Risk Factors Comparison 2024-02-27 to 2023-02-23 Form: 10-K

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You should consider carefully the following information about the risks described below, together with the other information contained in this Annual Report before you decide to buy or maintain an investment in our common stock. We believe the risks described below are the risks that are material to us as of the date of this Annual Report. Additional risks and uncertainties that we are unaware of may also become important factors that affect us. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or part of the money you paid to buy our common stock. RISKS RELATED TO OUR BUSINESS The products that we or our collaboration partner are commercializing may only achieve a limited degree of commercial success. Successful commercialization of therapeutic products is subject to many risks, including some that are outside our control. There are numerous examples of failures to fully exploit the market potential of therapeutic products, including by biopharmaceutical and device companies with more experience and resources than us. ~~The products~~ **Products** ~~,~~ **that we commercialize ourselves (** including **any** products that we ~~commercialize ourselves and any~~ **may develop or acquire in the** future **)** ~~, products that we may develop or acquire in the future~~ and the product that is commercialized by our **current** collaboration partner ~~and~~ **(including** future products that may be commercialized by ~~a~~ **our** collaboration partner ~~,~~ **)** may not gain market acceptance among physicians, patients, third- party payers and the healthcare community. The degree of market acceptance of our or a collaboration partner' s products depends on many factors, including the following: • approved labeling claims; • effectiveness of efforts by us and / or any current or future collaboration or marketing partner to support and educate patients and physicians about the benefits and proper administration of our products, and the perceived advantages of our products and the disadvantages of competitive products; • willingness of the healthcare community and patients to adopt new technologies; • ability to manufacture the product in sufficient quantities with acceptable quality and cost; • perception of patients and the healthcare community, including third- party payers, regarding the safety, efficacy and benefits compared to competing products or therapies; • convenience and ease of administration relative to existing treatment methods; • coverage and reimbursement, as well as pricing relative to other treatment therapeutics and methods; and • marketing and distribution support. Because of these and other factors, the products described above may not gain market acceptance or otherwise be commercially successful. Failure to achieve market acceptance would limit our ability to generate revenue and would adversely affect our results of operations. We ~~or~~ **and** our current or any future collaboration partner may need to enhance our / their commercialization capabilities in order to successfully commercialize such products in the United States or any other jurisdiction in which ~~the~~ **such** product is approved for commercial sale, and we or the collaboration partner may not have sufficient resources to do so **. In order to increase adoption and sales of our products, we need to continue to develop our commercial organization, including maintaining and growing a highly experienced and skilled workforce with qualified sales representatives. We have built a sales force that promotes Afrezza and V- Go to endocrinologists and selected primary care physicians. In order to successfully commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other commercial capabilities** . The market for skilled commercial personnel is highly competitive, and we may not be able to hire all of the personnel we need on a timely basis or retain them for a sufficient period. ~~In order to increase adoption and sales of our products, we need to continue to develop our commercial organization, including maintaining and growing a highly experienced and skilled workforce with qualified sales representatives. In order to successfully commercialize our products in the United States, we have built a sales force that promotes Afrezza and V- Go to endocrinologists and selected primary care physicians. In order to successfully commercialize any approved products, we must continue to build our sales, marketing, distribution, managerial and other non-technical capabilities.~~ Factors that may hinder our ability to successfully market and commercially distribute our products include: • inability to recruit, retain and effectively manage adequate numbers of effective sales personnel; • lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies that have more extensive product lines; and • unforeseen delays, costs and expenses associated with maintaining our sales organization. If we are unable to maintain an effective sales force for our products, including any other potential future approved products, we may not be able to generate sufficient product revenue in the United States. We are required to expend significant time and resources to train our sales force to **educate** ~~be credible and persuasive in convincing~~ physicians **about** ~~to prescribe and pharmacists to dispense~~ our products. In addition, we must continually train our sales force and equip them with effective marketing materials to ensure that a consistent and appropriate message about our products is being delivered to our potential customers. We currently have limited resources compared to some of our competitors, and the continued development of our own commercial organization to market our products and any additional products we may develop or acquire will be expensive and time- consuming. We also cannot be certain that we will be able to continue to successfully develop this capability. Similarly, if **UT** ~~United Therapeutics~~ does not effectively engage or maintain its sales force for Tyvaso DPI, our ability to recognize royalties and manufacturing revenue from this collaboration will be adversely affected. Manufacturing risks may adversely affect our ability to manufacture our products and Tyvaso DPI, which and could reduce our gross margin and profitability. We use our Danbury, Connecticut facility to formulate both the Afrezza and Tyvaso DPI inhalation powders, fill plastic cartridges with the powders, and package the cartridges into secondary packaging. We also assemble the inhalers from their individual molded parts. These semi- finished goods are then assembled into the final kits for commercial sale by a contract packager. The manufacture of pharmaceutical products requires significant expertise and capital investment, including

the development of advanced manufacturing techniques and process controls. Manufacturers of pharmaceutical products often encounter difficulties in production, especially in scaling up production to commercial batch sizes. These problems include difficulties with production costs, capacity utilization and yields. We may **also** experience shortages of qualified personnel, which could impact our ability to meet manufacturing requirements. **In addition,** ~~There~~ **there** is ~~also~~ a need to comply with strictly enforced federal, state and foreign regulations, including inspections. Our facility is inspected on a regular basis by the FDA ~~, most recently in July 2021 when the FDA conducted a pre- approval inspection related to Tyvaso DPI and a GMP inspection related to Afrezza. The FDA made one observation during its most recent inspection, which we corrected and addressed with the FDA following the site visit~~ . If the FDA makes any major observations during future inspections, the corrective actions required could be onerous and time- consuming. Any of these factors could cause us to delay or suspend production, could entail higher costs and may result in our being unable to obtain sufficient quantities for the commercialization of drug products at the costs that we currently anticipate. Furthermore, if we or a third- party manufacturer fail to deliver the required commercial quantities of the product or any raw material on a timely basis, and at commercially reasonable prices, sustainable compliance and acceptable quality, and we were unable to promptly find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volume and quality on a timely basis, we would likely be unable to meet demand for such drug products and we would lose potential revenues **. As demand for our products increases, we may have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, we may be unable to support commercialization of Tyvaso DPI** . In addition, we rely on our contract manufacturers in Southern China to manufacture V- Go. Our contract manufacturer uses MannKind- owned custom- designed, semi- automated manufacturing equipment and production lines to meet our quality requirements. Separate contract manufacturers in China perform release testing, sterilization, inspection and packaging functions. As a result, our business is subject to risks associated with doing business in China, including: • adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China; • trade protection measures, such as tariff increases, and import and export licensing and control requirements; • potentially negative consequences from changes in tax laws; • difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China; • historically lower protection of intellectual property rights; • unexpected or unfavorable changes in regulatory requirements; • changes and volatility in currency exchange rates; • possible patient or physician preferences for more established pharmaceutical products and medical devices manufactured in the United States; and • difficulties in managing foreign relationships and operations generally. These risks are likely to be exacerbated by our limited experience with V- Go and its manufacturing processes. ~~As demand increases, we may have to invest additional resources to purchase components, hire and train employees, and enhance our manufacturing processes. If we fail to increase our production capacity efficiently, our sales may not increase in line with our forecasts and our operating margins could fluctuate or decline. In addition, we may be unable to support commercialization of Tyvaso DPI.~~ If our suppliers fail to deliver materials and services needed for commercial manufacturing in a timely and sufficient manner or fail to comply with applicable regulations, and if we fail to timely identify and qualify alternative suppliers, our business, financial condition and results of operations would be harmed and the market price of our common stock and other securities could decline. For the commercial manufacture of inhaled drug products, we need access to sufficient, reliable and affordable supplies of FDKP, the inhaler, the related cartridges and other materials. For Afrezza, we also require a supply of insulin. Currently, the only source of insulin that we have qualified for Afrezza is manufactured by Amphastar. We must rely on all of our suppliers to comply with relevant regulatory and other legal requirements, including the production of insulin and FDKP in accordance with ~~current good manufacturing practices (“~~ cGMP ~~”)~~ for drug products, and the molding of the inhaler and cartridges components in accordance with ~~quality system regulations (“~~ QSRs ~~”)~~. For V- Go, we obtain parts from a small number of suppliers, including some parts and components that are purchased from single- source vendors. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. In addition, we do not have long- term supply agreements with most of our suppliers and, in many cases, we make our purchases on a purchase order basis. Under many of our supply agreements, we have no obligation to buy any given quantity of components, and our suppliers have no obligation to manufacture for us or sell to us any given quantity of components. Because we do not have long- standing relationships with **all of** our suppliers, we may not be able to convince them to continue to make components available to us unless there is demand for such components from their other customers. If any one or more of our suppliers cease to provide us with sufficient quantities of components in a timely manner or on terms acceptable to us, we would have to seek alternative sources of supply. Because of factors such as the proprietary nature of our product, our quality control standards and regulatory requirements, we cannot quickly engage additional or replacement suppliers for some of our critical components. We may also have difficulty obtaining similar components from other suppliers that meet the requirements of the FDA or other regulatory agencies. Although we conduct our own inspections and review and / or approve investigations of each supplier, there can be no assurance that the FDA, upon inspection, would find that the supplier substantially complies with the QSR or cGMP requirements, where applicable. If a supplier fails to comply with these requirements or the comparable requirements in foreign countries, regulatory authorities may subject us to regulatory action, including criminal prosecutions, fines and suspension of the manufacture of our products. If we are required to find a new or additional supplier, we will need to evaluate that supplier’ s ability to provide material that meets regulatory requirements, including cGMP or QSR requirements, as well as our specifications and quality requirements, which would require significant time and expense and could delay production. As a result, our ability to purchase adequate quantities of the components for our products may be limited. Additionally, our suppliers may encounter problems that limit their ability to manufacture components for us, including financial difficulties or damage to their manufacturing equipment

