Risk Factors Comparison 2025-03-18 to 2024-03-14 Form: 10-K

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We operate in a dynamic and rapidly changing environment that involves numerous risks and uncertainties. Certain factors may have a material adverse effect on our business, financial condition and results of operations, and you should carefully consider them. Accordingly, in evaluating our business, we encourage you to consider the following discussion of risk factors, in its entirety, in addition to other information contained in this Annual Report on Form 10- K and our other public filings with the SEC. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our results of operations and financial condition. Risks Relating to Our Business We may need to grow the size of our organization, and we could experience difficulties in managing this growth. As our development and commercialization plans and strategies develop, we may need to expand the size of our employee and consultant / contractor base. Future growth would impose significant added responsibilities on members of management, including the need to identify, recruit, maintain, motivate and integrate additional employees. In addition, our management may have to divert a disproportionate amount of its attention away from our day- to- day activities and devote a substantial amount of time to managing these growth activities. Our future financial performance and our ability to commercialize our product candidates and any other future product candidates and our ability to compete effectively will depend, in part, on our ability to effectively manage our future growth. We focus on rare diseases, which may create additional risks and challenges, including that the target patient populations of our products and product candidates may be small. Because we focus on developing drugs as treatments for rare diseases, we may seek orphan drug, breakthrough therapy or fast track designations for our product candidates. Often, regulatory authorities have broad discretion in determining whether or not to grant such designations. We cannot guarantee that our product candidates will receive orphan drug status from the FDA or equivalent designations from other regulatory authorities. Even with an orphan drug designation for our current and potential future product candidates, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain orphan drug exclusivity for an existing or future product candidate, that exclusivity may not effectively protect the product from competition. We also cannot guarantee that we will receive breakthrough therapy, fast track, or equivalent designations, which provide certain potential benefits such as more frequent meetings with the applicable regulatory authorities to discuss development plans, intensive guidance on efficient drug development programs, and potential eligibility for rolling review or priority review. Even if we are successful in obtaining any such designations for our product candidates, such designations may not lead to faster development or regulatory review or approval and do not increase the likelihood that our product candidates will receive marketing approval. We may not be able to obtain or maintain these designations for our product candidates that receive them, and our competitors may obtain these designations for their product candidates, which could impact our ability to develop and commercialize our products and product candidates or compete with such competitors, which may adversely impact our business, financial condition or results of operations. Given the small number of patients who have the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these rare diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our products and product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, surveys of clinics, patient foundations, or market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for each of our products and product candidates may be limited or may not be amenable to treatment with our products and product candidates, and new patients may become increasingly difficult to identify or access. Further, even if we obtain significant market share for our products and product candidates, because the potential target populations are small, we may struggle to remain profitable or generate sufficient revenue growth to sustain our business. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We face a potential risk of product liability as a result of the commercialization of our approved products and clinical testing of our new product candidates and will face an even greater risk if we commercialize our current product candidates or any other future product. For example, we may be sued if our approved products or any product we develop, including any of our product candidates, or any materials that we use in our products allegedly ~~causes~~ **cause** injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and a breach of warranties. In the United States, claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even **a** successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for our current products or any of our product candidates or any future products that we may develop; ● injury to our reputation; ● withdrawal of clinical trial participants; ● costs to defend the related litigation; ● a diversion of management' s time and our resources; ● substantial monetary awards to trial participants or patients; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● the inability to commercialize some or all of our product candidates; and ● a decline in the value of our stock. We carry product liability insurance we consider adequate for our current level of expected product sales, clinical testing and product development. Our inability to obtain and retain sufficient product

liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of our approved products or additional products we develop. Although we will endeavor to obtain and maintain such insurance in coverage amounts which we deem adequate, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. We may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions. We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cybersecurity incidents, could harm our ability to operate our business effectively. Significant disruptions of IT systems or breaches of information security could adversely affect our business. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. We rely on technology developed, supplied, and / or maintained by third parties that may make us vulnerable to " supply chain " style cyber- attacks. System failures, accidents or security breaches could cause interruptions in our operations, and result in a material disruption of our product development and clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. Cybersecurity attacks in particular are evolving and include, but are not limited to, malicious software, attempts to gain unauthorized access to data and other electronic security breaches that could lead to disruptions in systems, misappropriation of our confidential or otherwise protected information and corruption of data. The loss, theft or sabotage of product development or clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our development programs and the development of our product candidates could be delayed. Any technology service interruption or breach of our systems could adversely affect our business operations and / or result in the loss of personal data, confidential information or intellectual property. Such incidents require disclosure to government authorities and / or regulators and any incident could result in financial, legal, business and reputational harm to us. We maintain cyber liability insurance; however, this insurance may not be sufficient to cover the financial, legal, business or reputational losses that may result from an interruption or breach of our systems **. Use of artificial intelligence- based software by us or third parties with which we contract, may lead to the release of confidential information which may impact our ability to realize the benefits of our intellectual property** . Artificial intelligence- based software is increasingly being used in the biopharmaceutical and healthcare industries. As with many developing technologies, artificial intelligence- based software presents risks and challenges. For example, algorithms may be flawed, data sets may be insufficient, of poor quality, or contain biased information; and inappropriate or controversial data practices by data scientists, engineers, and end- users could impair results. If the analyses that artificial intelligence- based applications assist in producing are deficient or inaccurate, we could be subjected to competitive harm, potential legal liability and brand or reputational harm. Furthermore, use of artificial intelligence-based software **by us or third parties with which we contract,** may lead to the release of confidential information which may impact our ability to realize the benefits of our intellectual property **and could negatively impact our competitive position, financial condition, results of operations and prospects** . Sales of counterfeits of any of our product candidates, as well as unauthorized sales of any of our product candidates, may have adverse effects on our revenues, business and results of operations and damage our brand and reputation. Our current approved products or our new product candidates may become subject to competition from counterfeit pharmaceutical products, which are pharmaceutical products sold under the same or very similar brand names and / or having a similar appearance to genuine products, but which are sold without proper licenses or approvals. Such products divert sales from genuine products, often are of lower cost, often are of lower quality (having different ingredients or formulations, for example), and have the potential to damage the reputation for quality and effectiveness of the genuine product. Obtaining regulatory approval for our product candidates is a complex and lengthy process. If during the period while the regulatory approval is pending, illegal sales of counterfeit products begin, consumers may buy such counterfeit products, which could have an adverse impact on our revenues, business and results of operations. In addition, if illegal sales of counterfeits result in adverse side effects to consumers, we may be associated with any negative publicity resulting from such incidents. Although pharmaceutical regulation, control and enforcement systems throughout the world have been increasingly active in policing counterfeit pharmaceuticals, we may not be able to prevent third parties from manufacturing, selling or purporting to sell counterfeit products competing with our current products or our new product candidates. Such sales may also be occurring without our knowledge. The existence and any increase in production or sales of counterfeit products or unauthorized sales could negatively impact our revenues, brand reputation, business and results of operations. Risks Related to Product Development, Regulatory Approval, Manufacturing and Commercialization We depend entirely on the success of current approved products and our new product candidates. If we are unable to generate revenues from our approved products and new product candidates, our ability to create stockholder value will be limited. We may not be successful in obtaining

