which we operate; • potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers; • regulations related to customs and import / export matters (including sanctions); • tax issues, such as tax law changes and variations in tax laws; • challenges in collecting accounts receivable from customers in the jurisdictions in which we operate; • complying with laws, rules and regulations relating to the manufacturing, marketing, distribution and sale of pharmaceutical products in the jurisdictions in which we do or will operate; • operating under regulations in jurisdictions related to obtaining eligibility for government or private payor reimbursement for our products at the wholesale / retail level; • competition from local, regional and international competitors; • difficulties and costs of staffing and managing foreign operations, including cultural and language differences and additional employment regulations, union workforce negotiations and potential disputes in the jurisdictions in which we operate; • difficulties associated with compliance with a variety of laws and regulations governing international trade, including the Foreign Corrupt Practices Act; • difficulties protecting or procuring intellectual property rights; and • fluctuations in foreign currency exchange rates. Any of these factors may, individually or as a group, have a material adverse effect on our business and results of operations. These or other similar risks could adversely affect our revenue and profitability. As we continue to develop internationally, our exposure to these factors will increase. We may decide not to commercialize one of our drug candidates once it obtains regulatory approval if we determine that commercialization of that product would require more capital and time than we are willing to invest. Even if any of our drug candidates receives regulatory approval, it could be subject to matters such as post- regulatory surveillance, additional clinical trials or testing, reformulation, changes in labeling, warnings to the public, recall, competition from similar or superior products, and lack of sufficient payor reimbursement by insurance companies or Medicare. As a result, we may not commercialize or continue to commercialize a product that has obtained regulatory approval. Any approved drug product that we bring to the market may not gain market acceptance by physicians, patients, healthcare payors and others in the medical community. Even if we are successful in gaining regulatory approval of any of our drug candidates or acquire rights to approved drug products, we may not generate significant product revenues and we may not become profitable if these drug products do not achieve an adequate level of acceptance. Physicians may not recommend our drug products until longer- term clinical data or other factors demonstrate the safety and efficacy of our drug products as compared to other alternative treatments. Even if the clinical safety and efficacy of our drug products is established, physicians may elect not to prescribe these drug products for a variety of reasons, including the reimbursement policies of government and other third- party payors and the effectiveness of our competitors in marketing their products. Market acceptance of our drug products, if approved for commercial sale, will depend on a number of factors, including: • the willingness and ability of patients and the healthcare community to use our drug products; • the ability to manufacture our drug products in sufficient quantities with acceptable quality and to offer our drug products for sale at competitive prices; • the perception of patients and the healthcare community, including third- party payors, regarding the safety, efficacy and benefits of our drug products compared to those of competing products or therapies; • the label and promotional claims allowed by the FDA; and • the pricing and reimbursement of our drug products relative to existing treatments. We may acquire businesses or assets, form joint ventures or make investments in other

companies that may be unsuccessful, divert our management' s attention and harm our operating results and prospects. As part of our business strategy, we may pursue additional acquisitions of what we believe to be complementary businesses or assets or seek to enter into joint ventures. We also may pursue strategic alliances in an effort to leverage our existing infrastructure and industry experience to expand our product offerings or distribution, or make investments in other companies. The success of our acquisitions, joint ventures, strategic alliances and investments will depend on our ability to identify, negotiate, complete and, in the case of acquisitions, integrate those transactions and, if necessary, obtain satisfactory debt or equity financing to fund those transactions. We may not realize the anticipated benefits of any acquisition, joint venture, strategic alliance or investment. We may not be able to integrate acquisitions successfully into our existing business, maintain the key business relationships of businesses we acquire, or retain key personnel of an acquired business, and we could assume unknown or contingent liabilities or incur unanticipated expenses. Integration of acquired companies or businesses also may require management resources that otherwise would be available for ongoing development of our existing business. Any acquisitions or investments made by us also could result in significant write- offs or the incurrence of debt and contingent liabilities, any of which could harm our operating results. In addition, if we choose to issue shares of our stock as consideration for any acquisition, dilution to our shareholders could result. We may be required to modify our business practices, pay fines and significant expenses or experience other losses due to governmental investigations or other enforcement activities. We may become subject to litigation or governmental investigations in the United States and foreign jurisdictions that may arise from the conduct of our business. Like many companies in our industry, we have from time to time received inquiries and other types of information requests from government authorities. While the ultimate outcomes of investigations and legal proceedings are difficult to predict, adverse resolutions or settlements of those matters could result in, among other things: • significant damage awards, fines, penalties or other payments, and administrative remedies, such as exclusion and / or debarment from government