or facilities. In general, if any of our suppliers is unwilling or unable to meet its supply obligations or if we encounter delays or difficulties in our relationships with manufacturers or suppliers, and we are unable to secure an alternative supply source in a timely manner and on favorable terms, our business, financial condition, and results of operations may be harmed and the market price of our common stock and other securities may decline. If third- party payers do not cover our approved products, such products might not be prescribed, used or purchased, which would adversely affect our revenues. In the United States and elsewhere, sales of prescription pharmaceuticals ~~still~~ depend in large part on the availability of coverage and adequate reimbursement to the consumer from third- party payers, such as government health administration authorities and private insurance plans. Third- party payers are increasingly challenging the prices charged for medical products and services. The market for our approved products ~~will depend~~ **depends** significantly on access to third- party payers' formularies, which are the lists of medications and devices for which third- party payers provide coverage and reimbursement. The industry competition to be included in such formularies often leads to downward pricing pressures on pharmaceutical and device companies. Also, third- party payers may refuse to include a particular branded product in their formularies or otherwise restrict patient access to a branded product when a less costly generic equivalent or other alternative is available. Even if favorable coverage and reimbursement status is attained for our products, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, because each third- party payer individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time- consuming and costly process. We may be required to provide scientific and clinical support for the use of any product to each third- party payer separately with no assurance that approval would be obtained. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. Even if we succeed in bringing more products to market, we cannot be certain that any such products would be considered cost- effective or that coverage and adequate reimbursement to the consumer would be available. Patients will be unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of government and other third- party payers to contain or reduce the costs of healthcare through various means. In the United States, there have been several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, the IRA ~~, which was signed into law in August 2022, will limit~~ **limited** insulin copays to $ 35 per month for Medicare Part D beneficiaries starting in 2023. In certain foreign markets **,** the pricing of prescription pharmaceuticals is subject to direct governmental control. The European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. If we or any collaboration or marketing partner is unable to obtain and maintain coverage of, and adequate third- party reimbursement for, our approved products, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our or any collaboration or marketing partner' s ability to successfully commercialize such products and would impact our profitability, results of operations, financial condition, and prospects. We may need to raise additional capital to fund our operations. We may need to raise additional capital, whether through the sale of equity or debt securities, additional strategic business collaborations, the establishment of other funding facilities, licensing arrangements, asset sales or other means, in order to support our ongoing activities, including the commercialization of our products and the development of our product candidates. It may be difficult for us to raise additional funds on favorable terms, or at all. The extent of our additional funding requirements will depend on a number of factors, including: • the degree to which we are able to generate revenue from products that we or a collaboration partner commercialize; • the costs of developing Afrezza and of commercializing Afrezza and V- Go on our own in the United States; • the degree to which revenue from Afrezza exceeds or ~~does~~ not ~~exceed~~ the minimum revenue covenants under our credit and security agreement with MidCap Financial Trust (the " MidCap credit facility "), if applicable; • the demand by any or all of the holders of our debt instruments to require us to repay or repurchase such debt securities if and when required; • our ability to repay or refinance existing indebtedness, and the extent to which our notes with conversion options or any other convertible debt securities we may issue are converted into or exchanged for shares of our common stock; • the rate of progress and costs of our clinical studies and ~~research and development~~ **R & D** activities; • the costs of procuring raw materials and operating our manufacturing facility ~~; • our obligation to make lease payments and milestone payments~~ ; • our success in establishing additional strategic business collaborations or other sales or licensing of assets, and the timing and amount of any payments we might receive from any such transactions; • actions taken by the FDA and other regulatory authorities affecting Afrezza, V- Go, Tyvaso DPI, our product candidates or competitive products; • the emergence of competing technologies and products and other market developments; • the costs of preparing, filing, prosecuting, maintaining and enforcing patent claims and other intellectual property rights or defending against claims of infringement by others; • the level of our legal and litigation expenses; and • the costs of discontinuing projects and technologies, and / or decommissioning existing facilities, if we undertake any such activities. We have raised capital in the past through the sale of equity and debt securities and ~~we may in~~ **the sale of certain assets. In** the future **, we may** pursue the sale of additional equity **,** ~~and / or~~ debt securities **and / or assets** , or the establishment of other funding facilities including asset- based borrowings. There can be no assurances, however, that we will be able to raise additional capital in the future on acceptable terms, or at all. Volatility and disruptions of the global supply chain and financial markets, if sustained or recurrent, could prevent us or make it more difficult for us to access capital. Issuances of additional debt or equity securities or the issuance of common stock upon conversion of outstanding convertible debt securities for shares of our common stock could impact the rights of the holders of our common stock and will dilute their ownership percentage.