acceptance from the FDA or comparable foreign regulatory authorities to start our clinical trials. If we do not obtain such acceptance, the time in which we expect to commence clinical programs for any product candidate will be extended and such extension will increase our expenses and increase our need for additional capital. Moreover, there is no guarantee that our clinical trials will be successful or that we will continue clinical development in support of additional product approvals from the FDA or comparable foreign regulatory authorities for any indication. We note that most product candidates never reach the clinical development stage and even those that do commence clinical development have only a small chance of successfully completing clinical development and gaining regulatory approval. Therefore, our business ~~substantially~~ depends entirely on the successful development, regulatory approval and commercialization of our product candidates, which may never occur. We face competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively. The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. We have existing competitors and potential new competitors in a number of jurisdictions, many of which have or will have substantially greater name recognition, commercial infrastructures and financial, technical and personnel resources than we have. Established competitors may invest heavily to quickly discover and develop novel compounds that could make any of our product candidates obsolete or uneconomical. In addition, mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors, potentially reducing or eliminating our commercial opportunity. Furthermore, such potential competitors may enter the market before us, and their products may be designed to circumvent our pending patent applications and any patents we may receive. They may also challenge, narrow or invalidate any granted patents or our patent applications, and such patents and patent applications may fail to provide adequate protection for our product candidates. Any new product that competes with an approved product may need to demonstrate compelling advantages in efficacy, cost, convenience, tolerability and safety to be commercially successful. Other competitive factors, including generic competition, could force us to lower prices or could result in reduced sales. In addition, new products developed by others could emerge as competitors to our product candidates. If we are not able to compete effectively against our current and future competitors, our business will not grow and our financial condition and operations will suffer. We face substantial competition, which may result in others discovering, developing and commercializing products before or more successfully than our product candidates. The development and commercialization of new drugs is highly competitive. We face competition (from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide) with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future. We compete directly with companies that focus on 505 (b) (2) and generic drugs, and companies dedicating their resources to novel forms of therapies for these indications. Many of these competitors are attempting to develop products for our target indications. We face the risk that our competitors will develop a competing product using the same 505 (b) (2) pathway that we intend to pursue. Our business model is to focus on product candidates that we consider to have a shorter timeline to, and lower cost of, regulatory approval. These attributes can also be taken advantage of by our competitors to develop and obtain marketing approval ~~of~~ **for** a competing product. In addition, following FDA approval of our product candidates for which we have no patent protection, our competitors may seek to develop a competing product pursuant to the 505 (j) pathway, which is an abbreviated pathway used for the regulatory approval of generic product candidates. As a result of the foregoing, we may find that the market opportunity for our product candidates for which we have no patent protection is relatively small due to the fact that barriers to entry are low and generic competition may follow within relatively short time periods after our product is approved. With the proliferation of new drugs and therapies in these areas, we expect to face increasingly intense competition as new technologies become available. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future. There are products already approved for all of the indications we are targeting. Many of these approved products are well established therapies and are widely accepted by physicians, patients and third- party payors. This may make it difficult for us to achieve our business strategy of replacing existing products with our product candidates. In addition, where we are able to offer benefits over existing products offered by our competitors, those competitors may reformulate their drugs in a manner that mimics the benefits offered by our product candidates. As noted below, many of our product candidates are not eligible for patent protection or the market and data exclusivity provisions under the FDCA. Consequently, our commercial operations face significant direct competition and our competitors may develop products that are similar to ours and perhaps safer, more effective, more convenient or less costly than any that we are developing or that would render our product candidates obsolete or non- competitive. Our inability to successfully compete could negatively impact our business, results of operations and stock price. Our competitors may obtain FDA or other regulatory approval for comparable products more rapidly than we may obtain approval for ours, and the risk of our competitors doing so may lead us to develop drug candidates without disclosing certain information with regard to such candidates. The FDCA provides three years of marketing exclusivity for an NDA, 505 (b) (2) NDA, or supplement to an existing NDA or 505 (b) (2) NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, (e. g., for new indications, dosages, strengths or dosage forms of an existing drug). Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. As a result, many of our competitors have the ability to bring a product candidate to market more rapidly than we can and depending on the nature of their product candidate they could substantially delay the introduction of our product candidate into the market if their product qualifies for the market and data exclusivity provisions under the FDCA. In order to preserve any competitive advantage, we will, at times, make the decision to pursue a product candidate for which we will not disclose the API, dosage or reference drug until such time as we believe that any competitive advantage would not be materially compromised by public disclosure of such information, which in some cases may be as late as our receipt of marketing approval from the FDA. Our business currently depends on our ability to bring our product candidates to market in a

manner that preserves our perceived competitive advantage, and any loss of that competitive advantage could negatively impact our business, results of operations and stock price. If we are not able to obtain any required regulatory approvals for our product candidates, we will not be able to commercialize our product candidate and our ability to generate revenue will be limited. We may be required to successfully complete clinical trials for our product candidates before we can apply for marketing approval. Even if we complete any such clinical trials, it does not assure marketing approval. Any such clinical trials may be unsuccessful, which would materially harm our business. Even if such initial clinical trials are successful, we may be required to conduct additional clinical trials to establish our product candidates' safety and efficacy before an NDA or foreign equivalents can be submitted to the FDA or comparable foreign regulatory authorities for marketing approval of our product candidates. Our success depends on the receipt of regulatory approval and the issuance of such regulatory approvals is uncertain and subject to a number of risks, including the following: ● the results of any required toxicology studies may not support the submission of an IND for our product candidates; ● the FDA or comparable foreign regulatory authorities or Institutional Review Boards (" IRB "), may disagree with the design or implementation of our clinical trials; ● we may not be able to provide acceptable evidence of our product candidates' safety and efficacy; ● the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval; ● the dosing of our product candidates in any required clinical trial may not be at an optimal level; ● the results of our clinical trials may not be satisfactory or may not meet the level of statistical or clinical significance required by the FDA or other regulatory agencies for marketing approval; ● the dosing of our product candidates in any required clinical trial may not be at an optimal level; ● patients in our clinical trials may suffer adverse effects for reasons that may or may not be related to our product candidates; ● the data collected from clinical trials may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere; ● the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and ● the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval. Failure to obtain regulatory approval for our product candidates for the foregoing, or any other reasons, will prevent us from commercializing our product candidates, and our ability to generate sufficient revenue will be materially impaired. We cannot guarantee that regulators will agree with our assessment of the results of the clinical trials we intend to conduct in the future or that such trials will be successful. The FDA and other regulators have substantial discretion in the approval process and may refuse to accept any application or may decide that our data is insufficient for approval and require additional clinical trials, or pre- clinical or other studies. In addition, varying interpretations of the data obtained from pre- clinical and clinical testing could delay, limit or prevent regulatory approval of our product candidates. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon, among other things, the type, complexity and novelty of the product candidates involved, the jurisdiction in which regulatory approval is sought and the substantial discretion of the regulatory authorities. Changes in regulatory approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for a submitted product application may cause delays in the approval or rejection of an application. Regulatory approval obtained in one jurisdiction does not necessarily mean that a product candidate will receive regulatory approval in all jurisdictions in which we may seek approval, but the failure to obtain approval in one jurisdiction may negatively impact our ability to seek approval in a different jurisdiction. Failure to obtain regulatory marketing approval for our product candidates will prevent us from commercializing the product candidate, and our ability to generate sufficient revenue will be materially impaired. If the FDA does not conclude that our product candidates satisfy the requirements for the 505 (b) (2) regulatory approval pathway, or if the requirements for approval of any of our product candidates under Section 505 (b) (2) are not as we expect, the approval pathway for our product candidates will likely take significantly longer, cost significantly more and encounter significantly greater complications and risks than anticipated, and in any case may not be successful. We intend to seek FDA approval through the 505 (b) (2) regulatory pathway for the majority of our product candidates. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch- Waxman Act, added Section 505 (b) (2) to the FDCA. Section 505 (b) (2) permits the filing of an NDA where at least some of the information required for approval comes from studies that were not conducted by or for the applicant. If the FDA does not allow us to pursue the 505 (b) (2) regulatory pathway for our product candidates as anticipated, we may need to conduct additional clinical trials, provide additional data and information and meet additional standards for regulatory approval. If this were to occur, the time and financial resources required to obtain FDA approval for our product candidates would likely substantially increase. Moreover, the inability to pursue the 505 (b) (2) regulatory pathway could result in new competitive products reaching the market faster than our product candidates, which could materially adversely impact our competitive position and prospects. Even if we are allowed to pursue the 505 (b) (2) regulatory pathway for a product candidate, we cannot assure you that we will receive the requisite or timely approvals for commercialization of such product candidate. For example, we had under development a patented injectable pentoxifylline therapeutic candidate, which we believed would satisfy the requirements of the 505 (b) (2) regulatory pathway. However, based on a pre- IND meeting with the FDA in March 2018 to discuss the clinical and regulatory pathway for the product, we ~~have~~ decided to suspend all further development activities for this candidate indefinitely due to extraordinarily high costs of the clinical trials that would be required by the FDA. Notwithstanding the approval of many products by the FDA pursuant to Section 505 (b) (2), over the last few years some pharmaceutical companies and others have objected to the FDA' s interpretation of Section 505 (b) (2) to allow reliance on the FDA' s prior findings of safety and effectiveness. If the FDA changes its interpretation of Section 505 (b) (2), or if the FDA' s interpretation is successfully challenged in court, this could delay or even prevent the FDA from approving any Section 505 (b) (2) application that we submit. In addition, we expect that our competitors will file citizens' petitions with the FDA in an attempt to persuade the FDA that our product ~~candidate~~ **candidates** , or the clinical studies that support their approval, contain deficiencies. Such actions by our competitors could delay