programs, or other rulings that preclude us from operating our business in a certain manner; • changes and additional costs to our business operations to avoid risks associated with such litigation or investigations; • product recalls; • reputational damage and decreased demand for our products; and • expenditure of significant time and resources that would otherwise be available for operating our business. RISKS RELATING TO GOVERNMENT REGULATION Virtually all aspects of our business activities are regulated by government agencies. The manufacturing, processing, formulation, packaging, labeling, distribution, promotion and sampling, advertising of our products, and disposal of waste products arising from such activities are subject to governmental regulation. These activities are regulated by one or more of the FDA, the Federal Trade Commission, (" FTC"), the Consumer Product Safety Commission, the U. S. Department of Agriculture and the U. S. Environmental Protection Agency, (" EPA"), as well as by comparable agencies in foreign countries. These activities are also regulated by various agencies of the states and localities in which our products are sold. For more information, see " Business — Government Regulation" in Part I, Item 1 of this Form 10- K. Like all pharmaceutical manufacturers, we are subject to regulation by the FDA under the Federal Food, Drug and Cosmetic Act (" FDCA"). All new drugs must be the subject of an FDA- approved new drug application, (" NDA"), before they may be marketed in the United States. The FDA has the authority to withdraw existing NDA approvals and to review the regulatory status of products marketed under the enforcement policy. The FDA may require an approved NDA for any drug product marketed under the enforcement policy if new information reveals questions about the drug' s safety and effectiveness. All drugs must be manufactured in conformity with GMP, and drug products subject to an approved NDA must be manufactured, processed, packaged, held and labeled in accordance with information contained in the NDA. Since we rely on third parties to manufacture our products, GMP requirements directly affect our third party manufacturers and indirectly affect us. The manufacturing facilities of our third- party manufacturers are continually subject to inspection by such governmental agencies, and manufacturing operations could be interrupted or halted in any such facilities if such inspections prove unsatisfactory. Our third- party manufacturers are subject to periodic inspection by the FDA to assure such compliance. Even after regulatory approval, certain developments may decrease demand for our products, including the following: • the re- review of products that are already marketed; • new scientific information and evolution of scientific theories; • the recall or loss of marketing approval of products that are already marketed; • changing government standards or public expectations regarding safety, efficacy or labeling changes; and • greater scrutiny in advertising and promotion. Certain regulatory changes or decisions could make it more difficult for us to sell our products and could have a material adverse effect on our business, results of operations, financial condition and cash flows. Manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP and other applicable regulations. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with a facility where the product is manufactured, a regulatory agency may impose restrictions on that product or the manufacturer, including withdrawal of the product from the market or suspension of manufacturing. If we, our partners or the manufacturing facilities for our products fail to comply with applicable regulatory requirements or violate healthcare laws, a regulatory agency may take the following actions, among others: • issue warning letters or untitled letters; • impose civil or criminal penalties • suspend or withdraw regulatory approval; • suspend any ongoing clinical trials; • refuse to approve pending applications or supplements to applications submitted by us; • impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products or require us to initiate a product recall. Any change in the FDA' s enforcement policy could have a material adverse effect on our business, financial condition and results of operations. We cannot determine what effect changes in regulations or statutes or legal interpretation, when and if promulgated or enacted, may have on our business in the future. Such changes, or new legislation, could have a material adverse effect on our business, financial condition and results of operations. Proposed legislation may permit re- importation of drugs from other countries into the U. S., including foreign countries where the drugs are sold at lower prices than in the U. S., which could materially and adversely affect our operating results and our overall financial condition. In previous years, legislation has been introduced in Congress that, if enacted, would permit more widespread re- importation of drugs from foreign countries into the U. S., which

may include re- importation from foreign countries where the drugs are sold at lower prices than in the U. S. Such legislation, or similar regulatory changes, if enacted, could decrease the price we receive for any approved products which, in turn, could materially and adversely affect our operating results and our overall financial condition. We must comply with the CREATES Act. There have been a number of recent regulatory and legislative initiatives designed to encourage generic competition for pharmaceutical products, including expedited review procedures for generic manufacturers and incentives designed to spur generic competition of branded drugs. In particular, FDA and FTC have been focused on brand companies' denial of drug supply to potential generic competitors for testing. In December 2019, the Creating and Restoring Equal Access to Equivalent Samples Act, or the CREATES Act, was enacted, which provides a legislatively defined private right of action under which eligible product developers can bring suit against companies who refuse to sell sufficient quantities of their branded products on commercially reasonable, market- based terms to support such eligible product developers' marketing applications. We cannot currently predict the specific outcome or impact on our business of such regulatory and legislative initiatives. We must comply with the Foreign Corrupt Practices Act. We are required to comply with the United States