Moreover, the establishment of other funding facilities may impose restrictions on our operations. These restrictions could include limitations on additional borrowing and specific restrictions on the use of our assets, as well as prohibitions on our ability to create liens, pay dividends, redeem our stock or make investments. We may also raise additional capital by pursuing opportunities for the licensing or sale of certain intellectual property and other assets. We cannot offer assurances, however, that any strategic collaboration, sales of securities or sales or licenses of assets will be available to us on a timely basis or on acceptable terms, if at all. We may be required to enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop independently, and any such relationships may not be on terms as commercially favorable to us as might otherwise be the case. In the event that sufficient additional funds are not obtained through strategic collaboration opportunities, sales of securities, funding facilities, licensing arrangements, borrowing arrangements and / or asset sales on a timely basis, we may be required to reduce expenses through the delay, reduction or curtailment of our projects, or further reduction of costs for facilities and administration. We cannot provide assurances that changed or unexpected circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. There can be no assurances that we will be able to raise additional capital in sufficient amounts or on favorable terms, or at all. If we are unable to raise adequate additional capital when required or in sufficient amounts or on terms acceptable to us, we may have to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities, significantly reduce expenses, sell assets (potentially at a loss), enter into relationships with third parties to develop or commercialize products or technologies that we otherwise would have sought to develop or commercialize independently, cease operations altogether, pursue an acquisition of our company at a price that may result in up to a total loss on investment for our stockholders, file for bankruptcy or seek other protection from creditors, or liquidate all of our assets. We expect that our results of operations..... that we are required to perform. If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences. We, and third parties acting on our behalf, employ and are increasingly dependent upon information technology systems, infrastructure, applications, websites and other resources. Our business requires collecting, receiving, manipulating, analyzing, storing, processing, generating, using, disclosing, protecting, securing, transmitting, sharing, disposing of, and making accessible (collectively " ~~processing~~ --- **process** ") large amounts of data, including proprietary, confidential and sensitive data (such as personal or health- related data), intellectual property, and trade secrets (collectively, " sensitive information "). ~~Cyberattacks~~ **Cyber- attacks** , malicious internet- based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to increase **,** are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors " hacktivists, " organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation- states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors, for geopolitical reasons and in conjunction with military conflicts and defense activities. **During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.** We and the third parties upon which we rely may be subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through **deep fakes, which may be increasingly more difficult to identify as fake, and** phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks (such as credential stuffing), credentials harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, **attacks enhanced or facilitated by artificial intelligence,** and other similar threats. Ransomware attacks, including by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments ~~. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services~~ . Some of our workforce works remotely, which also poses increased risks to our information technology systems and data, as employees working from home, in transit or in public locations, utilize network connections, computers and devices outside our premises or network. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. We may rely on third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, cloud- based infrastructure, data center facilities, encryption and authentication technology, employee email, and other functions. We may also rely on third- party service providers to provide other products or services, or otherwise to operate our business. For example, we rely on an enterprise software system to operate and manage our business. Our business, including our ability to manufacture drug products and conduct clinical trials, therefore depends on the continuous, effective, reliable and secure operation of our information technology resources and those of third parties acting

on our behalf, including computer hardware, software, networks, Internet servers and related infrastructure. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. In particular, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our products) or the third- party information technology systems that support us and our services. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. ~~Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our products. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry- standards or reasonable security measures to protect our information technology systems and sensitive information.~~ While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We **take steps to detect and remediate vulnerabilities in our information security systems (such as our hardware and / or software, including that of third parties upon which we rely), but we may not be able to detect, mitigate, and remediate all such vulnerabilities on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. We** have ~~not always been able~~ in the past ~~and~~ **experienced security incidents. For example, like** ~~may~~ **many** ~~be unable in the future~~ **companies, we use SolarWinds** to **help manage** ~~detect vulnerabilities in~~ our information technology systems ~~because such threats and techniques change frequently, are often sophisticated in nature, and may not be detected until after a security incident has occurred. For example, like many companies, we use SolarWinds to help manage our information technology systems~~ . A ~~cyberattack~~ **cyber- attack** on SolarWinds was discovered in December 2020 and widely exploited by threat actors. Upon learning of this vulnerability, we applied the software patch provided by SolarWinds and remediated the incident. The incident did not appear to have any negative impact on our operations or the sensitive information we may process. In addition, a ransomware attack on Ultimate Kronos Group' s (" UKG ") Kronos Private Cloud service was discovered in December 2021. ~~We~~ **At the time, we** ~~use~~ **used** UKG Pro, a product offered through UKG that is not in the Kronos Private Cloud, for human capital management. UKG is not aware of an impact on UKG Pro and the incident did not appear to have any negative impact on our operations or the sensitive information we may process. ~~Thus,~~ **These incidents illustrate that** despite our efforts to identify and remediate vulnerabilities, if any, in our information technology systems, our efforts may not be successful. ~~Further, we may experience delays~~ **Any of the previously identified or similar threats could cause a security incident or other interruption that could result** in ~~developing~~ **unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (** and ~~deploying remedial~~ **that of third parties upon whom we rely) to provide our products. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security** measures ~~designed~~ **, industry- standards or reasonable security measures** to ~~address any such identified vulnerabilities~~ **protect our information technology systems and sensitive information** . Applicable data privacy and security obligations may require us to notify relevant stakeholders **, including affected individuals, customers, regulators, and investors,** of security incidents. Such disclosures are costly, and the disclosures or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; **diversion of management attention;** interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. Additionally, our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our cybersecurity insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims **We may not be able to generate sufficient cash to service all of our indebtedness and commitments.We may be forced to take other actions to satisfy our obligations or we may experience a financial failure.Our ability to make scheduled payments on our lease and debt obligations will depend on our financial and operating performance,which is subject to the commercial success of our products,** the extent to which we ~~enter into additional collaboration~~ **are able to successfully develop and commercialize** ~~or~~ **our products** ~~licensing arrangements~~ ,prevailing economic and competitive conditions,and **to** certain financial,business and other factors beyond our control.We cannot assure you that we will maintain a level of cash flows from operating activities sufficient to permit us to pay the

principal,premium,if any,and interest on our indebtedness.If ~~we fail to pay interest on,or repay,our outstanding term loan under the MidCap credit facility or borrowings under the Senior convertible notes or the Mann Group convertible note when required,we will be in default under the instrument for such debt securities or loans,and may also suffer an event of default under the terms of other borrowing arrangements that we may enter into from time to time.If~~ our cash flows and capital resources are insufficient to fund our obligations,we may be forced to reduce or delay capital expenditures,sell assets or operations,seek additional capital or restructure or refinance our **indebtedness and** lease obligations.We cannot assure you that we would be able to take any of these actions,that these actions would be successful and permit us to meet our scheduled obligations or that these actions would be permitted under the terms of our future debt agreements.In the absence of sufficient operating results and resources,we could face substantial liquidity problems and might be required to dispose of material assets or operations to meet our debt service and other obligations.We may not be able to consummate those dispositions or obtain sufficient proceeds from those dispositions to meet our debt service and other obligations when due **.** . Changes in funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical ~~FDA, SEC and other~~ government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations **. Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations. Adverse developments that affect financial institutions, such as events involving liquidity that are rumored or actual, have in the past and may in the future lead to bank failures and market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (" SVB ") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (" FDIC ") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. In addition, on May 1, 2023, the FDIC seized First Republic Bank and sold its assets to JPMorgan Chase & Co. While the U. S. Department of Treasury, FDIC and Federal Reserve Board have implemented a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediate liquidity may exceed the capacity of such program, there is no guarantee that such programs will be sufficient. Additionally, it is uncertain whether the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, widespread investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. We maintain our cash at financial institutions, often in balances that exceed federally insured limits. We maintain the majority of our cash and cash equivalents in accounts at banking institutions in the United States that we believe are of high quality. Cash held in these accounts often exceed the FDIC insurance limits. If such banking institutions were to**