or even prevent the FDA from approving any NDA that we submit under Section 505 (b) (2). Moreover, the FDA recently adopted an interpretation of the three- year exclusivity provisions whereby a 505 (b) (2) application can be blocked by exclusivity even if does not rely on the previously approved drug that has exclusivity (or any safety or effectiveness information regarding that drug). Under the FDA' s new interpretation, approval may be blocked by exclusivity awarded to a previously- approved drug product that shares certain innovative features with our product, even if our 505 (b) (2) application does not identify the previously- approved drug product as a listed drug or rely upon any of its safety or efficacy data. Any failure to obtain regulatory approval of our product candidates would significantly limit our ability to generate sufficient revenues, and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenues. An NDA submitted under Section 505 (b) (2) subjects us to the risk that we may be subject to a patent infringement lawsuit that would delay or prevent the review or approval of our product candidate. The 505 (b) (2) application would enable us to reference published literature or the FDA' s previous findings of safety and effectiveness for the branded reference drug. For NDAs submitted under Section 505 (b) (2) of the FDCA, the patent certification and related provisions of the Hatch- Waxman Act apply. In accordance with Hatch- Waxman Act, in seeking approval for a drug through such an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant' s product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA' s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown to be bioequivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct or submit results of pre- clinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as " generic equivalents " to the listed drug and can often be substituted by pharmacists under prescriptions written for the original listed drug. The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA' s Orange Book. Specifically, the applicant must certify that either: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method- of- use rather than certify to a listed method- of- use patent. If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product' s listed patents, or that such patents are invalid or unenforceable, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. Under the Hatch- Waxman Act, the holder of patents that the 505 (b) (2) application references may file a patent infringement lawsuit after receiving notice of the Paragraph IV certification. Filing of a patent infringement lawsuit against the filer of the 505 (b) (2) applicant within 45 days of the patent owner' s receipt of notice triggers a one- time, automatic, 30- month stay of the FDA' s ability to approve the 505 (b) (2) NDA, unless patent litigation is resolved in favor of the Paragraph IV filer or the patent expires before that time. Accordingly, we may invest a significant amount of time and expense in the development of one or more product candidates only to be subject to significant delay and patent litigation before such product candidates may be commercialized, if at all. In addition, a 505 (b) (2) application will not be approved until any non- patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity listed in the Orange Book for the referenced product has expired. The FDA may also require us to perform one or more additional clinical studies or measurements to support the change from the branded reference drug, which could be time- consuming and could substantially delay our achievement of regulatory approvals for such product candidates. The FDA may also reject our future 505 (b) (2) submissions and require us to file such submissions under Section 505 (b) (1) of the FDCA, which would require us to provide extensive data to establish safety and effectiveness of the drug for the proposed use and could cause delay and be considerably more expensive and time- consuming. These factors, among others, may limit our ability to successfully commercialize our product candidates. Companies that produce branded reference drugs routinely bring litigation against ANDA or 505 (b) (2) applicants that seek regulatory approval to manufacture and market generic and reformulated forms of their branded products. These companies often allege patent infringement or other violations of intellectual property rights as the basis for filing suit against an ANDA or 505 (b) (2) applicant. Likewise, patent holders may bring patent infringement suits against companies that are currently marketing and selling their approved generic or reformulated products. Litigation to enforce or defend intellectual property rights is often complex and often involves significant expense and can delay or prevent introduction or sale of our product candidates. If patents are held to be valid and infringed by our product candidates in a particular jurisdiction, we would, unless we could obtain a license from the patent holder, be required to cease selling in that jurisdiction and may need to relinquish or destroy existing stock in that jurisdiction. There may also be situations where we use our business judgment and decide to market and sell our approved products, notwithstanding the fact that allegations of patent infringement (s) have not been finally resolved by the courts, which is known as an " at- risk launch. " The risk involved in doing so can be substantial because the remedies available to the owner of a patent for infringement may include, among other things, damages measured by the profits lost by the patent owner and not necessarily by the profits earned by the infringer. In the case of a willful infringement, the definition of which is subjective, such damages may be increased up to three times. Moreover, because of the discount pricing typically involved with bioequivalent and, to a lesser extent, 505 (b) (2) products, patented branded products generally realize a substantially higher profit margin than bioequivalent and, to a lesser extent, 505 (b) (2) products, resulting in disproportionate damages compared to any profits earned by the

infringer. An adverse decision in patent litigation could have a material adverse effect on our business, financial position and results of operations and could cause the market value of our common stock to decline. Even if we receive regulatory approval for our additional product candidates, we may not be able to successfully commercialize these products, and the revenue that we generate from those sales, if any, may be limited. If approved for marketing, the commercial success of our product candidates will depend upon each product' s acceptance by the medical community, including physicians, patients and health- care payors. The degree of market acceptance for any of our product candidates will depend on a number of factors, including: ● demonstration of clinical safety and efficacy; ● relative convenience, dosing burden and ease of administration; ● the willingness of physicians to prescribe our product candidates, and the target patient population to try new therapies; ● efficacy of our product candidates compared to competing products; ● the introduction of any new products that may in the future become available targeting indications for which our product candidates may be approved; ● new procedures or therapies that may reduce the incidences of any of the indications in which our product candidates may show utility; ● pricing and cost-effectiveness; ● the inclusion or omission of our product candidates in applicable therapeutic and vaccine guidelines; ● the effectiveness of our own or any future collaborators' sales and marketing strategies; ● limitations or warnings contained in approved labeling from regulatory authorities; ● our ability to obtain and maintain sufficient third- party coverage and adequate reimbursement from government health care programs, including Medicare and Medicaid, private health insurers and other third- party payors or to receive the necessary pricing approvals from government bodies regulating the pricing and usage of therapeutics; and ● the willingness of patients to pay out- of- pocket in the absence of third- party coverage or adequate reimbursement or government pricing approvals. If any of our product candidates are approved, but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue and we may not be able to achieve or sustain profitability. Our efforts to educate the medical community and third- party payors on the benefits of our product candidates may require significant resources and may never be successful. In addition, even if we obtain regulatory approvals for our product candidates, the timing or scope of any approvals may prohibit or reduce our ability to commercialize our product candidates successfully. For example, if the approval process takes too long, we may miss market opportunities and give other companies the ability to develop competing products or establish market dominance. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render our product candidates not commercially viable. For example, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for any of our product candidates, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve any of our product candidates with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that indication. Further, the FDA or comparable foreign regulatory authorities may place conditions on approvals or require risk management plans or a REMS, to assure the safe use of the drug. If the FDA concludes a REMS is needed, the FDA will not approve the NDA without an approved REMS, if required. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA may also require a REMS for an approved product when new safety information emerges. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of our product candidates. Moreover, product approvals may be withdrawn for non- compliance with regulatory standards or if problems occur following the initial marketing of the product. Any of the foregoing scenarios could materially harm the commercial success of our product candidates. We are subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates could be subject to labeling and other restrictions and withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our product candidates. The FDA or foreign equivalent may still impose significant restrictions on our products indicated uses or the conditions of approval, or impose ongoing requirements for potentially costly and time- consuming post- approval studies, including Phase 4 clinical trials, and post- market surveillance to monitor safety and efficacy. Our product candidates will also be subject to ongoing regulatory requirements governing the manufacturing, labeling, packaging, storage, distribution, safety surveillance, advertising, promotion, recordkeeping and reporting of adverse events and other post- market information. These requirements include registration with the FDA, as well as continued compliance with current GCP regulations for any clinical trials that we conduct post- approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP requirements relating to quality control, quality assurance and corresponding maintenance of records and documents. The FDA has the authority to require a REMS as part of an NDA or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria or requiring patient testing, monitoring and / or enrollment in a registry. With respect to sales and marketing activities by us or any future partner, advertising and promotional materials must comply with FDA rules in addition to other applicable federal, state and local laws in the United States and similar legal requirements in other countries. In the United States, the distribution of product samples to physicians must comply with the requirements of the U. S. Prescription Drug Marketing Act. Application holders must obtain FDA approval for product and manufacturing changes, depending on the nature of the change. We may also be subject, directly or indirectly through our customers and partners, to various fraud and abuse laws, including, without limitation, the U. S. Anti- Kickback Statute, U. S. False Claims Act, and similar state laws, which impact, among other things, our proposed sales, marketing and scientific / educational grant programs. If we participate in the U. S. Medicaid Drug Rebate Program, the Federal Supply Schedule of the U. S. Department of Veterans Affairs, or other government drug programs, we will be subject to complex laws and regulations regarding reporting and payment obligations. All of these activities are also potentially subject to U. S. federal and state consumer protection and unfair competition laws. Similar