Foreign Corrupt Practices Act, which prohibits U. S. companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Foreign companies, including some of our competitors, are not subject to these prohibitions. If our competitors engage in these practices, they may receive preferential treatment from officials or agencies in some countries, giving our competitors an advantage in securing business from government officials who might give them priority in obtaining new licenses, which would put us at a disadvantage. We have established formal policies or procedures for prohibiting or monitoring this conduct, but we cannot assure you that our employees or other agents will not engage in such conduct for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties. We must comply with the Physician Payment Sunshine Act. We are required to comply with the United States Physician Payment Sunshine Act, which requires manufacturers of drugs, medical devices and biologicals that participate in U. S. federal healthcare programs to report certain payments and items of value given to physicians and teaching hospitals. Manufacturers are required to report this information annually to The Centers for Medicare & Medicaid Services (" CMS"). In addition, some states require reporting information concerning payments to health care providers or other transfers of value by drug manufacturers beyond the requirements of the Federal Sunshine Act. Cumberland has implemented a series of policies and procedures for every employee involved in the data collection process, and has systems in place to capture the data, which is verified by an outside firm that specializes in reporting the payments. Cumberland has also established a system to ensure that data was reported completely, in the correct format, and on time. Despite these policies, procedures and systems, we cannot assure you that we will collect and report all data accurately. If we fail to accurately report this information, we could suffer severe penalties. If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate program or other governmental pricing programs, we could be subject to additional reimbursement requirements, penalties, sanctions and fines, which could have a material adverse effect on our business, financial condition, results of operations and growth prospects. We participate in the Medicaid Drug Rebate program, the 340B program, and other governmental pricing programs and have obligations to report the average sales price for certain of our drugs to CMS. These programs and rebate calculations vary across products and programs, are complex, and are often subject to interpretation by us, governmental or regulatory agencies and the courts, which can change over time. In the case of our Medicaid pricing data, if we become aware that our reporting for a prior quarter was incorrect or has changed as a result of recalculation of the pricing data, we are obligated to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the Medicaid Drug Rebate program and could result in an overage or underage in our rebate liability for past quarters. Price recalculations also may affect the ceiling price at which we are required to offer our products under the 340B program. Civil monetary penalties can be applied if we are found to have knowingly submitted any false price or product information to the government, if we are found to have made a misrepresentation in the reporting of our average sales price, if we fail to submit the required price data on a timely basis, or if we are found to have charged 340B covered entities more than the statutorily mandated ceiling price. CMS, could also decide to terminate our Medicaid drug rebate agreement, in which case federal payments may not be available under Medicaid or Medicare Part B for our covered outpatient drugs. We cannot assure you that our submissions will not be found by CMS to be incomplete or incorrect. Our failure to comply with our reporting and payment obligations under the Medicaid Drug Rebate program and other governmental programs could negatively impact our financial results. We may be subject to foreign, federal, and state data privacy and security laws, and failure to protect our information systems against security breaches, service interruptions, or misappropriation of data could disrupt operations, compromise sensitive data, and expose us to liability, possibly causing our business and reputation to suffer. In the United States, numerous federal and state laws and regulations govern the collection, use, disclosure and protection of health- related and other personal information and could apply to our operations or the operations of our collaborators and third- party providers. Certain of these laws grant individual rights with respect to their information, and we may be required to expend significant resources to comply with these laws. For example, the California Consumer Privacy Act, or CCPA, was enacted in 2020. These laws and regulations are evolving and subject to interpretation and may impose limitations on our activities or otherwise adversely affect our business. Similarly, there are a number of legislative proposals in the European Union, the United States, at both the federal and state level, as well as other jurisdictions that could impose new obligations or limitations in areas affecting our business. These changes may lead to additional costs and increase our overall risk exposure. RISKS RELATING TO INTELLECTUAL PROPERTY Our strategy to secure and extend marketing exclusivity or patent rights may provide only limited or no protection from competition. We seek to secure and extend marketing exclusivity for our products through a variety of means, including FDA exclusivity and patent rights. Additional barriers for competitors seeking to enter the market include the time and cost associated with the development, regulatory approval and manufacturing of a similar product formulation. As discussed in Part I, Item 1, Business-