fail, we could lose all or a portion of amounts held in excess of such insurance limitations. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position . RISKS RELATED TO GOVERNMENT REGULATION Our product candidates must undergo costly and time- consuming rigorous nonclinical and clinical testing and we must obtain regulatory approval prior to the sale and marketing of any product in each jurisdiction. The results of this testing or issues that develop in the review and approval by a regulatory agency may subject us to unanticipated delays or prevent us from marketing any products. Our research and development activities for product candidates, as well as the manufacturing and marketing of approved products, are subject to regulation, including regulation for safety, efficacy and quality, by the FDA in the United States and comparable authorities in other countries. FDA regulations and the regulations of comparable foreign regulatory authorities are wide- ranging and govern, among other things: • product design, development, manufacture and testing; • product labeling; • product storage and shipping; • pre- market clearance or approval; • advertising and promotion; and • product sales and distribution. The requirements governing the conduct of clinical studies as well as the manufacturing and marketing of drug products outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical study designs. Foreign regulatory approval processes include essentially all of the risks associated with the FDA approval processes. Some of those agencies also must approve prices of the products. Approval of a product by the FDA does not ensure approval of the same product by the health authorities of other countries. In addition, changes in regulatory policy in the United States or in foreign countries for product approval during the period of product development and regulatory agency review of each submitted new application may cause delays or rejections. Clinical testing can be costly and take many years, and the outcome is uncertain and susceptible to varying interpretations. We cannot be certain if or when regulatory agencies might request additional studies, under what conditions such studies might be requested, or what the size or length of any such studies might be. The clinical studies of our product candidates may not be completed on schedule, regulatory agencies may order us to stop or modify our research, or these agencies may not ultimately approve any of our product candidates for commercial sale. The data collected from our clinical studies may not be sufficient to support regulatory approval of our product candidates. Even if we believe the data collected from our clinical studies are sufficient, regulatory agencies have substantial discretion in the approval process and may disagree with our interpretation of the data. Our failure to adequately demonstrate the safety and efficacy of any of our product candidates would delay or prevent regulatory approval of our product candidates, which could prevent us from achieving profitability. Questions that have been raised about the safety of marketed drugs generally, including pertaining to the lack of adequate labeling, may result in increased cautiousness by regulatory agencies in reviewing new drugs based on safety, efficacy, or other regulatory considerations and may result in significant delays in obtaining regulatory approvals. Such regulatory considerations may also result in the imposition of more restrictive drug labeling or marketing requirements as conditions of approval, which may significantly affect the marketability of our drug products. If we do not comply with regulatory requirements at any stage, whether before or after marketing approval is obtained, we may be fined or forced to remove a product from the market, subject to criminal prosecution, or experience other adverse consequences, including restrictions or delays in obtaining regulatory marketing approval. Even if we comply with regulatory requirements, we may not be able to obtain the labeling claims necessary or desirable for product promotion. We may also be required to undertake post- marketing studies. In addition, if we or other parties identify adverse effects after any of our products are on the market, or if manufacturing problems occur, regulatory approval may be withdrawn and a reformulation of our products, additional clinical studies, changes in labeling of, or indications of use for, our products and / or additional marketing applications may be required. If we encounter any of the foregoing problems, our business, financial condition and results of operations will be harmed and the market price of our common stock and other securities may decline. We are subject to stringent, ongoing government regulation. The FDA and comparable foreign regulatory authorities subject any approved therapeutic product to extensive and ongoing regulatory requirements concerning the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and ~~GCP requirements~~ **good clinical practice guidelines** for any clinical trials that we conduct post- approval. Later discovery of previously unknown problems, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls; • revisions to the approved labeling to add new safety information; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals; • product seizure or detention, or refusal to permit the import or export of our product candidates; and • injunctions or the imposition of civil or criminal penalties. We also are required to register our establishments and list our products with the FDA and certain state agencies. We and any third- party manufacturers or suppliers must continually adhere to federal regulations setting forth cGMP (for drugs) and QSR (for medical devices), and their foreign equivalents, which are enforced by the FDA and other national regulatory bodies through their facilities inspection programs. In complying with cGMP and foreign regulatory requirements, we and any of our third- party manufacturers or suppliers will be obligated to expend time, money and effort in production, record- keeping and quality control to ensure that our products meet applicable specifications and other requirements. QSR requirements also impose extensive testing, control and documentation requirements. State regulatory agencies and the regulatory agencies of other countries have similar requirements. In addition, we will be required to comply with regulatory requirements of the FDA, state regulatory agencies and the regulatory agencies of other countries concerning the reporting of adverse events and device malfunctions, corrections and removals (e. g., recalls),

promotion and advertising and general prohibitions against the manufacture and distribution of adulterated and misbranded devices. Failure to comply with these regulatory requirements could result in significant civil fines, product seizures, injunctions and / or criminal prosecution of responsible individuals and us. Any such actions would have a material adverse effect on our business, financial condition and results of operations. As part of the approval of Afrezza, the FDA required us to conduct certain additional clinical studies of Afrezza. **One** ~~We have initiated one~~ of these studies, a Phase 3 clinical trial to evaluate the safety and efficacy of Afrezza in 4- 17 year- old children and adolescents **, is ongoing** ~~. We have engaged a clinical research organization to assist us with conducting this study and have budgeted the projected costs of the study in our operating plans~~ . The other required study is a long- term safety study that was originally intended to compare the incidence of pulmonary malignancy observed with Afrezza to that observed in a standard of care control group. We have an ongoing dialogue with the FDA regarding the agency' s current interest in the long- term safety of Afrezza and an appropriate study design **or registry** to address any concerns. To date, we have not commenced a long- term safety study or budgeted any amount for it, but such a study in its original design would be anticipated to require substantial capital resources that we may not be able to obtain. The FDA and other regulatory authorities impose significant restrictions on approved products through regulations on advertising, promotional and distribution activities. This oversight encompasses, but is not limited to, direct- to- consumer advertising, healthcare provider- directed advertising and promotion, sales representative communications to healthcare professionals, promotional programming and promotional activities involving the Internet. Regulatory authorities may also review industry- sponsored scientific and educational activities that make representations regarding product safety or efficacy in a promotional context. Prescription drugs may be promoted only for the approved indications in accordance with the approved label. The FDA and other regulatory authorities may take enforcement action against a company for promoting unapproved uses of a product or for other violations of its advertising and labeling laws and regulations. However, physicians may, in their independent medical judgment, prescribe legally available products for off- label uses. The FDA does not regulate the behavior of physicians in their choice of treatments, but the FDA does restrict manufacturer' s communications on the subject of off- label use of their products. Enforcement action may include product seizures, injunctions, significant civil or criminal penalties or regulatory letters, which may require corrective advertising or other corrective communications to healthcare professionals. Failure to comply with such regulations also can result in adverse publicity or increased scrutiny of company activities by the U. S. Congress or other legislators. Certain states have also adopted regulations and reporting requirements surrounding the promotion of pharmaceuticals. Failure to comply with state requirements may affect our ability to promote or sell our products in certain states. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates, delay the submission or review of an application or require additional expenditures by us. In addition, interested parties (such as individuals, advocacy groups and competing pharmaceutical companies) can file a citizen petition with the FDA to request policy change or some form of administrative action on the FDA' s part, including with respect to an NDA. For example, in July 2021, a third party submitted a citizen petition to the FDA requesting that the FDA refuse to approve Tyvaso DPI, and / or impose additional requirements in order to approve the product. This prompted the FDA to request additional information concerning Tyvaso DPI prior to granting approval in May 2022. If successful, a citizen petition can significantly delay, or even prevent, the approval of a drug product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. We also cannot be sure that actions by foreign regulatory bodies pertaining to the safety of drugs or medical devices will not adversely affect our operations. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be denied marketing approval or lose any marketing approval that we have already obtained. There can be no assurance that we will be able to obtain necessary regulatory clearances or approvals on a timely basis, if at all, for any of our product candidates under development, and delays in receipt or failure to receive such clearances or approvals, the loss of previously received clearances or approvals, or failure to comply with existing or future regulatory requirements could have a material adverse effect on our business and results of operations. Healthcare legislation may make it more difficult to receive revenues. In both the United States and certain foreign jurisdictions, there has been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products profitably. The most recent significant healthcare legislation was the ~~Patient Protection and Affordable Care Act, as amended by the Health Care Education and Reconciliation Act (collectively, the "~~ PPACA ~~")~~ , enacted in March 2010, which substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly affect the healthcare industry. There have been executive, judicial and congressional challenges to certain provisions of the PPACA, although the constitutionality of the PPACA appears to now be settled. In addition, there have been proposed and enacted health reform initiatives affecting the PPACA. For example, on August 16, 2022, President Biden signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in PPACA marketplaces through plan year 2025, eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program, and ~~caps~~ **capped** the out- of- pocket cost of insulin (including Afrezza) at $ 35 per month for Medicare recipients beginning in 2023. It is possible that the PPACA will be subject to judicial or Congressional challenges in the future. It is unclear how any such challenges, other litigation, and the healthcare reform measures of the current administration will impact the PPACA. Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. Specifically, there have been several recent U. S. Presidential executive orders, Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. These new laws and initiatives may result in additional reductions in