requirements exist in many of these areas in other countries. In addition, if any of our product candidates are approved for a particular indication, our product labeling, advertising and promotion would be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with the product' s approved FDA labeling. If we receive marketing approval for our product candidates, physicians may nevertheless legally prescribe our products to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees of permanent injunctions under which specified promotional conduct is changed or curtailed. If we or a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, problems with the facility where the product is manufactured, or we or our manufacturers fail to comply with applicable regulatory requirements, we may be subject to the following administrative or judicial sanctions: ● restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls; ● issuance of warning letters or untitled letters; ● clinical holds; ● injunctions or the imposition of civil or criminal penalties or monetary fines; ● suspension or withdrawal of regulatory approval; ● suspension of any ongoing clinical trials; ● refusal to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals; ● suspension or imposition of restrictions on operations, including costly new manufacturing requirements; or ● product seizure or detention or refusal to permit the import or export of product. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Adverse regulatory action, whether pre- or post- approval, can also potentially lead to product liability claims and increase our product liability exposure. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. Significant additional labeling or warning requirements or limitations on the availability of our products may inhibit sales of affected products. Various jurisdictions may seek to adopt significant additional product labeling or warning requirements or limitations on the availability of our products relating to the content or perceived adverse health consequences of our products. Federal laws may preempt some or all of these attempts by state or localities to impose additional labeling or warning requirements. If these types of requirements become applicable to our products under current or future environmental or health laws or regulations, they may inhibit sales of our products. Moreover, if we fail to meet compliance deadlines for any such new requirements, our products may be deemed misbranded or mislabeled and could be subject to enforcement action, or we could be exposed to private lawsuits alleging misleading labels or product promotion. Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval for our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell our product candidates. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We do not know whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. For additional information on legislative and regulatory changes, see the Item 1. Business — Healthcare Reform section. In the United States, the Medicare Modernization Act (" MMA ") changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for drugs. In addition, this legislation authorized Medicare Part D prescription drug plans to use formularies where they can limit the number of drugs that will be covered in any therapeutic class. As a result of this legislation and the expansion of federal coverage of drug products, we expect that there will be additional pressure to contain and reduce costs. These cost reduction initiatives and other provisions of this legislation could decrease the coverage and price that we receive for our product candidates and could seriously harm our business. While the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, and any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the Health Care Reform Law, was enacted, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U. S. pharmaceutical industry. The Health Care Reform Law, among other things, imposed reporting requirements on manufacturers related to drug samples and financial relationships with physicians and teaching hospitals, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and established a Medicare Part D coverage gap discount program. Some of the provisions of the Health Care Reform

Law have yet to be implemented, and there have been judicial and Congressional challenges to certain aspects of the Health Care Reform Law, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Health Care Reform Law. Since January 2017, former President Trump had signed two executive orders and other directives designed to delay, circumvent or loosen certain requirements mandated by the Health Care Reform Law. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Health Care Reform Law. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Health Care Reform Law have been signed into law. The Tax Act included a provision which repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Health Care Reform Law on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the " individual mandate. " On January 22, 2018, former President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Health Care Reform Law- mandated fees, including the so- called " Cadillac " tax on certain high-cost employer- sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non- exempt medical devices. The Bipartisan Budget Act of 2018, among other things, amended the Health Care Reform Law, effective January 1, 2019, to increase from 50 % to 70 % the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole ". On December 14, 2018, a Texas U. S. District Court Judge ruled that the Health Care Reform Law is unconstitutional in its entirety because the " individual mandate " was repealed by Congress as part of the Tax Act. In June 2021, the U. S. Supreme Court overturned the 2018 Texas U. S. District Court decision. It is unclear how subsequent appeals, and other efforts to repeal and replace the Health Care Reform will impact our business. We cannot predict the impact on our business of changes to current laws and regulations. However, any changes that lower reimbursements for products for which we may obtain regulatory approval, or that impose administrative and financial burdens on us, could adversely affect our business. In addition, other legislative changes have been proposed and adopted in the United States since the Health Care Reform Law was enacted. These changes include, among others, aggregate reductions of Medicare payments to providers of up to 2 % per fiscal year. We expect that additional state and federal health care reform measures will be adopted in the future, which may alter or completely replace the existing health care financing structure. Any of these reform measures could limit the amounts that federal and state governments will pay for health care products and services, which could result in reduced demand for any such product candidate that we may have developed or additional pricing pressures on our business. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent 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 Trump administration released a " Blueprint " to lower drug prices and reduce out- of- pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out- of-pocket costs of drug products paid by consumers. On January 31, 2019, the U. S. Department of Health and Human Services, Office of Inspector General, proposed modifications to the federal Anti- Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require additional authorization to become effective, Congress and government administration officials have each indicated that they will continue to seek new legislative and / or administrative measures to control drug costs. The policies of the FDA or similar regulatory authorities may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the 21st Century Cures Act was signed into law. The 21st Century Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation, but it has not yet been fully implemented and its ultimate implementation is unclear. Furthermore, the Trump administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA' s ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. If these executive actions impose constraints on the FDA' s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. 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, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

Changes in U. S. trade policy, threats of international tariffs, and changes to the U. S. political landscape may adversely affect our business, results of operations, financial condition, and prospects. Rising threats of international tariffs, including tariffs applied to goods traded between the U. S. and Canada, Mexico, Europe and other international markets, could materially and adversely affect our business, results of operations, financial condition, and prospects. Over the past several years, legislative and executive action from U. S. and foreign leaders has led to both threats of and the imposition of tariffs on certain materials and products, including pharmaceutical products. Changes in U. S. relations with these international trading partners, including the current trade tensions, are difficult to predict and could adversely affect our operations or financial condition. We cannot predict the extent to which the U. S. or other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon the import or export of our products in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action

related to tariffs or trade agreements or policies has the potential to adversely impact demand for our products, our costs, our customers, our suppliers, and the U. S. economy, which in turn could have a material adverse effect on our business, results of operations, financial condition, and prospects. If we market our existing approved products or any of our new product candidates in a manner that violates health care fraud and abuse laws, or if we violate government price reporting laws, we may be subject to civil or criminal penalties. The FDA enforces laws and regulations, which require that the promotion of pharmaceutical products be consistent with the approved prescribing information. While physicians may prescribe an approved product for a so- called " off label " use, it is unlawful for a pharmaceutical company to promote its products in a manner that is inconsistent with its approved label and any company which engages in such conduct can be subject to significant liability. Similarly, industry codes in the EU and other foreign jurisdictions prohibit companies from engaging in off- label promotion and regulatory agencies in various countries enforce violations of the code with civil penalties. While we intend to ensure that our promotional materials are consistent with our label, regulatory agencies may disagree with our assessment and may issue untitled letters, warning letters or may institute other civil or criminal enforcement proceedings. In addition to FDA restrictions on marketing of pharmaceutical products, several other types of state and federal health care fraud and abuse laws have been applied in recent years to restrict certain marketing practices in the pharmaceutical industry. These laws include, among others, the U. S. Anti- Kickback Statute, U. S. False Claims Act and similar state laws. Because of the breadth of these laws and the narrowness of their exceptions and safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of these laws. The U. S. Anti- Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any health care item or service reimbursable under Medicare, Medicaid or other federally financed health care programs. This statute has been interpreted broadly to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, formulary managers, and others on the other hand. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Federal Anti- Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case- by- case basis based on a cumulative review of all of its facts and circumstances. Our practices may not, in all cases, meet all of the criteria for safe harbor protection from anti- kickback liability. Moreover, recent health care reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amended the intent requirement of the U. S. Anti- Kickback Statute and other criminal health care fraud statutes; a person or entity no longer needs to have actual knowledge of the statutes or specific intent to violate them in order to have committed a violation. In addition, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the U. S. Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the U. S. False Claims Act. Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Over the past few years, several pharmaceutical and other health care companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, such as: allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off- label promotion that caused claims to be submitted to Medicare or Medicaid for non- covered, off- label uses; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Most states also have statutes or regulations similar to the U. S. Anti- Kickback Statute and the U. S. False Claims Act, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Sanctions under these federal and state laws may include significant administrative, criminal, and civil monetary penalties, exclusion of a manufacturer' s products from reimbursement under government programs, fines and imprisonment. Due to the breadth of these federal and state anti- kickback laws, and the potential for additional legal or regulatory change in this area, it is possible that our future business activities, including our sales and marketing practices and / or our future relationships with physicians and the medical community might be challenged under anti-kickback laws, which could harm us. We are completely dependent on third parties to manufacture our approved products and new product candidates, and our commercialization of our product candidates could be halted, delayed or made less profitable if those third parties fail to obtain manufacturing approval from the FDA or comparable foreign regulatory authorities, fail to provide us with sufficient quantities of our product candidates or fail to do so at acceptable quality levels or prices. We do not currently have, nor do we plan to acquire, the capability or infrastructure to manufacture the API in our product candidates for use in our clinical trials or for commercial product, if any. In addition, we do not have the capability to encapsulate any of our product candidates as a finished drug product for commercial distribution. As a result, we will be obligated to rely on contract manufacturers, if and when any of our product candidates are approved for commercialization. While we have entered into certain agreements with contract manufacturers for clinical and commercial supply, there can be no assurance we will be able to maintain those relationships or engage additional contract manufacturers for clinical or commercial supply of any of our product candidates on favorable terms to us, or at all. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after we submit an NDA to the FDA or their equivalents to other relevant regulatory authorities. We will not control the manufacturing process of, and will be completely dependent on, our contract manufacturing partners for compliance with GMPs for manufacture of both active drug substances and finished drug products. These GMP regulations cover all aspects of the manufacturing, testing, quality control and record keeping relating to our product candidates. If our contract manufacturers