Patents, Trademarks, and Other Intellectual Proprietary Rights, of this report on Form 10- K, we have several patents for formulations of Acetadote, and have previously engaged in litigation to enforce our patent rights. We intend to continue to vigorously defend and protect our Acetadote product and related intellectual property rights. If we are unsuccessful in protecting our Acetadote intellectual property rights, our competitors may be able to introduce products into the marketplace that reduce the sales and market share of our Acetadote product which may require us to take measures such as reducing prices or increasing our marketing expense, any of which may result in a material adverse effect to our financial condition and results of operations. While we consider patent protection when evaluating product acquisition opportunities, any products we acquire in the future may not have significant patent protection. Neither the USPTO nor the courts have a consistent policy regarding the breadth of claims allowed or the degree of protection afforded under many pharmaceutical patents. Patent applications in the U. S. and many foreign jurisdictions are typically not published until 18 months following the filing date of the first related application, and in some cases not at all. In addition, publication of discoveries in scientific literature often lags significantly behind actual discoveries. Therefore, neither we nor our licensors can be certain that we or they were the first to make the inventions claimed in our issued patents or pending patent applications, or that we or they were the first to file for protection of the inventions set forth in these patent applications. **Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain.** In addition, changes in either patent laws or in interpretations of patent laws in the U. S. and other countries may **increase the uncertainties and costs,** diminish the value of our intellectual property **,** or narrow the scope of our patent protection. Furthermore, our competitors may independently develop similar technologies or duplicate technology developed by us in a manner that does not infringe our patents or other intellectual property. As a result of these factors, our patent rights may not provide any commercially valuable protection from competing products. If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected. In addition to patents, we rely upon trade secrets, unpatented proprietary know- how and continuing technological innovation where we do not believe patent protection is appropriate or attainable. For example, the manufacturing process for Kristalose involves substantial trade secrets and proprietary know- how. We have entered into confidentiality agreements with certain key employees and consultants pursuant to which such employees and consultants must assign to us any inventions relating to our business if made by them while they are our employees, as well as certain confidentiality agreements relating to the acquisition of rights to products. Confidentiality agreements can be breached, though, and we might not have adequate remedies for any breach. Also, others could acquire or independently develop similar technology. We may depend on certain licensors for the maintenance and enforcement of intellectual property rights and have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf. When we license products, we often depend on our licensors to protect the proprietary rights covering those products. We have limited, if any, control over the amount or timing of resources that our licensors devote on our behalf or the priority they place on maintaining patent or other rights and prosecuting patent applications to our advantage. While any such licensor is expected to be contractually obligated to diligently pursue its patent applications and allow us the opportunity to consult, review and comment on patent office communications, we cannot be sure that it will perform as required. If a licensor does not perform and if we do not assume the maintenance of the licensed patents in sufficient time to make required payments or filings with the appropriate governmental agencies, we risk losing the benefit of all or some of those patent rights. If the use of our technology conflicts with the intellectual property rights of third parties, we may incur substantial liabilities, and we may be unable to commercialize products based on this technology in a profitable manner or at all. If our products conflict with the intellectual property rights of others, they could bring legal action against us or our licensors, licensees, manufacturers, customers or collaborators. If we were found to be infringing a patent or other intellectual property rights held by a third party, we could be forced to seek a license to use the patented or otherwise protected technology. We might not be able to obtain such a license on terms acceptable to us or at all. If legal action involving an alleged infringement or misappropriation were to be brought against us or our licensors, we would incur substantial costs in defending the action. If such a dispute were to be resolved against us, we could be subject to significant damages, and the manufacturing or sale of one or more of our products could be enjoined. We may be involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, which could be costly and time consuming. We have been involved in lawsuits for infringement of the Acetadote Patents as previously described. Because of their nature, these lawsuits can be costly and time- consuming, and we only experience limited benefits and patent protection. A significant adverse ruling in any such lawsuit could put our patents at risk of being invalidated or interpreted narrowly and could compromise the issuance of our existing patent applications. Competitors may infringe on our patents or the patents of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to our patent applications or those of our collaborators or licensors. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be disclosed during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. We may be involved in lawsuits to protect or enforce our trademarks or for allegedly infringing the trademark rights of others, which could be costly and time consuming. We own certain trademark registrations for