Medicare and other healthcare funding, which could have a material adverse effect on our customers and accordingly, our financial operations. Our future revenues and ability to generate positive cash flow from operations may be affected by the continuing efforts of government and other third- party payers to contain or reduce the costs of healthcare through various means. In the United States, there have been several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the U. S. Department of Health and Human Services (" HHS ") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions ~~will~~ take effect progressively starting in fiscal year 2023 **. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations** , although ~~they~~ **the** ~~may be~~ **Medicare drug price negotiation program is currently** subject to legal challenges. ~~It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.~~ Further, **in response to** the Biden administration ~~released an additional~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS **released** ~~to submit~~ a report **outlining** ~~on how the~~ **three** ~~Center for Medicare and Medicaid Innovation can be further leveraged to test~~ new models for **testing by the CMS Innovation Center which will be evaluated on their ability to** ~~lowering~~ **lower** ~~drug~~ **the** ~~costs~~ **cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march- in rights under the Bayh- Dole Act. On December 8, 2023, the National Institute of Standards and Technology published** for ~~Medicare~~ **comment a Draft Interagency Guidance Framework for Considering the Exercise of March- In Rights which for the first time includes the price of a product as one factor** ~~and~~ **an** ~~Medicaid beneficiaries~~ **agency can use when deciding to exercise march- in rights. While march- in rights have not previously been exercised, it is uncertain if that will continue under the new framework** . At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing **. For example, on January 5, 2024, the FDA approved Florida' s Section 804 Importation Program (SIP) proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear how this program will be implemented, including which drugs will be chosen, and whether it will be subject to legal challenges in the United States or Canada. Other states have also submitted SIP proposals that are pending review by the FDA. Any such approved importation plans, when implemented, may result in lower drug prices for products covered by those programs** . We expect that there will continue to be a number of federal and state proposals to implement similar and / or additional governmental controls. We cannot be certain what legislative proposals will be adopted or what actions federal, state or private third- party payers may take in response to any drug pricing and reimbursement reform proposals or legislation. Further, to the extent that such reforms have a material adverse effect on our ability to commercialize our products and product candidates under development, our business, financial condition and profitability may be adversely affected. We expect that ~~PPACA,~~ the IRA, as well as other healthcare reform measures that may be adopted in the future **, are likely to have a significant effect on the pharmaceutical industry** , may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private third- party payers. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products. If we or any future partner fails to comply with federal and state healthcare laws, including fraud and abuse and health information laws, we could face substantial penalties and our business, results of operations, financial condition and prospects could be adversely affected. As a biopharmaceutical company, even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payers, certain federal and state healthcare laws and regulations, including those pertaining to fraud and abuse and patients' rights, are and will be applicable to our business. The number and scope of these laws, regulations and industry standards are changing, subject to differing applications and interpretations, and may be inconsistent between jurisdictions or in conflict with each other, making compliance difficult. The key laws that may affect our ability to operate include, among others: • The federal Anti- Kickback Statute (as amended by PPACA, which modified the intent requirement of the federal Anti- Kickback Statute so that a person or entity no longer needs to have actual knowledge of the Statute or specific intent to violate it to have committed a violation), which constrains our business activities, including our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; • Federal civil and criminal false claims laws, including without limitation the False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other federal healthcare programs that are false or fraudulent, and knowingly making, or causing to be made, a false record or statement material to a false or fraudulent claim to avoid, decrease or

conceal an obligation to pay money to the federal government, and under PPACA, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal false claims laws; • The federal Physician Payments Sunshine Act under PPACA, which requires certain manufacturers of drugs, devices, biologics, and medical supplies to report annually to Centers for Medicare & Medicaid Services (" CMS ") information related to payments and other transfers of value to physicians (defined to include defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members. • The federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which created new federal criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program or falsifying, concealing, or covering up a material fact in connection with the delivery of or payment for health care benefits. • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH "), and their respective implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information on entities subject to the law, such as certain healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the creation, use, maintenance or disclosure of, individually identifiable health information as well as their covered subcontractors. • Other state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third- party payer, including commercial insurers, and state and foreign laws governing the privacy and security and other processing of personal data (including health information) in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; state laws that require pharmaceutical companies to comply with the industry' s voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government that otherwise restricts certain payments that may be made to healthcare providers and entities; state and local laws that require the registration of pharmaceutical sales representatives; and state laws that require drug manufacturers to report information related to payments and other transfer of value to physicians and other healthcare providers and entities, marketing expenditures or drug pricing. Because of the breadth of these laws and the narrowness of available statutory exceptions and regulatory safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws. With Afrezza approved in Brazil and as ~~we~~ **our partners** pursue additional international approvals, we will be subject to similar foreign laws and regulations. If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, or any contractual obligations related to the same, we may be subject to governmental enforcement actions, investigations, litigation (including class action lawsuits) and other penalties, including significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, defense costs, exclusion from U. S. federal or state healthcare programs, additional reporting requirements and / or oversight (including if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws), bans or restrictions on our processing of personal data, indemnity obligations and the curtailment or restructuring of our operations. Any such event or consequence, including penalties, damages, fines, and curtailment or restructuring of our operations, could materially adversely affect our ability to operate our business, including our ability to run clinical trials, and our financial results and harm our reputation. Although compliance programs can help mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly. We are subject to stringent and changing U. S. and foreign laws, regulations, **and** rules, contractual obligations **, industry standards** , policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation **(including class claims) and mass arbitration demands** ; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences. In the ordinary course of business, we process sensitive information (as those terms are defined above). Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security. In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), and other similar laws (e. g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. In ~~addition,~~ the ~~CCPA~~ **past few years, numerous U. S. states — including California, Virginia, Colorado, Connecticut, and Utah — have enacted comprehensive privacy laws that** ~~imposes~~ **impose certain** obligations on covered businesses **,** ~~. These obligations include~~ **including** ~~, but are not limited to,~~ providing specific disclosures in privacy notices and affording **residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (" CPRA "), (collectively, " CCPA ") applies to personal data of consumers, business representatives, and employees who are** California residents **, and requires businesses to provide specific disclosures in privacy notices and honor** certain **privacy**