do not successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure or maintain regulatory approval for their manufacturing facilities. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Our contract manufacturers will be subject to ongoing periodic unannounced inspections by the FDA and corresponding state and foreign agencies for compliance with GMPs and similar regulatory requirements. We will not have control over our contract manufacturers' compliance with these regulations and standards. Failure by any of our contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, failure to grant approval to market any of our product candidates, delays, suspensions or withdrawals of approvals, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business. In addition, we will not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. Failure by our contract manufacturers to comply with or maintain any of these standards could adversely affect our ability to develop, obtain regulatory approval for or market any of our product candidates. If, for any reason, these third parties are unable or unwilling to perform, we may not be able to terminate our agreements with them, and we may not be able to locate alternative manufacturers or formulators or enter into favorable agreements with them and we cannot be certain that any such third parties will have the manufacturing capacity to meet future requirements. If these manufacturers or any alternate manufacturer of finished drug product experiences any significant difficulties in its respective manufacturing processes for our API or finished products or should cease doing business with us, we could experience significant interruptions in the supply of any of our product candidates or may not be able to create a supply of our product candidates at all. Were we to encounter manufacturing issues, our ability to produce a sufficient supply of any of our product candidates might be negatively affected. Our inability to coordinate the efforts of our third- party manufacturing partners, or the lack of capacity available at our third- party manufacturing partners, could impair our ability to supply any of our product candidates at required levels. Because of the significant regulatory requirements that we would need to satisfy in order to qualify a new bulk or finished product manufacturer, if we face these or other difficulties with our current manufacturing partners, we could experience significant interruptions in the supply of any of our product candidates if we decided to transfer the manufacture of any of our product candidates to one or more alternative manufacturers in an effort to deal with the difficulties. Any manufacturing problem or the loss of a contract manufacturer could be disruptive to our operations and result in lost sales. Additionally, we rely on third parties to supply the raw materials needed to manufacture our potential products. Any reliance on suppliers may involve several risks, including a potential inability to obtain critical materials and reduced control over production costs, delivery schedules, reliability and quality. Any unanticipated disruption to a contract manufacturer caused by problems at suppliers could delay shipment of any of our approved products or product candidates in development, increase our cost of goods sold and result in lost sales. We cannot guarantee that our future manufacturing and supply partners will be able to reduce the costs of commercial- scale manufacturing of any of our product candidates over time. If the commercial- scale manufacturing costs of any of our product candidates are higher than expected, these costs may significantly impact our operating results. In order to reduce costs, we may need to develop and implement process improvements. However, in order to do so, we will need, from time to time, to notify or make submissions with regulatory authorities, and the improvements may be subject to approval by such regulatory authorities. We cannot be sure that we will receive these necessary approvals or that these approvals will be granted in a timely fashion. We also cannot guarantee that we will be able to enhance and optimize output in our commercial manufacturing process. If we cannot enhance and optimize output, we may not be able to reduce our costs over time. We may not be able to establish agreements with third parties with whom we wish to collaborate and, if we are able to establish them, we may not be able to establish them on commercially reasonable terms, which could result in alterations or delays of our development and commercialization plans. We face significant competition in seeking appropriate third parties to assist us in our business operations. Whether we reach a definitive agreement will depend, among other things, upon our assessment of the third parties' resources and expertise, the terms and conditions of the proposed agreement, and the proposed parties' evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Potential third parties may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. The terms of any arrangements that we may establish may also not be favorable to us. Agreements with third parties are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future third parties to assist us in our business operations. We may not be able to negotiate agreements on a timely basis, on acceptable terms or at all. If we are unable to do so, we may have to curtail the development of the product candidate, reduce or delay its development program, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or bring it to market and generate product revenue. In addition, any future agreements that we enter into may not be successful. The success of our arrangements will depend heavily on the efforts and activities of our third- party collaborators.

Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Disagreements between parties to an agreement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the agreement. These disagreements can be difficult to resolve if neither of the parties has final decision- making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation. We may need to rely on third parties to conduct clinical trials for our future product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize any of our product candidates and our business would be substantially harmed. We have entered into agreements with third- party CROs to conduct and manage our clinical programs including contracting with clinical sites to perform our clinical studies. We plan to rely heavily on these parties for execution of clinical studies for our product candidates and will control only certain aspects of their activities. Nevertheless, we will be responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on CROs and clinical sites will not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any products in clinical development. The FDA and its foreign equivalents enforce these GCP regulations through periodic inspections of trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA or other regulatory authorities will determine that any of our clinical trials comply with GCPs. In addition, our clinical trials must be conducted with products produced under GMP regulations and will require a large number of test subjects. Our failure or the failure of our CROs or clinical sites to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process and could also subject us to enforcement action up to and including civil and criminal penalties. Although we intend to design the clinical trials for our product candidates in consultation with CROs, we expect that the CROs will manage all of the clinical trials conducted at contracted clinical sites. As a result, many important aspects of our drug development programs would be outside of our direct control. In addition, the CROs and clinical sites may not perform all of their obligations under arrangements with us or in compliance with regulatory requirements. If the CROs or clinical sites do not perform clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development and commercialization of any of our product candidates for the subject indication may be delayed or our development program materially and irreversibly harmed. We cannot control the amount and timing of resources these CROs and clinical sites will devote to our program or any of our product candidates. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of our clinical trials, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third- party CROs or clinical sites terminate, we may not be able to enter into arrangements with alternative CROs or clinical sites. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any such clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for any of our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. We enter into various contracts in the normal course of our business, some or all of which may require us to indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have an adverse effect on our business, financial condition and results of operations. In the normal course of business, we periodically may enter into commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to our commercial agreements, vendors typically ask for indemnification from any third- party product liability claims that could result from the production, use or consumption of the product, as well as for alleged infringements of any patent or other intellectual property right by a third party. Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a third party to indemnify us and the party is denied insurance coverage, or the indemnification obligation exceeds the applicable insurance coverage and does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected. Any termination or suspension of, or delays in the commencement or completion of, any necessary studies of any of our product candidates for any indications could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. The commencement and completion of clinical studies can be delayed for a number of reasons, including delays related to: ● the FDA or a comparable foreign regulatory authority failing to grant permission to proceed and placing the clinical study on hold; ● subjects for clinical testing failing to enroll or remain in our trials at the rate we expect; ● a facility manufacturing any of our product candidates being ordered by the FDA or other government or regulatory authorities to temporarily or permanently shut down due to violations of GMP requirements or other applicable requirements, or cross- contaminations of product candidates in the manufacturing process; ● any changes to our manufacturing process that may be necessary or desired; ● subjects choosing an alternative treatment for the indications for which we are developing our product candidates, or participating in competing clinical studies; ● subjects experiencing severe or unexpected drug- related adverse effects; ● reports from clinical testing on similar technologies and products raising safety and / or efficacy concerns; ● third- party clinical investigators losing their license or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or

employing methods consistent with the clinical trial protocol, GMP requirements, or other third parties not performing data collection and analysis in a timely or accurate manner; ● inspections of clinical study sites by the FDA, comparable foreign regulatory authorities, or IRBs finding regulatory violations that require us to undertake corrective action, result in suspension or termination of one or more sites or the imposition of a clinical hold on the entire study, or that prohibit us from using some or all of the data in support of our marketing applications; ● third- party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or any of the data produced by such contractors in support of our marketing applications; ● one or more IRBs refusing to approve, suspending or terminating the study at an investigational site, precluding enrollment of additional subjects, or withdrawing its approval of the trial; reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● deviations of the clinical sites from trial protocols or dropping out of a trial; ● adding new clinical trial sites; ● the inability of the CRO to execute any clinical trials for any reason; and ● government or regulatory delays or " clinical holds " requiring suspension or termination of a trial. Product development costs for any of our product candidates will increase if we have delays in testing or approval or if we need to perform more or larger clinical studies than planned. Additionally, changes in regulatory requirements and policies may occur and we may need to amend study protocols to reflect these changes. Amendments may require us to resubmit our study protocols to the FDA, comparable foreign regulatory authorities, and IRBs for reexamination, which may impact the costs, timing or successful completion of that study. If we experience delays in completion of, or if we, the FDA or other regulatory authorities, the IRB, or other reviewing entities, or any of our clinical study sites suspend or terminate any of our clinical studies of any of our product candidates, its commercial prospects may be materially harmed and our ability to generate sufficient product revenues will be delayed. Any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to generate sufficient revenues. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. In addition, if one or more clinical studies are delayed, our competitors may be able to bring products to market before we do, and the commercial viability of any of our product candidates could be significantly reduced. Clinical drug development involves a lengthy and expensive process with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. Clinical testing of drug product candidates is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre- clinical studies and early clinical trials may not be predictive of the results of later- stage clinical trials. We cannot assure you that the FDA or comparable foreign regulatory authorities will view the results as we do or that any future trials of any of our product candidates will achieve positive results. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre- clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Any future clinical trial results for our product candidates may not be successful. In addition, a number of factors could contribute to a lack of favorable safety and efficacy results for any of our product candidates. For example, such trials could result in increased variability due to varying site characteristics, such as local standards of care, differences in evaluation period and surgical technique, and due to varying patient characteristics including demographic factors and health status. We may need to conduct clinical trials for our new product candidates and we may be delayed in commercializing or fail to find success in these trials. Further, the results of any clinical trial may not be predictive of future trial results. Positive results in preclinical testing and early clinical trials do not ensure that later clinical trials will be successful. A number of pharmaceutical companies have suffered significant setbacks in clinical trials, including in Phase 3, after promising results in preclinical testing and early clinical trials. These setbacks have included negative safety and efficacy observations in later clinical trials, including previously unreported adverse events. Phase 3 clinical trials often produce unsatisfactory results even though prior clinical trials were successful. Moreover, the results of clinical trials may be unsatisfactory to the FDA or foreign regulatory authorities even if we believe those clinical trials to be successful. The FDA or applicable foreign regulatory agencies may suspend one or all of our clinical trials or require that we conduct additional clinical, nonclinical, manufacturing, validation or drug product quality studies and submit that data before considering or reconsidering any NDA or similar foreign regulatory application we may submit. Depending on the extent of these additional studies, approval of any applications that we submit may be significantly delayed or may require us to expend more resources than we have available. It is also possible that additional studies we conduct may not be considered sufficient by the FDA or applicable foreign regulatory agencies to provide regulatory approval. If any of these outcomes occur, we may not receive approval for our product ~~candidate~~ **candidates , which could negatively impact our business, financial condition, or results of operations** . We are subject to extensive laws and regulations related to data privacy, and our failure to comply with these laws and regulations could harm our business. We are subject to data privacy and security laws and regulations by both the federal government and the states in which we conduct our business. HIPAA and their respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, govern our processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, destruction and disposal of personal data. There are foreign and state law versions of these laws and regulations to which we are currently and / or may in the future, be subject. For example, the collection and use of personal health data in the European Union is governed by the GDPR. The GDPR, which is wide- ranging in scope, imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, the security and confidentiality of the personal data, data breach notification and the use of third- party processors in connection with the processing of personal data. The GDPR also

imposes strict rules on the transfer of personal data out of the European Union to the United States, provides an enforcement authority and imposes large monetary penalties for noncompliance. The GDPR requirements apply not only to third- party transactions, but also to transfers of information within our company, including employee information. In the United States, there are numerous privacy laws that may be applicable to our activities, and a range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. New laws also are being considered or have been implemented at both the state and federal levels. For example, the California Consumer Privacy Act of 2018 (effective on January 1, 2020), as amended by the California Privacy Rights and Enforcement Act of 2020 (effective on January 1, 2023) (" CCPA "), requires companies that process information of California residents (" consumers, " as defined under the CCPA) to make specific disclosures about their data collection, use and disclosure practices, provides consumers with individual data privacy rights, including enabling consumers to limit the use of their sensitive personal information, imposes new operational requirements for covered businesses, imposes data retention limitations, provides a private right of action for data breaches, creates a statutory damages framework and creates a new state agency, the California Privacy Protection Agency, that is vested with the authority to implement and enforce the CCPA. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities in the future depending on our revenue growth, how much consumer data we process, and how such laws are interpreted. Additionally, four additional states have enacted privacy laws, which could increase our potential liability and adversely affect our business in the future. In particular, the Virginia Consumer Data Protection Act (" VCDPA ") became effective on January 1, 2023; the Colorado Privacy Act (" CPA ") and the Connecticut Data Privacy Act (" CTDPA ") ~~will become~~ **became** effective on July 1, 2023; and the Utah Consumer Privacy Act (" UCPA ") ~~will become~~ **became** effective on December 31, 2023. While these regulations incorporate many similar concepts to the CCPA, there are also several key differences in their scope, application, and enforcement that will, among other things, impact how regulated businesses collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Other states are considering similar legislation and a broad range of legislative measures also have been introduced at the federal level. Such proposed legislation, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country makes our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. Further, regulations promulgated pursuant to HIPAA ~~imposes~~ **impose** privacy, security and breach notification obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA establishes privacy and security standards that limit the use and disclosure of individually identifiable health information and protected health information, or PHI, and requires the implementation of administrative, physical, and technological safeguards to protect the privacy of PHI and ensure the confidentiality, integrity, and availability of electronic PHI. Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA. We do not believe that we are currently acting as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA' s criminal provisions either directly or under aiding- and- abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare provider or research institution that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information. The global legislative and regulatory landscape for privacy and data protection continues to evolve, and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. This evolution may create uncertainty in our business, result in liability or impose additional costs on us. The cost of compliance with these laws, regulations and standards is high and is likely to continue to increase in the future. It is possible that privacy laws may be interpreted and applied in a manner that is inconsistent with our practices. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self- regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In many jurisdictions, enforcement actions and consequences for noncompliance are rising. As we continue to expand into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Further, any failure by our third- party collaborators, service providers, contractors or consultants to comply with applicable law, regulations or contractual obligations related to data privacy or security could result in proceedings against us by governmental entities or others. We may also publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information and / or other confidential information. Although we endeavor to comply with applicable regulations, our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies and documentation. Such failures can subject us to potential international, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. We also face a threat of consumer class actions related to these laws and the overall

protection of personal information. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business, financial condition, results of operations or prospects. Risks Relating to Our Intellectual Property Rights We will depend on rights to certain pharmaceutical compounds that have been acquired by us. We do not have complete control over these pharmaceutical compounds and any loss of our rights to them could prevent us from selling our products. We are dependent on the assignment and licensing from third parties for certain of our pharmaceutical compounds and potential product candidates. Our rights to use the pharmaceutical compounds we were assigned are subject to the negotiation of, continuation of and compliance with the terms of those assignments and licenses. Moreover, under these agreements, any related patents may remain under the control of the assignor or licensor. Our rights to develop and commercialize the product candidates are subject to the validity of the intellectual property rights. Enforcement of any assigned or licensed patents or defense or any claims asserting the invalidity of these patents is often subject to the control or cooperation of the assignor or licensor. Legal action could be initiated against the original owners of the intellectual property that we acquired and an adverse outcome in such legal action could harm our business because it might prevent such companies or institutions from continuing to assign intellectual property that we may need to operate our business. In addition, our rights to practice the inventions claimed in any patents and patent applications are subject to our assignors and licensors abiding by the terms of those agreements and not terminating them. These agreements may be terminated by the assignor or licensor if we are in material breach of certain terms or conditions of the agreement or in certain other circumstances. Our rights under these agreements are subject to our continued compliance with the terms of the agreements, including the payment of royalties and other payment due under the agreements. Termination of these agreements could prevent us from marketing some or all of our products. Because of the complexity of our products and the patents, determining the scope of the assignment or license and related royalty obligations can be difficult and can lead to disputes between us and the assignor or licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the agreement. If the assignor or licensor believed we were not paying the royalties due under the agreement or were otherwise not in compliance with the terms of the agreement, the assignor or licensor might attempt to revoke the agreement. If such an attempt were successful, we might be barred from producing and selling some or all of our products. It may be difficult and costly to protect our intellectual property rights, and we cannot ensure the protection of these rights. Our commercial success depends, in part, on obtaining and maintaining patent protection for our technologies, products and processes, successfully defending these patents against third- party challenges and successfully enforcing these patents against third- party competitors. Proprietary rights relating to our current and potential products will be protected from unauthorized use by third parties only to the extent that they are covered by valid and enforceable patents or are effectively maintained as trade secrets. Patents owned by or licensed to us may not afford protection against competitors, and our pending patent applications now or hereafter filed by or licensed to us may not result in patents being issued. Our patents or patent applications, or those licensed to us, if issued, may be challenged, invalidated or circumvented, and the rights granted thereunder may not provide proprietary protection or competitive advantages to us against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent, which could adversely affect our ability to protect future product development and, consequently, our operating results and financial position. If we cannot maintain the confidentiality of our proprietary technology and other confidential information, our ability to receive patent protection and our ability to protect valuable information owned by us may be imperiled. Litigation may be necessary to assert claims of infringement, to enforce patents issued to us, to protect trade secrets or know- how owned by us, or to determine the scope and validity of the proprietary rights of others. In addition, interference, derivation, post- grant oppositions, and similar proceedings may be necessary to determine rights to inventions in our patents and patent applications. Litigation or similar proceedings could result in substantial costs to and diversion of effort by us and could have a material adverse effect on our business, financial condition and results of operations. These efforts by us may not be successful. Additionally, if we or one of our licensing partners initiated legal proceedings against a third party to enforce a patent covering any product candidate, the defendant could counterclaim that the patent covering any other product candidate is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post grant review and equivalent proceedings in foreign jurisdictions, e. g., opposition proceedings. Such proceedings could result in revocation or amendment of our patents or our licensors' patents in such a way that they no longer cover product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on any product candidate. Such a loss of patent protection would have a material adverse impact on our business. We also rely on our know-how, trade secrets, and continuing technological innovation to develop and maintain our proprietary position. However, know-how and trade secrets are difficult to protect. While we require and continue to intend to require employees, academic collaborators, consultants and other contractors to enter into confidentiality agreements, we may not be able to adequately protect our trade secrets or other proprietary or licensed information. There can be no assurance that these agreements will not be

breached, that we will have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know- how and inventions. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those offered in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we do not have, or where we do not pursue and obtain, patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing. Further, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country- by- country basis, which is an expensive and time- consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Moreover, proceedings to enforce our patent rights, or those of our licensors or partners, in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our in- licensed patents, or any patents that we may own in the future, at risk of being invalidated or interpreted narrowly, could put our owned or in- licensed patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If we fail to obtain or maintain patent protection or trade secret protection for our product candidates or our technologies, third parties could use our proprietary information, which could impair our ability to compete in the market and adversely affect our ability to generate revenues and attain profitability. We may also rely on the trademarks we may develop to distinguish our products from the products of our competitors. We cannot guarantee that any trademark applications filed by us or our business partners will be approved. Third parties may also oppose such trademark applications, or otherwise challenge our use of the trademarks. In the event that the trademarks we use are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. Further, we cannot provide assurance that competitors will not infringe the trademarks we use, or that we will have adequate resources to enforce these trademarks. Changes in either U. S. patent law or interpretation of such laws could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and it therefore is costly, time-consuming and inherently uncertain. In addition, on September 16, 2011, the Leahy- Smith America Invents Act (“ AIA ”), was signed into law. The AIA includes a number of significant changes to U. S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a “ first- to- file ” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the U. S. PTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard necessary to invalidate a patent claim in the USPTO proceedings compared to the evidentiary standard in U. S. federal court, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Depending on decisions by the U. S. Congress, the federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing in- licensed patents and patents that we might obtain in the future. Our product candidates may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development and commercialization efforts. Our success depends in part on avoiding infringement of the proprietary technologies of others. The pharmaceutical industry has been characterized by frequent litigation regarding patent and other intellectual property rights.

Identification of third- party patent rights that may be relevant to our proprietary technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. Additionally, because patent applications are maintained in secrecy until the application is published, we cannot be certain that we were the first to make inventions or file for protection of inventions set forth in our patents or patent applications. There may also be issued patents and patent applications claiming subject matter that we may be required to license in order to research, develop or commercialize any of our product candidates, and we do not know if such patents and patent applications would be available to license on commercially reasonable terms, or at all. Any claims of patent infringement asserted by third parties would be time- consuming and may: ● result in costly litigation; ● divert the time and attention of our technical personnel and management; ● prevent us from commercializing a product until the asserted patent expires or is held finally invalid or not infringed in a court of law; ● require us to cease or modify our use of the technology and / or develop non-infringing technology; or ● require us to enter into royalty or licensing agreements. Third parties may hold proprietary rights that could prevent any of our product candidates from being marketed. Any patent- related legal action against us claiming damages and seeking to enjoin commercial activities relating to any of our product candidates or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market any of our product candidates or any future product candidates. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. In addition, we cannot be sure that we could redesign our product candidates or any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing any of our product candidates or a future product candidate, which could harm our business, financial condition and operating results. We expect that there are other companies, including major pharmaceutical companies, working in the areas competitive to our proposed product candidates which either has resulted, or may result, in the filing of patent applications that may be deemed related to our activities. If we were to challenge the validity of these or any issued U. S. patent in court, we would need to overcome a statutory presumption of validity that attaches to every issued U. S. patent. This means that, in order to prevail, we would have to present clear and convincing evidence as to the invalidity of the patent' s claims. If we were to challenge the validity of these or any issued U. S. patent in an administrative trial before the Patent Trial and Appeal Board in the USPTO, we would have to prove that the claims are unpatentable by a preponderance of the evidence. There is no assurance that a jury and / or court would find in our favor on questions of infringement, validity or enforceability. Others may claim an ownership interest in our intellectual property, which could expose us to litigation and have an adverse effect on our prospects. A third party may claim an ownership interest in one or more of our or our licensors' patents or other proprietary or intellectual property rights. A third party could bring legal actions against us and seek monetary damages and / or enjoin clinical testing, manufacturing and marketing of the affected product or products. We cannot guarantee that a third party will not assert a claim or an interest in any of such patents or intellectual property. If we become involved in any litigation, it could consume a substantial portion of our resources, and cause a significant diversion of effort by our technical and management personnel. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to continue to manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross- licenses to our patents. We cannot, however, assure you that any such license will be available on acceptable terms, if at all. Ultimately, we could be prevented from commercializing a product candidate, or be forced to cease some aspect of our business operations as a result of claims of patent infringement or violation of other intellectual property rights. Further, the outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree. We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers. As is commonplace in our industry, we will employ individuals who were previously employed at other pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject in the future to claims that our employees or prospective employees are subject to a continuing obligation to their former employers (such as non- competition or non- solicitation obligations) or claims that our employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. Risks Related to Owning Our Common Stock **We are currently unable to comply with the requirement to provide separate audited financial statements and unaudited pro forma financial information for the INCRELEX ® product acquisition, specified by Item 9. 01 of Form 8- K. As previously reported in our Form 8- K / A filed on March 7, 2025, we are currently unable to file an amendment to our Form 8- K reporting the completion of our acquisition of the INCRELEX ® product containing the separate audited financial statements and unaudited pro forma financial information required by Item 9. 01 of Form 8- K by the required due date. As such, we are no longer in compliance with our reporting obligations under the Securities Exchange Act of 1934, as amended (the " Exchange Act "). Our inability to obtain such information by the deadline has resulted in noncompliance with our reporting obligations under the Exchange Act. Such noncompliance, in turn: ● has, in the absence of receiving the requested waiver from the SEC, rendered us ineligible to use the SEC' s short- form registration statement on Form S- 3 to register the issuance of our securities for any capital raising activities; and ● could, depending on if and / or when the financial statements are created and become available and we file them, have other material and adverse consequences that are summarized below. Until the earlier of the date on which we receive the requested waiver or the audited financial statements and unaudited pro forma financial information specified by Item 9. 01 of Form 8- K**

are filed with the SEC, no new registration statement that we file with the SEC seeking to register our securities for issuance, sale or resale, including for capital raising transactions, additional acquisitions or for our employee benefit programs, will be declared effective by the SEC and thus our capital raising activities and ability to provide new equity incentives to our employees will be substantially curtailed during that period. An active, liquid and orderly trading market for our shares may not continue to be developed or sustained. Our common stock is listed on the Nasdaq Global Market. However, trading volume has been limited and a more active public market for our common stock may not develop or be sustained over time. The market price of our common stock could be subject to significant fluctuations. The price of our stock may change in response to variations in our operating results and also may change in response to other factors, including factors specific to companies in our industry many of which are beyond our control. Our shares may be less liquid than the shares of other public companies and there may be imbalances between supply and demand for our shares. As a result, our share price may experience significant volatility and may not necessarily reflect the value of our expected performance. Moreover, sales of our common stock in the public market, or the perception that such sales could occur, could negatively impact the price of our common stock. As a result, you may not be able to sell your shares of our common stock in short time periods, or possibly at all, and the price per share of our common stock may fluctuate significantly. Future capital raises may dilute our existing stockholders' ownership, could depress the market price for our common stock and have other adverse effects on our operations. We have an effective Form S- 3 registration statement (" Shelf Registration ") on file with the SEC which allows us to sell any combination of common stock, preferred stock, debt securities, warrants to purchase any of these securities, subscription rights to purchase any of these securities, and / or units consisting of one or more of the foregoing in one or more offerings up to a total dollar amount of $ 100 million ~~(including the $ 22. 5 million raised in our October 2020 offering of common stock)~~. The issuance of additional shares of our common stock pursuant to the Shelf Registration, or issuances of securities convertible into or exercisable for our common stock or other equity- linked securities, including preferred stock, warrants, debt securities or units, would dilute the ownership interest of our common shareholders and could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities. If we raise additional funds by issuing debt securities, these debt securities would have rights senior to those of our common stock and the terms of the debt securities issued could impose significant restrictions on our operations, including liens on our assets. If we raise additional funds through collaborations and licensing arrangements, we may be required to relinquish some rights to our technologies or candidate products, or to grant licenses on terms that are not favorable to us. The trading price of the shares of our common stock may continue to be volatile, and purchasers of our common stock could incur substantial losses. The trading price of our common stock has fluctuated significantly in the past and is likely to be volatile. The stock market in general, and early stage public companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of such companies. The stock market in general has been, and the market price of our shares in particular will likely be, subject to fluctuation, whether due to, or irrespective of, our operating results and financial condition. The market price of our shares on the Nasdaq Global Market may fluctuate as a result of a number of factors, some of which are beyond our control, including, but not limited to: ● actual or anticipated variations in our and our competitors' results of operations and financial condition; ● market acceptance of our products; ● the mix of products that we sell and related services that we provide; ● changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts; ● not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 (" Sarbanes- Oxley Act "); ● changes in earnings estimates or recommendations by securities analysts, if our shares are covered by analysts; ● development of technological innovations or new competitive products by others; ● announcements of technological innovations or new products by us; ● publication of the results of preclinical or clinical trials for our other product candidates; ● failure by us to achieve a publicly announced milestone; ● delays between our expenditures to develop and market new or enhanced products and the generation of sales from those products; ● developments concerning intellectual property rights, including our involvement in litigation brought by or against us; ● regulatory developments and the decisions of regulatory authorities as to the approval or rejection of new or modified products; ● changes in the structure of healthcare payment systems; ● changes in the amounts that we spend to develop, acquire or license new products, technologies or businesses; ● changes in our expenditures to promote our products; ● our sale or proposed sale, or the sale by our significant stockholders, of our shares or other securities in the future; ● changes in key personnel; ● success or failure of our research and development projects or those of our competitors; ● the trading volume of our shares; and ● general economic and market conditions and other factors, including factors unrelated to our operating performance. These factors and any corresponding price fluctuations may materially and adversely affect the market price of our shares and result in substantial losses being incurred by our investors. In the past, following periods of market volatility, public company stockholders have often instituted securities class action litigation. If we were involved in securities litigation, it could impose a substantial cost upon us and divert the resources and attention of our management from our business. We are a " smaller reporting company " and we cannot be certain if the reduced disclosure requirements applicable to smaller reporting companies will make our common stock less attractive to investors. We are a " smaller reporting company " pursuant to the Securities Exchange Act of 1934. As a smaller reporting company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not smaller reporting companies. These exemptions include, but are not limited to, presenting only two years of audited financial statements in our registration statement and annual reports on Form 10- K, selected financial data in such registration statements and annual reports, and reduced disclosure obligations on executive compensation. As a result of our reduced disclosure requirements, the information we provide stockholders will be different than the information that is available with respect to other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile. If we fail to maintain

an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares. Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act, or the subsequent testing by our independent registered public accounting firm when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retrospective changes to our ~~consolidated~~ financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares. There is also a risk that neither we nor our independent registered public accounting firm (when applicable in the future) will be able to conclude within the prescribed timeframe that internal controls over financial reporting ~~is~~ **are** effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. We have not paid dividends in the past and have no immediate plans to pay dividends, so any returns will be limited to the value of our stock. We plan to reinvest all of our earnings, to the extent we have earnings, to cover operating costs and otherwise become and remain competitive. We do not plan to pay any cash dividends with respect to our securities in the foreseeable future. We cannot assure you that we would, at any time, generate sufficient surplus cash that would be available for distribution to the holders of our common stock as a dividend. Therefore, you should not expect to receive cash dividends on our common stock, and any return to stockholders will therefore be limited to the appreciation of their stock. If equity research analysts do not publish research or reports about our business or if they issue unfavorable commentary or downgrade our shares, the price of our shares could decline. The trading market for our shares will rely in part on the research and reports that equity research analysts publish about us and our business, if at all. We do not have control over these analysts, and we do not have commitments from them to write research reports about us. The price of our shares could decline if no research reports are published about us or our business, or if one or more equity research analysts downgrades our shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Under the Tax Act, federal **Net Operating Losses (“** NOLs **”)** incurred in taxable years ending after December 31, 2017, may be carried forward indefinitely, but ~~the deductibility~~ **can only be applied to 80 %** of **taxable income for the year. As of December 31, 2024, our remaining** federal NOLs **were** generated ~~in~~ **after the 2017** tax ~~years~~ **year** ~~beginning before~~ **. Our significant state NOLs as of** December 31, **2024 were generated** ~~2017, is limited. We filed~~ in ~~GA,~~ IL **and** ~~, MN,~~ TN, **which begin to expire in 2037** and ~~FL for 2022~~ **2034, respectively** . ~~Only GA and FL~~ **Neither IL nor TN** conform to the ~~Tax Act.~~ **federal 80 % utilization limitation, but** IL **has suspended annual** ~~and TN do not conform (their~~ NOL ~~will expire~~ **utilization above $ 0. 5 million of IL taxable income until the 2027 tax year. IL NOLs that would have been utilized** if not ~~used and there is no limit deduction on their NOL). MN does conform with the 80 % of taxable income limitation section of the Tax Act~~ for **this suspension are granted** ~~the years 2018 through 2022 and~~ **an additional** ~~has a 70 % limitation for 2023, but not the indefinite~~ carryforward **year** ~~section. MN NOL will expire if not used~~ . In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an “ ownership change, ” which is generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period, the corporation’ s ability to use its pre- change NOL carryforwards, or NOLs, and other pre- change tax attributes (such as research tax credits) to offset its post- change income may be limited. We are performing a study to determine if we have triggered any “ ownership change ” limitations. We may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership some of which may be outside of our control. As a result, if we earn net taxable income, our ability to use our pre- ownership change NOL carryforwards to offset U. S. federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Assuming a market for our common stock continues to develop, sales of a substantial number of shares of our common stock in the public market by our existing stockholders could cause our stock price to fall. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that such sales may have on the prevailing market price of our common stock. As of March ~~5~~ **10** , ~~2024~~ **2025** , we had ~~25~~ **26** , ~~688~~ **817** , ~~062~~ **535** shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, are eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including volume limitations and manner of sale requirements. Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act of 1933, as amended (the “ Securities Act ”). Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. We may be at an increased risk of securities class action litigation. Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management’ s attention and resources, which could harm our business. Our charter documents and Delaware law may inhibit a takeover that stockholders consider favorable. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and applicable provisions of Delaware law may delay or discourage transactions involving an actual or

potential change in control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. The provisions in our amended and restated certificate of incorporation and amended and restated bylaws: ● authorize our board of directors to issue, without further action by the stockholders, shares of undesignated preferred stock with terms, rights and preferences determined by our board of directors that may be senior to our common stock; ● establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for election to our board of directors; ● establish that our board of directors is divided into three classes, with each class serving three- year staggered terms; ● require the approval of our board of directors or the holders of at least seventy- five percent (75 %) of our outstanding shares of capital stock to amend our bylaws and certain provisions of our certificate of incorporation; ● limit who may call stockholder meetings; ● do not provide for cumulative voting rights; and ● provide that all vacancies may be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum. In addition, Section 203 of the Delaware General Corporation Law may limit our ability to engage in any business combination with a person who beneficially owns 15 % or more of our outstanding voting stock unless certain conditions are satisfied. This restriction lasts for a period of three years following the share acquisition. These provisions may have the effect of entrenching our management team and may deprive our stockholders of the opportunity to sell their shares to potential acquirers at a premium over prevailing prices. This potential inability to obtain a control premium could reduce the price of our common stock. Our amended and restated certificate of incorporation designates the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or stockholders. Provisions in our amended and restated certificate of incorporation provide that the Court of Chancery of the State of Delaware will, to the fullest extent permitted by law, be the sole and exclusive forum for: ● any derivative action or proceeding brought on our behalf; ● any action asserting a claim of breach of a fiduciary duty owed to us or our stockholders by any of our directors, officers or other employees; ● any action asserting a claim against us or any of our directors, officers or other employees arising pursuant to any provision of Delaware law or our charter documents; or ● any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, but excluding actions to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. In addition, unless we consent in writing to the selection of an alternative forum, the Federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. However, a court may determine that this provision is unenforceable. Ownership portions held by our executives and directors ~~, as well as by our former parent company, Harrow Health, Inc.,~~ may limit our stockholders' ability to influence corporate matters. Our directors and executive officers beneficially own approximately ~~14~~ **16** . 9 % of our common stock ~~. Additionally, Harrow Health, Inc. (" Harrow "), our former parent company, holds approximately 7. 7 % of our outstanding common stock as of March 5, 2024~~ . Accordingly, these parties, together, can significantly influence, though not independently determine, the outcome of matters required to be submitted to our stockholders for approval, including decisions relating to the election of our board of directors and the outcome of any proposed merger or consolidation of our company. These interests may not be consistent with those of our other stockholders. In addition, the significant interest held by these parties ~~, and particularly by Harrow,~~ may discourage third parties from seeking to acquire control of us, which may adversely affect the market price of our shares. As stockholders in our company, you will be deemed to have notice of and have consented to the provisions of our amended and restated certificate of incorporation related to choice of forum, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. The choice of forum provisions in our amended and restated certificate of incorporation may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or any of our directors, officers or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provision contained in our restated charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.