each of our branded pharmaceutical products as well as for our corporate name and logo. We have applied for trademark registration for other various names and logos. We also may have common law trademark rights in unregistered names, phrases, and logos under which we market or offer certain products and services. Over time, we intend to obtain and maintain registrations on trademarks that remain valuable to our business. Third parties may oppose registration of our federal trademark applications. Further, we could be involved in lawsuits for allegedly infringing the rights of others with respect to their prior-existing trademarks. These lawsuits or opposition proceedings can be costly and time- consuming. A significant adverse ruling in any such lawsuit could put our trademarks at risk of being invalidated and could compromise the issuance of our existing trademark applications. Competitors may infringe on our trademarks or the trademarks of our collaborators or licensors. To counter infringement or unauthorized use, we may be required to file trademark infringement claims, which can be expensive and time- consuming. In addition, in a trademark infringement proceeding, a court may decide that a trademark registration of ours is not valid or is unenforceable, or may refuse to stop the other party from using the mark or a mark that is similar to our registered mark at issue on the grounds that the competitor' s use of the mark is not confusingly similar to our registered trademark. An adverse result in any litigation or defense proceeding could put one or more of our trademark registrations at risk of being invalidated or interpreted narrowly and could put our trademark applications at risk of not registering. If we breach any of the agreements under which we license rights to our products and product candidates from others, we could lose the ability to continue commercialization of our products and development and commercialization of our product candidates. We have exclusive licenses for the marketing and sale of certain products and may acquire additional licenses. Such licenses may terminate prior to expiration if we breach our obligations under the license agreement related to these pharmaceutical products. For example, the licenses may terminate if we fail to meet specified quality control standards, including GMP with respect to the products, or commit a material breach of other terms and conditions of the licenses. Such early termination could have a material adverse effect on our business, financial condition and results of operations. We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers. As is common in the biotechnology and pharmaceutical industry, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we or these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. We are subject to stringent government regulation. All of our products face regulatory challenges. RISKS RELATED TO OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS Our operating results are likely to fluctuate from period to period. We are a company actively seeking to deliver significant growth. As we execute our business strategy of adding new products, increasing market share in our existing growth products and striving to maintain market share in our other products, we anticipate that there may be fluctuations in our future operating results. We may not be able to maintain or improve our current levels of revenue or income. Potential causes of future fluctuations in our operating results may include: • New product launches, which could increase revenues but also increase sales and marketing expenses; • Acquisition activity and other charges; • Increases in research and development expenses resulting from the acquisition of a product candidate that requires significant additional studies and development; • Ability to utilize unrecognized federal and state net operating loss carryforwards as a result of the exercise of nonqualified options • Changes in the competitive, regulatory or reimbursement environment, which could drive down revenues or drive up sales and marketing or compliance costs; and • Unexpected product liability or intellectual property claims and lawsuits. See also " Management' s discussion and analysis of financial condition and results of operations — Liquidity and capital resources. " Fluctuation in operating results, particularly if not anticipated by investors and other members of the financial community, could add to volatility in our stock price. Our focus on acquisitions as a growth strategy has created intangible assets whose amortization could negatively affect our results of operations. Our total assets include intangible assets related to our acquisitions. As of December 31, ~~2022~~ **2023** , intangible assets relating to products, which are being amortized, represented approximately ~~33 %~~ **28 percent** of our total assets. We may never realize the value of these assets. U. S. Generally Accepted Accounting Principles (" GAAP") require that we evaluate on a regular basis whether events and circumstances have occurred that indicate that all or a portion of the carrying amount of the asset may no longer be recoverable, in which case we would write down the value of the asset and take a corresponding charge to earnings. Any determination requiring the write- off of a significant portion of unamortized intangible assets would adversely affect our results of operations. We may need additional funding and may be unable to raise capital when needed, which could force us to delay, reduce or eliminate our product development or commercialization and marketing efforts. We may need to raise additional funds in order to meet the capital requirements of running our business and acquiring and developing new pharmaceutical products. If we require additional funding, we may seek to sell common stock or other equity or equity- linked securities, which could result in dilution to our shareholders. We may also seek to raise capital through a debt financing, which would result in ongoing debt- service payments and increased interest expense. Furthermore, the terms of any additional debt securities we may issue in the future may impose restrictions on our operations, which may include limiting our ability to incur additional indebtedness, pay dividends on or repurchase our common shares, or make certain acquisitions or investments. In addition, we may be subject to covenants requiring us to satisfy certain financial tests and ratios, and our ability to satisfy such covenants may be affected by events outside of our control. Any financings would also likely involve operational and financial restrictions being imposed on us. If we are unable to obtain any needed additional funding, we may be required to reduce the scope of, delay, or eliminate some or all of, our planned research, development and commercialization activities or to license to third parties the rights to develop and / or commercialize products or technologies that we would otherwise seek to develop and / or commercialize ourselves or on terms that are less attractive than they might otherwise be, any of which could materially harm our business. We might also seek to sell assets or rights in one or more commercial products or product development programs.