rights related to their personal data. The CCPA provides for **fines** ~~civil penalties~~ (up to $ 7, 500 per **intentional** violation **)** and allows private litigants affected by certain data breaches to recover significant statutory damages **. Although the CCPA (like other U. S. comprehensive privacy laws**) ~~. Although the CCPA~~ exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we maintain about California residents. **Similar laws are being considered in several** ~~In addition, the California Privacy Rights Act of 2020 (" CPRA "), which became operative January 1, 2023, expands the CCPA' s requirements, including by applying to personal information of business representatives and employees. Additionally, the CPRA establishes a new California Privacy Protection Agency to implement and enforce the CPRA, which could increase the risk of enforcement. Other~~ **other** states ~~also have enacted comprehensive data privacy laws. For example~~ , **as well as** ~~Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act, both of which become effective in 2023. In addition, data privacy and security laws have been proposed~~ at the federal ~~, state,~~ and local levels ~~in recent years~~ , ~~which could further complicate compliance efforts~~ **and we expect more states to pass similar laws in the future** . Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the **European Union' s** General Data Protection Regulation (" **EU** GDPR ") ~~and~~ , the United Kingdom' s GDPR (" UK **GDPR ") (EU GDPR and UK GDPR, collectively "** GDPR "), Brazil' s General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or " LGPD ") (Law No. 13, 709 / 2018), and Australia' s Privacy Act ~~1988~~ impose strict requirements for processing personal data. For example, under the ~~EU~~ GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million euros **under the EU GDPR, 17. 5 million pounds sterling under the UK GDPR** or **, in each case,** 4 % of annual global revenue, whichever is greater; or private litigation related to the processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests **. Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages** . In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (**"** EEA **"**) and the United Kingdom (**"** UK **"**) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it **generally** believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA ~~and~~ **standard contractual clauses, the** UK' s ~~standard contractual clauses~~ **International Data Transfer Agreement / Addendum** , **and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U. S.- based organizations who self- certify compliance and participate in the Framework)** these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these reasons to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions **(such as Europe)** at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Some European regulators have prevented companies from transferring personal data out of Europe for allegedly violating the GDPR' s cross- border data transfer limitations. We ~~may~~ **are** also ~~be~~ bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers. We publish privacy policies, marketing materials and other statements, such as compliance with certain certifications or self- regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. In addition, privacy advocates and industry groups have proposed, and may propose, standards with which we are legally or contractually bound to comply **, or may become subject to in the future** . Our obligations related to data privacy and security are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class- related claims) **and mass arbitration demands** ; additional reporting requirements and / or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. **In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class claims and mass**

arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the United States, we could be subject to additional reimbursement requirements, fines, sanctions and exposure under other laws which could have a material adverse effect on our business, results of operations and financial condition. We participate in the Medicaid Drug Rebate Program, as administered by CMS, and other federal and state government pricing programs in the United States, and we may participate in additional government pricing programs in the future. These programs generally require us to pay rebates or otherwise provide discounts to government payers in connection with drugs that are dispensed to beneficiaries / recipients of these programs. In some cases, such as with the Medicaid Drug Rebate Program, the rebates are based on pricing that we report on a monthly and quarterly basis to the government agencies that administer the programs. Pricing requirements and rebate / discount calculations are complex, vary among products and programs, and are often subject to interpretation by governmental or regulatory agencies and the courts. The requirements of these programs, including, by way of example, their respective terms and scope, change frequently. For example, ~~on~~ **in** March ~~11,~~ 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s AMP, for single source and innovator multiple source drugs, ~~beginning~~ **which became effective** January 1, 2024. Responding to current and future changes may increase our costs, and the complexity of compliance will be time consuming. Invoicing for rebates is provided in arrears, and there is frequently a time lag of up to several months between the sales to which rebate notices relate and our receipt of those notices, which further complicates our ability to accurately estimate and accrue for rebates related to the Medicaid program as implemented by individual states. Thus, there can be no assurance that we will be able to identify all factors that may cause our discount and rebate payment obligations to vary from period to period, and our actual results may differ significantly from our estimated allowances for discounts and rebates. Changes in estimates and assumptions may have a material adverse effect on our business, results of operations and financial condition. In addition, the Office of Inspector General of the HHS and other Congressional, enforcement and administrative bodies have recently increased their focus on pricing requirements for products, including, but not limited to the methodologies used by manufacturers to calculate AMP and best price (" BP ") for compliance with reporting requirements under the Medicaid Drug Rebate Program. We are liable for errors associated with our submission of pricing data and for any overcharging of government payers. For example, failure to submit monthly / quarterly AMP and BP data on a timely basis could result in a civil monetary penalty. Failure to make necessary disclosures and / or to identify overpayments could result in allegations against us under the False Claims Act and other laws and regulations. Any required refunds to the U. S. government or responding to a government investigation or enforcement action would be expensive and time consuming and could have a material adverse effect on our business, results of operations and financial condition. In addition, in the event that the CMS were to terminate our rebate agreement, no federal payments would be available under Medicaid or Medicare for our covered outpatient drugs. Our business could be negatively impacted by environmental, social and corporate governance (ESG) matters or our reporting of such matters. There is an increasing focus from certain investors, employees, partners, and other stakeholders concerning ESG matters. We may be, or be perceived to be, not acting responsibly in connection with these matters, which could negatively impact us. Moreover, the SEC has recently proposed, and may continue to propose, certain mandated ESG reporting requirements, such as the SEC' s proposed rules designed to enhance and standardize climate- related disclosures, which, if finally approved, would significantly increase our compliance and reporting costs and may also result in disclosures that certain investors or other stakeholders deem to **impact our reputation** negatively ~~impact our reputation~~ and / or that harm our stock price. We currently do not report our environmental emissions and absent a legal requirement to do so we currently do not plan to report our environmental emissions, and lack of reporting could result in certain investors declining to invest in our common stock. Our portfolio of investment securities may require us to register with the SEC as an " investment company " in accordance with the Investment Company Act of 1940 (" ' 40 Act "). The rules and interpretations of the SEC and the courts relating to the definition of" investment company" are very complex. Although we are a biopharmaceutical company and we do not hold ourselves out as an investment company, the value of our investment securities relative to our total assets (exclusive of government securities and cash items) has in the past exceeded safe harbor limits prescribed in the ~~2~~ **'** 40 Act. If our asset mix does not continue to qualify for one of the safe harbor limits prescribed in the ' 40 Act, it is possible that the SEC would take the position that we would be required to register under the ' 40 Act and comply with the ' 40 Act' s registration and reporting requirements, capital structure requirements, affiliate transaction restrictions, conflict of interest rules, requirements for disinterested directors, and other substantive provisions. If we were required to register as an " investment company " and be subject to the restrictions of the ' 40 Act, those restrictions likely would require significant changes in the way we do business and add significant administrative costs and burdens to our operations. RISKS RELATED TO INTELLECTUAL PROPERTY If we are unable to protect our proprietary rights, we may not be able to compete effectively, or operate profitably. Our commercial success depends, in large part, on our ability to obtain and maintain intellectual property protection for our technology. Our ability to do so will depend on, among other things, complex legal and factual questions, and it should be noted that the standards regarding intellectual property rights in our fields are still evolving. We attempt to protect our proprietary technology through a combination of patents, trade secrets and confidentiality agreements. We own a number of domestic and international patents, have a number of domestic and international patent applications pending and have licenses to additional patents. We cannot assure you that our patents and licenses will successfully preclude others from using our technologies, and

we could incur substantial costs in seeking enforcement of our proprietary rights against infringement. Even if issued, the patents may not give us an advantage over competitors with alternative technologies. For example, the coverage claimed in a patent application can be significantly reduced before a patent is issued, either in the United States or abroad. Statutory differences in patentable subject matter may limit the protection we can obtain on some of our inventions outside of the United States. For example, methods of treating patients are not patentable in many countries outside of the United States. These and other issues may limit the patent protection we are able to secure internationally. Consequently, we do not know whether any of our pending or future patent applications will result in the issuance of patents or, to the extent patents have been issued or will be issued, whether these patents will be subjected to further proceedings limiting their scope, will provide significant proprietary protection or competitive advantage, or will be circumvented or invalidated. Furthermore, patents already issued to us or our pending applications may become subject to disputes that could be resolved against us. In the United States and certain other countries, applications are generally published 18 months after the application' s priority date. Because publication of discoveries in scientific or patent literature often trails behind actual discoveries, we cannot be certain that we were the first inventor of the subject matter covered by our pending patent applications or that we were the first to file patent applications on such inventions. Assuming the other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, while outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy- Smith America Invents Act (" AIA "), the United States moved to a first inventor to file system. In general, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. Moreover, the term of a patent is limited and, as a result, the patents protecting our products expire at various dates. As and when these different patents expire, our products could become subject to increased competition. As a consequence, we may not be able to recover our development costs. An issued patent is presumed valid unless it is declared otherwise by a court of competent jurisdiction. However, the issuance of a patent is not conclusive as to its validity or enforceability and it is uncertain how much protection, if any, will be afforded by our patents. A third party may challenge the validity or enforceability of a patent after its issuance by various proceedings such as oppositions in foreign jurisdictions, or post grant proceedings, including, oppositions, re- examinations or other review in the United States. In some instances, we may seek re- examination or reissuance of our own patents. If we attempt to enforce our patents, they may be challenged in court where they could be held invalid, unenforceable, or have their breadth narrowed to an extent that would destroy their value. We also rely on unpatented technology, trade secrets, know- how and confidentiality agreements. We require our officers, employees, consultants and advisors to execute proprietary information and invention and assignment agreements upon commencement of their relationships with us. These agreements provide that all inventions developed by the individual on behalf of us must be assigned to us and that the individual will cooperate with us in connection with securing patent protection on the invention if we wish to pursue such protection. We also execute confidentiality agreements with outside collaborators. However, disputes may arise as to the ownership of proprietary rights to the extent that outside collaborators apply technological information to our projects that are developed independently by them or others, or apply our technology to outside projects, and there can be no assurance that any such disputes would be resolved in our favor. In addition, any of these parties may breach the agreements and disclose our confidential information or our competitors might learn of the information in some other way. Thus, there can be no assurance, however, that our inventions and assignment agreements and our confidentiality agreements will provide meaningful protection for our inventions, trade secrets, know- how or other proprietary information in the event of unauthorized use or disclosure of such information. If any trade secret, know-how or other technology not protected by a patent were to be disclosed to or independently developed by a competitor, our business, results of operations and financial condition could be adversely affected. If we become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, we would be required to devote substantial time and resources to prosecute or defend such proceedings. Competitors may infringe 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 its technology. A court may also decide to award us a royalty from an infringing party instead of issuing an injunction against the infringing activity. An adverse determination of any litigation or defense proceedings 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 pre- AIA patent applications or those of our collaborators or licensors. Additionally, the AIA has greatly expanded the options for post- grant review of patents that can be brought by third parties. In particular, Inter Partes Review (" IPR "), available against any issued United States patent (pre- and post- AIA), has resulted in a higher rate of claim invalidation, due in part to the much reduced opportunity to repair claims by amendment as compared to re- examination, as well as the lower standard of proof used at the USPTO as compared to the federal courts. With the passage of time an increasing number of patents related to successful pharmaceutical products are being subjected to IPR. Moreover, the filing of IPR petitions has been used by short-sellers as a tool to help drive down stock prices. We may not prevail in any litigation, post- grant review, or interference proceedings in which we are involved and, even if we are successful, these proceedings may result in substantial costs and be a distraction to our management. Further, 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, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings,

motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price of our common stock and other securities may decline. If our technologies conflict with the proprietary rights of others, we may incur substantial costs as a result of litigation or other proceedings and we could face substantial monetary damages and be precluded from commercializing our products, which would materially harm our business and financial condition. Biotechnology patents are numerous and may, at times, conflict with one another. As a result, it is not always clear to industry participants, including us, which patents cover the multitude of biotechnology product types. Ultimately, the courts must determine the scope of coverage afforded by a patent and the courts do not always arrive at uniform conclusions. A patent owner may claim that we are making, using, selling or offering for sale an invention covered by the owner' s patents and may go to court to stop us from engaging in such activities. Such litigation is not uncommon in our industry. Patent lawsuits can be expensive and would consume time and other resources. There is a risk that a court would decide that we are infringing a third party' s patents and would order us to stop the activities covered by the patents, including the commercialization of our products. In addition, there is a risk that we would have to pay the other party damages for having violated the other party' s patents (which damages may be increased, as well as attorneys' fees ordered paid, if infringement is found to be willful), or that we will be required to obtain a license from the other party in order to continue to commercialize the affected products, or to design our products in a manner that does not infringe a valid patent. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms or at all, requiring cessation of activities that were found to infringe a valid patent. We also may not be able to develop a non- infringing product design on commercially reasonable terms, or at all. Moreover, certain components of our products may be manufactured outside the United States and imported into the United States. As such, third parties could file complaints under 19 U. S. C. Section 337 (a) (1) (B) (a " 337 action ") with the International Trade Commission (the " ITC "). A 337 action can be expensive and would consume time and other resources. There is a risk that the ITC would decide that we are infringing a third party' s patents and either enjoin us from importing the infringing products or parts thereof into the United States or set a bond in an amount that the ITC considers would offset our competitive advantage from the continued importation during the statutory review period. The bond could be up to 100 % of the value of the patented products. We may not prevail in any legal action, and a required license under the patent may not be available on acceptable terms, or at all, resulting in a permanent injunction preventing any further importation of the infringing products or parts thereof into the United States. We also may not be able to develop a non- infringing product design on commercially reasonable terms, or at all. Although we do not believe that our products or product candidates infringe any third-party patents, if a plaintiff was to allege infringement of their patent rights, we would have to establish with the court that their patents are invalid or unenforceable in order to avoid legal liability for infringement of these patents. However, proving patent invalidity or unenforceability can be difficult because issued patents are presumed valid. Therefore, in the event that we are unable to prevail in a non- infringement or invalidity action we will have to either acquire the third- party patents outright or seek a royalty- bearing license. Royalty- bearing licenses effectively increase production costs and therefore may materially affect product profitability. Furthermore, should the patent holder refuse to either assign or license us the infringed patents, it may be necessary to cease manufacturing the product entirely and / or design around the patents, if possible. In either event, our business, financial condition and results of operations would be harmed and our profitability could be materially and adversely impacted. In addition, patent litigation may divert the attention of key personnel and we may not have sufficient resources to bring these actions to a successful conclusion. At the same time, some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. An adverse determination in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing and selling our products or result in substantial monetary damages, which would adversely affect our business, financial condition and results of operations and cause the market price of our common stock and other securities to decline. We may not obtain trademark registrations for our potential trade names. We have not selected trade names for some of our product candidates in our pipeline; therefore, we have not filed trademark registrations for such potential trade names for our product candidates, nor can we assure that we will be granted registration of any potential trade names for which we do file. No assurance can be given that any of our trademarks will be registered in the United States or elsewhere, or once registered that, prior to our being able to enter a particular market, they will not be cancelled for non- use. Nor can we give assurances, that the use of any of our trademarks will confer a competitive advantage in the marketplace. Furthermore, even if we are successful in our trademark registrations, the FDA has its own process for drug nomenclature and its own views concerning appropriate proprietary names. It also has the power, even after granting market approval, to request a company to reconsider the name for a product because of evidence of confusion in the marketplace. We cannot assure you that the FDA or any other regulatory authority will approve of any of our trademarks or will not request reconsideration of one of our trademarks at some time in the future. RISKS RELATED TO OUR COMMON STOCK We may not be able to generate..... service and other obligations when due. Our stock price is volatile. The trading price of our common stock has been and is likely to continue to be volatile. The volatility of pharmaceutical and biotechnology stocks often does not relate to the operating performance of the companies represented by the stock. Our business and the market price of our common stock may be influenced by a large variety of factors, including: • our ability to obtain marketing approval for our products outside of the United States and to find collaboration partners for the commercialization of our products in foreign jurisdictions; • future estimates of product sales, royalties, prescriptions or other operating metrics; • our ability to successfully commercialize other products based on our Technosphere drug delivery platform; • the progress and results of preclinical and clinical studies of our product candidates and of post- approval studies of approved products that are required by the FDA; • general economic, political or stock market conditions, especially for emerging growth and pharmaceutical market sectors; • geopolitical events, such as the current Russia-Ukraine **and Israel- Hamas** ~~conflict~~ **conflicts and Houthis rebel attacks on commercial marine vessels in the Red Sea** ; • legislative developments; • disruptions caused by man- made or natural disasters or public health pandemics or epidemics or