Additional capital might not be available to us when we need it. We are unable to predict the impact of global credit market trends, and if economic conditions deteriorate, our business, results of operations and ability to raise needed capital could be materially and adversely affected. If we are unable to raise additional capital when needed due to the reasons listed above and lack of creditworthiness, bank failures, or price decline in market investments, we could be forced to scale back our operations to conserve cash. We may incur losses in the future and we may not achieve or maintain profitability. We intend to continue to spend significant amounts on our efforts to discover and develop drugs. As a result, we may incur losses in future periods. We anticipate that our drug discovery and development efforts and related expenditures will increase as we focus on the studies, including clinical trials prior to seeking regulatory approval, that are required before we can sell a drug product. The development of drug products will require us to spend significant funds on research, development, testing, obtaining regulatory approvals, manufacturing and marketing. We cannot be certain whether or when we will achieve profitability because of the significant uncertainties relating to our ability to generate commercially successful drug products. Even if we are successful in obtaining regulatory approvals for manufacturing and commercializing additional drug products, we may incur losses if our drug products do not generate significant revenues. If we achieve profitability, we may not be able to sustain or increase profitability. Our officers, directors, and principal shareholders, acting as a group, could significantly influence corporate actions. As of December 31, ~~2022~~ **2023**, our officers and directors control approximately ~~41~~ **43**. ~~81~~ **3** percent of our common stock. Acting together, these shareholders could significantly influence any matter requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combinations. The interests of this group may not always coincide with our interests or the interests of other shareholders and may prevent or delay a change in control. This significant concentration of share ownership may adversely affect the trading price of our common stock because many investors perceive disadvantages to owning stock in companies with controlling shareholders. Research analysts may not continue to provide or initiate coverage of our common stock or may issue negative reports. The market for our common stock may be affected by the reports financial analysts publish about us. If one of the analysts covering us downgrades our stock, its price could decline rapidly and significantly. Securities analysts covering our common stock may discontinue coverage. A lack of research coverage may adversely affect our stock' s market price. RISKS RELATED TO OWNING OUR STOCK The market price of our common stock may fluctuate substantially. The price for the shares of our common stock sold in our initial public offering was determined by negotiation between the representatives of the underwriters and us. This price may not have reflected the market price of our common stock following our initial public offering. Moreover, the market price of our common stock might decline below current levels. In addition, the market price of our common stock is likely to be highly volatile and may fluctuate substantially. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales may occur could cause the market price of our common stock to decline. The realization of any of the risks described in these " Risk Factors " could have a dramatic and material adverse impact on the market price of our common stock. In addition, securities class action litigation has often been instituted against companies whose securities have experienced periods of volatility in market price. Any such securities litigation brought against us could result in substantial costs and a diversion of management' s attention and resources, which could negatively impact our business, operating results and financial condition. Unstable market conditions may have serious adverse consequences on our business. Our general business strategy may be adversely affected by unpredictable and unstable market conditions. While we believe we have adequate capital resources to meet current working capital and capital expenditure requirements, a radical economic downturn or increase in our expenses could require additional financing on less than attractive rates or on terms that are dilutive to existing shareholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical developments plans. There is a risk that one or more of our current service providers, manufacturers and other partners may encounter difficult economic circumstances, which would directly affect our ability to attain our operating goals on schedule and on budget. The equity and lending markets have been and will most likely continue to be negatively impacted for an unknown period of time due to global events such as the COVID- 19 pandemic, increased inflation and the U. S. government' s response thereto. We may not be able to maintain our listing on the NASDAQ Global Select Market (" NASDAQ "), which could have a material adverse effect on us and our stockholders. The standards for continued listing on NASDAQ include, among other things, that the minimum bid price for the listed securities not fall below $ 1. 00 for a period in excess of thirty consecutive business days. If the closing bid price of our common stock were to fail to meet NASDAQ' s minimum closing bid price requirement, or if we otherwise fail to meet any other applicable requirements of NASDAQ and we are unable to regain compliance, NASDAQ may make a determination to delist our common stock. The delisting of our common stock from NASDAQ could negatively impact us by (i) reducing the liquidity and market price of our common stock; (ii) reducing the number of investors willing to hold or acquire our common stock, which could negatively impact our ability to raise equity financing; (iii) impacting our ability to use a registration statement to offer and sell freely tradable securities, thereby preventing or limiting us from accessing the public capital markets; and (iv) impairing our ability to provide equity incentives to our employees. Some provisions of our third amended and restated charter, bylaws and Tennessee law may inhibit potential acquisition bids that you may consider favorable. Our corporate documents contain provisions that may enable our board of directors to resist a change in control of our company even if a change in control were to be considered favorable by you and other shareholders. These provisions include: • The authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without shareholder approval; • Advance notice procedures required for shareholders to nominate candidates for election as directors or to bring matters before an annual meeting of shareholders; • Limitations on persons authorized to call a special meeting of shareholders; • A staggered board of directors; • A restriction prohibiting shareholders from removing directors without cause; • A requirement that vacancies in directorships are to be filled by a majority of the directors then in office and the number of directors is to be fixed by the board of directors; and • No cumulative voting. These and other provisions contained in our third

amended and restated charter and bylaws could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which our shareholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of shareholders to remove our current management or approve transactions that our shareholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock. In addition, we are subject to control share acquisitions provisions and affiliated transaction provisions of the Tennessee Business Corporation Act, the applications of which may have the effect of delaying or preventing a merger, takeover or other change in control of us and therefore could discourage attempts to acquire our company. We have never paid cash dividends on our capital stock. We have never paid cash dividends on our capital stock. The availability of funds for distributions to shareholders will depend on our financial performance and assets. Any future decision to declare or pay dividends will be at the sole discretion of our Board of Directors. DEBT- RELATED RISKS Our Revolving Credit Agreement impose restrictive and financial covenants on us. Our failure to comply with these covenants could trigger events that would have a material adverse effect on our business. Our Revolving Credit Agreement contains covenants that restrict the way we conduct business and require us to satisfy certain financial tests in order to incur debt or take other actions. Additionally, our Revolving Credit Agreement contains financial covenants that, for example, require us to maintain certain financial ratios which are measured at the end of each fiscal quarter. Our Revolving Credit Agreement contains specified quarterly financial maintenance covenants. As of December 31, ~~2022~~ **2023** , we were in compliance with the Maximum Funded Debt Ratio financial covenant of the Revolving Credit Agreement. However, we can make no assurance that we will be able to comply with the restrictive and financial covenants contained in the Revolving Credit Agreement in the future. Our inability to comply with the covenants in our debt instruments could lead to a default or an event of default under the terms thereof, for which we may need to seek relief from our lender in order to waive the associated default or event of default and avoid a potential acceleration of the related indebtedness or cross- default or cross- acceleration to other debt. There can be no assurance that we would be able to obtain such relief on commercially reasonable terms or otherwise and we may be required to incur significant additional costs. In addition, the lender under our Revolving Credit Agreement may impose additional operating and financial restrictions on us as a condition to granting any such waiver. If an event of default is not cured or is not otherwise waived, the lender under our Revolving Credit Agreement may accelerate the maturity of the related debt, foreclose upon any collateral securing the debt and terminate any commitments to lend, any of which would have a material adverse effect on our business, financial condition, cash flows and results of operations and would cause the market value of our securities to decline. We have risks related to interest rates. Our revolving credit facility bears interest based on variable interest. Thus, a change in the short- term interest rate environment (especially a material change) could have a material adverse effect on our business, financial condition, cash flows and results of operations. As of December 31, ~~2022~~ **2023** , we did not have any outstanding interest rate swap contracts. ~~57~~