other business interruptions; • changes in the structure of the healthcare payment systems; • announcements by us, our collaborators, or our competitors concerning clinical study results, acquisitions, strategic alliances, technological innovations, newly approved commercial products, product discontinuations, or other developments; • the availability of critical materials used in developing and manufacturing our products and product candidates; • developments or disputes concerning our relationship with any of our current or future collaborators or third party manufacturers; • developments or disputes concerning our patents or proprietary rights; • the expense and time associated with, and the extent of our ultimate success in, securing regulatory approvals; • announcements by us concerning our financial condition or operating performance; • changes in securities analysts' estimates of our financial condition or operating performance; • sales of large blocks of our common stock, including sales by our executive officers, directors and significant stockholders; • the trades of short sellers; • our ability, or the perception of investors of our ability, to continue to meet all applicable requirements for continued listing of our common stock on The Nasdaq Global Market, and the possible delisting of our common stock if we are unable to do so; • the status of any legal proceedings or regulatory matters against or involving us or any of our executive officers and directors; and • discussion of our products, competitors' products, or our stock price by the financial and scientific press, the healthcare community and online investor communities such as chat rooms. In particular, it may be difficult to verify statements about us that appear on interactive websites that permit users to generate content anonymously or under a pseudonym. Statements attributed to company officials may, in fact, have originated elsewhere. Any of these risks, as well as other factors, could cause the market value of our common stock and other securities to decline. If we fail to continue to meet all applicable listing requirements, our common stock may be delisted from the Nasdaq Global Market, which could have an adverse impact on the liquidity and market price of our common stock. Our common stock is currently listed on The Nasdaq Global Market, which has qualitative and quantitative listing criteria. If we are unable to meet any of the Nasdaq listing requirements in the future, such as the corporate governance requirements, the minimum closing bid price requirement, or the minimum market value of listed securities requirement, Nasdaq could determine to delist our common stock. A delisting of our common stock could adversely affect the market liquidity of our common stock, decrease the market price of our common stock, adversely affect our ability to obtain financing for the continuation of our operations and result in the loss of confidence in our company. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. We are incorporated in Delaware. Certain anti- takeover provisions under Delaware law and in our certificate of incorporation and amended and restated bylaws, as currently in effect, may make a change of control of our company more difficult, even if a change in control would be beneficial to our stockholders or the holders of our other securities. Our anti- takeover provisions include provisions such as a prohibition on stockholder actions by written consent, the authority of our board of directors to issue preferred stock without stockholder approval, and supermajority voting requirements for specified actions. In addition, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which generally prohibits stockholders owning 15 % or more of our outstanding voting stock from merging or combining with us in certain circumstances. These provisions may delay or prevent an acquisition of us, even if the acquisition may be considered beneficial by some of our stockholders. In addition, they may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated bylaws provide that, to the fullest extent permitted by law and subject to the court' s having personal jurisdiction over the indispensable parties named as defendants, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: • any derivative action or proceeding brought on our behalf; • any action or proceeding asserting a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; • any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and certificate of incorporation or amended and restated bylaws; • any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; • any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and • any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine. This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act of 1933, as amended, or the Securities Act, creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws further provides that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These exclusive forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a

court were to find either exclusive forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business. Because we do not expect to pay dividends in the foreseeable future, you must rely on stock appreciation for any return on any investment in our common stock. We have paid no cash dividends on any of our capital stock to date, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, we do not expect to pay any cash dividends in the foreseeable future, and payment of cash dividends, if any, will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. In addition, pursuant to the MidCap credit facility, we are subject to contractual restrictions on the payment of dividends. There is no guarantee that our common stock will appreciate or maintain its current price. You could lose the entire value of any investment in our common stock. Future sales of shares of our common stock in the public market, or the perception that such sales may occur, may depress our stock price and adversely impact the market price of our common stock and other securities. We may need to raise substantial additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities or additional convertible debt, the market price of our common stock and other securities may decline. Similarly, if our existing stockholders sell substantial amounts of our common stock in the public market, the market price of our common stock and other securities could decrease. The perception in the public market that we or our existing stockholders might sell shares of common stock could also depress the market price of our common stock and the market price of our other securities. Likewise, the issuance of additional shares of our common stock upon the exchange or conversion of the Mann Group ~~promissory~~ **convertible** ~~notes~~ **note**, or the Senior convertible notes, could adversely affect the market price of our common stock and other securities. Moreover, the existence of these notes may encourage short selling of our common stock by market participants, which could adversely affect the market price of our common stock and other securities. In addition, a substantial number of shares of our common stock is reserved for issuance upon the exercise of stock options, the vesting of restricted stock unit awards and purchases under our employee stock purchase program. The issuance or sale of substantial amounts of common stock, or the perception that such issuances or sales may occur, could adversely affect the market price of our common stock and other securities. If other biotechnology and biopharmaceutical companies or the securities markets in general encounter problems, the market price of our common stock and other securities could be adversely affected. Public companies in general, including companies listed on The Nasdaq Stock Market, have experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of those companies. There has been particular volatility in the market prices of securities of biotechnology and other life sciences companies, and the market prices of these companies have often fluctuated because of problems or successes in a given market segment or because investor interest has shifted to other segments. These broad market and industry factors may cause the market price of our common stock and other securities to decline, regardless of our operating performance. We have no control over this volatility and can only focus our efforts on our own operations, and even these may be affected due to the state of the capital markets. In the past, following periods of large price declines in the public market price of a company' s securities, securities class action litigation has often been initiated against that company. Litigation of this type could result in substantial costs and diversion of management' s attention and resources, which would hurt our business. Any adverse determination in litigation could also subject us to significant liabilities. GENERAL RISK FACTORS Unstable market, economic and geopolitical conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have experienced extreme volatility and disruptions in the past. These disruptions can result in severely diminished liquidity and credit availability, increase in inflation, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that ~~further~~ deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment, **actual or anticipated bank failures,** higher inflation, or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Our portfolio of corporate and government bonds could also be adversely impacted. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our operations, growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive an economic downturn or rising inflation, which could directly affect our ability to attain our operating goals on schedule and on budget. Other international and geopolitical events could also have a serious adverse impact on our business. For instance, in February 2022, Russia initiated military action against Ukraine **and the two countries are now at war**. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions. **Additionally, in October 2023, Hamas initiated an attack against Israel, provoking a state of war and the risk of a larger conflict. Furthermore, following Hamas' attack on Israel, the Houthi movement, which controls parts of Yemen, launched a number of attacks on commercial marine vessels in the Red Sea. The Red Sea is an important maritime route for international trade and as such disruptions to these trade routes can have an impact on global supply chains. As a result of such disruptions, we may experience in the future extended lead times, delays in supplier deliveries, and increased freight costs.** While we cannot predict the broader consequences, ~~the~~ **these** ~~conflict~~ **conflicts** and retaliatory and counter-retaliatory actions could materially adversely affect global trade, currency exchange rates, inflation, regional economies, and the global economy, which in turn may increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations.