Risk Factors Comparison 2025-02-27 to 2024-02-29 Form: 10-K

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Our business, financial condition, operating results and cash flows can be affected by a number of factors, including, but not limited to, those set forth below, any one of which could cause our actual results to vary materially from recent results or from our anticipated future results. The risks described below are not the only ones we face, but those we currently consider to be material. There may be other risks which we now consider immaterial, or which are unknown or unpredictable, with respect to our business, our competition, the regulatory environment or otherwise that could have a material adverse effect on our business, financial condition and results of operations. RISKS RELATED TO OUR FINANCIAL CONDITION AND CAPITAL REQUIREMENTS We have incurred substantial losses and negative cash flow from operations in the past and expect to continue to incur losses and negative cash flow for the foreseeable future. We have a limited operating history as Lisata Therapeutics, Inc, limited capital, and limited sources of revenue. Since our inception in 1980 through December 31, ~~2023~~ **2024** , we have incurred aggregate net losses of approximately $ ~~528~~ **548** . 1 million. Our net losses from continuing operations attributable to common stockholders for the years ended December 31, ~~2023~~ **2024** and December 31, ~~2022~~ **2023** were approximately $ 20. **0 million and $ 20.** 8 million ~~and $ 54. 2 million~~ , respectively. As of December 31, ~~2023~~ **2024** , our cash and cash equivalents and marketable securities were $ ~~50~~ **31** . ~~5~~ **2** million. Our current business has not generated revenues in the past and for the foreseeable future we do not expect it to generate revenue to be sufficient to cover costs attributable to that business or to our operations as a whole, including our development activities associated with our product candidates. Ultimately, we may never generate sufficient revenue from our business to reach profitability, generate positive cash flow or sustain, on an ongoing basis, our current or projected levels of product development and other operations. We anticipate that we will need substantial additional financing to continue our operations; if we are unable to raise additional capital, we may be forced to delay, reduce or eliminate one or more of our product development programs, and our business will be **materially** harmed. Our current operating plan will require significant levels of additional capital to fund the continued development of our product candidates and our clinical development activities. **Based on our current expected capital needs, we believe that our projected capital will fund our current proposed operations into early 2026, encompassing anticipated data milestones from all of our ongoing and planned clinical trials.** Our clinical activities are expected to continue to ~~grow~~ **increase in size, complexity and geographic reach** as our programs are advanced and they will require significant investment over a period of several years before they **yield results that** could potentially be approved by health authorities and commercialized by us or a partner, if ever. Even if data from our current **Phase 2** clinical trials for our product candidates were deemed positive, we ~~may~~ **most likely would** be required to conduct additional clinical trials of the product candidates, including larger and more expensive pivotal Phase 3 trials, to pursue commercialization of the candidates. To do so, we will need to raise **substantial** additional capital, enter into collaboration agreements with third parties or undertake any combination thereof. If we are unsuccessful in our efforts to raise capital or find collaborative partners, we will likely need to otherwise delay or abandon the trials. The amount and timing of our future capital requirements also will likely depend on many other factors, including: • the scope, progress, results, costs, timing and outcomes of our research and development programs and product candidates; • our ability to **control timing of results availability as well as the timing and content of related public announcements based on existing contracts with collaborators, particularly if those contracts were inherited as part of a business transaction; • our ability to** enter into any collaboration agreements with third parties for our product candidates and the timing and terms of any such agreements; • the costs associated with the consummation of one or more strategic transactions; • the timing of, and the costs involved in obtaining, regulatory approvals for our product candidates, a process which could be particularly lengthy; • the costs of maintaining, expanding and protecting our intellectual property portfolio, including potential litigation costs and liabilities relating thereto; • the cost of expansion of our development operations and personnel; and **Index'** • the availability of, or our access to, state or federal government awards. To both fund our clinical trials and support our future operations, **it is highly probable that** we would ~~likely seek to~~ raise capital through a variety of different public and / or private financings vehicles. This could include, but not be limited to, utilization of our at- the- market offering agreement with H. C. Wainwright & Co., LLC, potential issuances of other debt or equity securities in public or private financings and / or sale or licensing of assets. If we raise capital through the sale of equity, or securities convertible into equity, it ~~will~~ **would likely** result in dilution to our then- existing stockholders. Servicing the interest and principal repayment obligations under debt ~~Index~~ we incur, or whether any such debt is called, would divert funds that might otherwise be available to support research and development, clinical or commercialization activities. In addition, debt financing involves covenants that restrict our ability to operate our business. In certain cases, we also may seek funding through collaborative arrangements that would likely require us to relinquish certain rights to our technology or product candidates and diminish our share in the future revenues associated with the partnered product. Ultimately, we may be unable to raise capital or enter into collaborative relationships on terms that are acceptable to us, if at all. Our inability to obtain the necessary capital or financing to fund our future operating needs ~~could~~ **would materially** adversely affect our business, results of operations and financial condition. We have never generated any revenue from product sales and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of factors. We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until sometime after we have received regulatory approval for the commercial sale of a product candidate, which may never occur. Our ability to generate revenue from product sales and achieve profitability depends significantly on our success in many factors, including: • completing research regarding, and non- clinical

and clinical development of, our current and future product candidates; • obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical trials; • developing a sustainable ~~and ,~~ scalable **and economically feasible** manufacturing process for our product candidates; • identifying and contracting with contract manufacturers that have the ability and capacity to manufacture our development products and make them **reliably** at an acceptable cost; • launching and commercializing product candidates for which we obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor; • obtaining market acceptance of our product candidates as viable treatment options; • ensuring ongoing regulatory compliance post- approval and with respect to sales and marketing of future products; • addressing any competing technological and market developments; • identifying, assessing, acquiring and / or developing new product candidates; • negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; • maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know- how; and • attracting, hiring, and retaining qualified personnel. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, non- clinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market one or more of our product candidates, our revenue will depend, in part, upon the size of the markets in the territories for which we obtain regulatory approval, the accepted price for the product, the ability to receive reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate **sufficient** revenue from the sale of any approved products, we may never become profitable ~~. We are involved in a litigation matter that may consume resources and management time, and an adverse resolution could require us to pay damages or otherwise adversely impact our business, financial condition or results of operations. We are currently involved in one litigation matter alleging breach of contract and fraud against our acquired company, Cend, and by extension now Lisata. Resolving this matter could require us to incur substantial costs and divert the attention of management and technical personnel. Any adverse ruling or perception of an adverse ruling could have an adverse impact on our business, financial condition or results of operations. We could incur substantial costs and expenses which could negatively affect our gross margins and earnings per share~~ . If our status as a smaller reporting company changes, Section 404 (b) of the Sarbanes- Oxley Act of 2002 may require an independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Any delays or difficulty in satisfying these requirements could adversely affect our future results of operations and our stock price. Section 404 (b) of the Sarbanes- Oxley Act of 2002 requires an independent registered public accounting firm to test the internal control over financial reporting of public companies, and to report on the effectiveness of such controls. Under the Dodd Frank Wall Street Reform and Consumer Protection Act of 2010, we are exempt from Section 404 (b) as long as we remain a smaller reporting company or a non-accelerated filer. If our status as a smaller reporting company changes, we may be required to comply with this auditor attestation requirement. In addition, we may in the future discover areas of our internal controls that need improvement, particularly with respect to businesses that we may acquire. If so, we cannot be certain that any remedial measure we take will ensure that we have adequate internal controls over our financial processes and reporting in the future. Any failure to implement the required new or improved controls, or difficulties encountered in their implementation could harm our operating results or cause us to fail to meet our reporting obligations. If we are unable to conclude that we have effective internal controls over financial reporting, or if it becomes necessary for our independent registered public accounting firm to provide us with an unqualified report regarding the effectiveness of our internal control over financial reporting and it is unable to do so, investors could lose confidence in the reliability of our financial statements. This could result in a decrease in the value of our common stock. Our ability to utilize our net operating loss carryforwards and tax credit carryforwards may be subject to limitations. Our ability to use our federal and state net operating losses (“ NOLs ”) to offset potential future taxable income and related income taxes that would otherwise be due is dependent upon our generation of future taxable income, and we cannot predict with certainty when, or whether, we will generate sufficient taxable income to use all of our NOLs. Under Section 382 and Section 383 of the Code and corresponding provisions of state law, if a corporation undergoes an “ ownership change, ” its ability to use its pre- change NOL carryforwards and other pre- change tax attributes (such as research tax credits) to offset its post- change income may be limited. A Section 382 “ ownership change ” is generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period. Even if we achieve profitability, we may not be able to utilize a material portion of our NOL carryforwards and other tax attributes, which could have a material adverse effect on cash flow and results of operations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and its financial condition and results of operations. Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, or SVB, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation, or the FDIC, as receiver. Similarly, on March 12, 2023, Signature Bank

and Silvergate Capital Corp. were each swept into receivership. The U. S. Department of Treasury, FDIC and Federal Reserve Board announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion. Although we assess our banking relationships as we believe necessary ~~or~~ **and** appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. ~~These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships but could also include factors involving financial markets or the financial services industry generally.~~ The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following: • Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; • Loss of access to revolving existing credit facilities or other working capital sources and / or the inability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources; • Potential or actual breach of contractual obligations that require us to maintain letters ~~or~~ **of** credit or other credit support arrangements; or • Termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. **Finally** ~~In addition~~ , any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by parties with whom we conduct business, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition. For example, a party with whom we conduct business may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy. Any bankruptcy or insolvency, or the failure to make payments when due, of any counterparty of ours, or the loss of any significant relationships, could result in material losses to us and may have material adverse impacts on our business. RISKS RELATED TO OUR PRODUCT DEVELOPMENT EFFORTS We are substantially dependent on our ~~lead~~ **investigational** product candidate, ~~LSTA1~~ **certepetide** . If we are unable to advance ~~LSTA1~~ **certepetide** or any of our future product candidates through clinical development, obtain regulatory approval and ultimately commercialize ~~LSTA1~~ **certepetide** or any of our other product candidates, or experience significant delays in doing so, our business will be materially harmed. Our ~~lead~~ **investigational** product candidate ~~LSTA1~~ **certepetide** is still in clinical development. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful clinical development and eventual commercialization of ~~LSTA1~~ **certepetide** and potentially one or more of our other product candidates. The success of our product candidates will depend on several factors, including the following: • successful completion of preclinical and clinical studies; • clearance of INDs, comparable foreign clinical trial applications (" CTAs ") and clinical protocols for our planned clinical trials or future clinical trials; • Regulator acceptance of our development strategy and resultant clinical data; • successful initiation of clinical trials; • successful patient enrollment in and completion of clinical trials; • safety, tolerability and efficacy profiles for our product candidates that are satisfactory to regulators for marketing approval; • receipt of marketing approvals for our product candidates from applicable regulatory authorities; • the extent of any required post- marketing approval commitments to applicable regulatory authorities; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; • making arrangements with third- party manufacturers, or establishing manufacturing capabilities, for both clinical and commercial supplies of our product candidates, if any product candidates are approved; • establishing sales, marketing and distribution capabilities and launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; • acceptance of our products, if and when approved, by patients, the medical community and third- party payors; • effectively competing with other therapies; • obtaining and maintaining third-party coverage and adequate reimbursement; • maintaining a continued acceptable safety profile of our products following approval; and • factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e. g. the COVID- 19 pandemic). There is no guarantee that the results obtained in our current clinical studies will be sufficient to obtain regulatory approval or marketing authorization for any of our product candidates. Negative results in the development of our ~~lead~~ **investigational** product candidate, ~~LSTA1~~ **certepetide** , **in any one indication** may also impact our ability to **obtain regulatory approval of certepetide in other indications, either at all or within anticipated timeframes because, even though the indications are different, the underlying technology platform, manufacturing process and development process are the same. Accordingly, a failure or major issue associated with any**

one indication may affect the ability to obtain regulatory approval to continue or conduct clinical programs and / or obtain regulatory approval for ~~certain of our other~~ **another** ~~product candidates, either at all or within anticipated timeframes because, although certain of our other product candidates may target different indications~~ **indication** ~~, the underlying technology platform, manufacturing process and development process is the same for several of our product candidates that are based on the same underlying technology platform~~ . **Furthermore** ~~Accordingly, a failure in any one program may affect the ability to obtain regulatory approval to continue or conduct clinical programs for other product candidates. For example~~ , although we believe based on ~~our~~ **available preclinical and** clinical ~~studies~~ **results** that a combination of ~~LSTA1~~ **certepetide** with certain anti- cancer therapeutics is more effective than the use of those therapeutics ~~in~~ alone, this may not prove true in clinical testing of ~~LSTA1~~ **certepetide** for all or any of the types of cancer. Anti- tumor activity may prove different in each of the different tumor types **and / or with each of the anti- cancer therapeutic combinations** we plan on evaluating. Therefore, ~~even though we plan on pursuing tumor- agnostic clinical development of LSTA1,~~ the tumor response **to certepetide plus the corresponding anti- cancer therapeutic (s) combination** may be less robust in patients with some cancers compared to others. This may result in discontinuation of development of ~~LSTA1~~ **certepetide** for certain tumor types **and / or certain anti- cancer therapeutic (s) combinations** due to insufficient clinical benefit ~~while continuing development for patients more likely to benefit. As a consequence, we may have to negotiate with regulators to reach agreement on defining the optimal patient population, study design and size in order to obtain regulatory approval, any of which may require significant additional resources and delay the timing of our clinical trials and ultimately the approval, if any, of any of our product candidates~~ . In addition, because we have limited financial and personnel resources and are placing significant focus on the development of our ~~lead~~ **investigational** product candidate, we may forego or delay pursuit of opportunities with other future product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and other future product candidates for specific indications may not yield any commercially viable future product candidates. If we do not accurately evaluate the commercial potential or target market for a particular future product candidate, we may relinquish valuable rights to those future product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such future product candidates. Our future success may be dependent on the timely and successful continued development and commercialization of our product candidates and if we encounter delays or difficulties in the development of these product candidates, our business prospects could be ~~significantly~~ **materially** harmed. We are dependent upon the successful development, approval and commercialization of our product candidates. Before we are able to seek regulatory approval of our product candidates, we must conduct and complete extensive clinical trials to demonstrate their safety and efficacy in humans. We have never taken a product through the regulatory approval process or successfully to U. S. or international commercialization. Clinical testing is expensive, difficult **and complex** to design and ~~implement~~ **execute** , and can take many years to complete. Importantly, a failure of one or more ~~of these or any other~~ clinical trials can occur at any stage of testing. We may experience numerous unforeseen events during, or as a result of clinical trials that could delay or prevent our ability to complete our clinical trials, receive regulatory approval or commercialize our product candidates, including the following: • suspensions, delays or changes in the design, initiation, enrollment, ~~implementation~~ **execution** or completion of required clinical **trials;** • adverse changes in our financial position or significant and unexpected increases in the cost of our ~~clinical~~ development ~~program~~ **programs** ; • changes or uncertainties in, or additions to, the regulatory approval process that require us to alter our current development strategy; • clinical trial results that are negative or inconclusive as to safety and / or efficacy, which ~~could~~ **would** result in the need for additional clinical trials or the termination of the product' s development; • delays in our ability to manufacture our product candidates in quantities ~~or~~ **,** in a form **and / or at a cost** that is suitable for any required clinical trials; • intellectual property constraints that prevent us from making, using, or commercializing any of our product candidates; • the supply or quality of our product candidates or other materials or equipment necessary to conduct clinical trials of these product candidates may be no longer available for purchase, insufficient or inadequate; • inability to generate sufficient non- clinical, toxicology, or other in vivo or in vitro data to support the initiation **and / or continuation** of clinical trials; • delays in reaching agreement on acceptable terms with prospective contract research organizations (" CROs "), contract manufacturing organizations (" CMOs "), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, CMOs and clinical trial sites; • delays in obtaining required ~~IRB~~ **institutional review board** approval at each clinical trial site; • inability to submit or obtain clearance for an IND or CTA with the applicable regulators for our development candidates; • imposition of a temporary or permanent clinical hold by the FDA or similar restrictions by other regulatory agencies for a number of reasons, including after review of an IND or protocol amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our **manufacturing sites,** clinical trial operations **(including those of any CRO involved)** or clinical trial sites; developments on trials conducted by competitors or approved products post- market for related technology that ~~raises~~ **raise** FDA concerns about risk to patients of the technology broadly; or if the FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives; • difficulty collaborating with patient groups ~~and~~ **, individual** investigators **and / or associated institutions** ; • failure by our CROs, CMOs **,** other third parties, or us to adhere to clinical trial requirements **and international regulatory standards** ; • failure to perform in accordance with the FDA or international GCP requirements; • failure to reach agreement with the FDA on a satisfactory development path of our development candidates **; • failure to resolve contradictory guidance issued by the FDA, EMA or other international regulatory bodies of relevance to our development program (s)** ; • delays in having patients qualify for or complete participation in a trial or return for post- treatment follow- up; • patients dropping out of a clinical trial; • occurrence of adverse events associated with the product candidate; • changes in the standard of care on which a clinical development plan

was based, which may require new or additional trials or abandoning existing trials; • transfer of manufacturing processes from **one manufacturer and /** ~~our~~ **or** ~~academic collaborators~~ **manufacturing site** to **another,** ~~larger- scale facilities~~ operated by either a CMO ~~,~~ or ~~by~~ us, and delays or failure by our CMOs or us to **qualify the transferred** ~~make any necessary changes to such manufacturing~~ process **and / or site** ; • delays in and / or the inability to complete manufacturing, testing, releasing, validating, or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing; and • the FDA may not accept clinical data from trials that are conducted in countries where the standard of care **or the nature of the disease** is potentially different from the United States **or for other reasons** . Any inability to successfully complete non- clinical and clinical development could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to, conduct bridging studies to demonstrate the equivalence of our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market ~~before we do~~ **earlier than expected** , which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations ~~. The impact of the COVID- 19 pandemic or as yet identified pandemics, the shift to a COVID- 19 endemic approach and related risks could materially affect our results of operations, financial position and / or liquidity. The COVID- 19 pandemic resulted in a global slowdown of economic activity and disruption of normal business travel and working habits. While we are shifting to a COVID- 19 endemic approach, there is still uncertainty about the impact of COVID- 19 variants in the long- term. The COVID- 19 pandemic may have impacted our results of operations, and a reversion to the COVID- 19 restrictions could have a significant effect on our future business, results of operations and financial performance. The pandemic initially resulted in a sharp contraction in the global economy, tightening liquidity and increasing volatility and uncertainty in the capital markets. Coincident global mitigation responses stabilized markets and stimulated economic recovery. Continued macroeconomic volatility may persist affecting our businesses and related market opportunities. The impact of an ongoing pandemic on the financial markets may also adversely affect our ability to fund through public or private equity offerings, debt financings, and through other means at acceptable terms~~ . Even if we are able to successfully complete our clinical development programs for our product candidates and receive regulatory approval to market one or more of the products, if the commercial opportunities are smaller than we anticipate, our future revenues ~~may~~ **will** be adversely affected, and our business may suffer. If the size of the commercial opportunities in any of our target indications is smaller than we anticipate, or if the FDA grants our candidates approval to treat only specific subpopulations or otherwise approves the products for more narrow indications ~~for~~ **of** use than we are seeking, we may not be able to achieve profitability and growth. Even if we are able to successfully complete our clinical development program for our product candidates, and ultimately receive regulatory approval to market one or more of the products, we may, among other things: • obtain approval for indications that are not as broad as the indications we sought; • have the product removed from the market after obtaining marketing approval; • encounter problems with respect to the manufacturing **and / or distribution** of commercial supplies; • be subject to additional post- marketing testing requirements; and / or • be subject to restrictions on how the product is distributed or used. We may experience delays in enrolling patients in our clinical trials, which ~~could~~ **would** delay or prevent the receipt of necessary regulatory approvals. We may not be able to initiate or complete as planned any clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in the clinical trials required by the FDA or other regulatory authorities. Some of our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. Enrollment challenges in clinical trials often result in increased development costs for a product candidate, significant delays and potentially the abandonment of the clinical trial **and / or product candidate** . We also may be unable to engage a sufficient number of clinical trial sites to conduct our trials. Moreover, our ability to conduct trials outside of the United States may be constrained by our inability to transport research materials to **or from** foreign destinations ~~within the expiry period of such materials unless and until we commence operation outside of the United States~~ or find another source of supply. Because our clinical trials for ~~LSTA1~~ **certepetide** are focused on patients with specific solid ~~tumor~~ **tumors** ~~cancers~~ , our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, we cannot be certain how many patients **with** ~~will have each of~~ the ~~solid tumor~~ cancers that ~~LSTA1~~ **certepetide** is designed to target **will choose to enroll in** ~~or~~ **our clinical trials and / or if** that ~~the~~ number ~~of patients enrolled~~ will **ultimately** suffice for regulatory approval ~~and inclusion of each such mutation in the approved label~~ . Patient enrollment in general is affected by many factors, including: **• patient, physician and / or treating institution financial considerations;** • size of the target patient population; • severity of the disease or disorder under investigation; • eligibility criteria for the clinical trial in question; • ~~other~~ **competing** clinical trials ~~being conducted at the same time~~ involving patients ~~who have~~ **diagnosed with** the disease or disorder under investigation; • perceived risks and benefits of the product candidate under study; • approval and availability of other therapies to treat the disease or disorder that is being investigated in the clinical trial; • willingness or unwillingness to participate in a placebo controlled clinical trial; • efforts to facilitate timely enrollment in clinical trials; • patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; and • proximity and availability of clinical trial sites for prospective patients. **In addition, the U. S. Congress amended the FDCA in 2023 to require sponsors of a Phase 3 clinical trial, or other " pivotal study " of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our investigational product candidates has reached Phase 3 of clinical development, we or our partners must submit a diversity action plan to the FDA by the time a Phase 3 trial, or pivotal study, protocol is submitted to the agency for review, unless we or our partners are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action**

plan may affect the planning and timing of any future Phase 3 trial for our product candidates. However, initiation of such trials may be delayed if the FDA objects to a proposed diversity action plans for any future Phase 3 trial of our product candidates, and we or our partners may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan. Our inability to enroll a sufficient number of patients in any of our planned clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the regulators may not permit us to proceed. We submitted an IND for ~~LSTA1~~ **certepetide** on April 14, 2021, and the IND was cleared by the FDA on May 14, 2021. Still, we may not be able to file INDs, or comparable foreign CTAs in other countries or jurisdictions, for our other product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND- enabling studies. Moreover, we cannot be sure that ~~submission~~ **acceptance** of an **initial** IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that lead to the suspension or termination of clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory authorizations for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. Results from a clinical trial, once completed, may be less clear than expected, which may hinder our efforts to obtain regulatory approval for our product candidates. Clinical trials by their nature ~~utilize~~ **evaluate the safety and effectiveness of an investigational product in** a **relatively small** sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including those listed below: • ~~we may encounter unforeseeable conditions, such as the COVID- 19 pandemic, which had a significantly negative impact on enrollment in clinical trials during its acute phase but may continue to create challenges if local or regional outbreaks occur; •~~ regulatory authorities may require the addition of labeling statements, such as a " boxed " warning or a contraindication; • we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates; • FDA may require a **Risk Evaluation and Mitigation Strategy (“** REMS ~~plan~~ **”)** to mitigate risks, which 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; • we may be subject to regulatory investigations and government enforcement actions; • we may decide to remove ~~such~~ **affected** product candidates from the marketplace; • we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and • our reputation may suffer. We believe that any of these events could prevent us from achieving or maintaining market acceptance of ~~the~~ **,** ~~affected~~ -- **affect** ~~product candidates~~ **our ability to successfully commercialize,** and ~~could~~ substantially increase the costs of commercializing ~~our~~ **, the affected** ~~product~~ **products** ~~candidates~~, if approved, and **could** significantly impact our ability to ~~successfully commercialize our product candidates and~~ generate revenues. We and our partners are conducting clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials. We have in the past conducted clinical trials in **Australia and** Japan, and we may in the future choose to conduct one or more clinical trials outside the United States, including in Canada, Australia, ~~or~~ Europe **and / or Asia** . The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority **, respectively,** may be subject to certain conditions or may not be accepted at all. ~~In~~ **For example, in** cases where data from foreign clinical trials are intended to **support** ~~serve as the basis for~~ marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign **clinical trial** data alone unless (i) the data are agreed by FDA to be applicable to the U. S. population and U. S. medical practice; ~~and~~ (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP requirements ~~.~~ **; and (iii) the data may be considered valid without the need for an on- site inspection** ~~For~~ **or** ~~example~~ , **if** ~~in February 2022,~~ the FDA **considers** ~~publicly rebuked~~ an **inspection necessary, the agency is able to validate the** ~~oncology product sponsor for submitting a marketing application with Phase III clinical~~ data **through** ~~solely from China and~~ **an on- site inspection or** ~~since that time, it has declined to approve~~ other **means** ~~applications that contained primarily China- generated clinical data. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements~~ . In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted ~~. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of their applicable jurisdiction~~ . If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time- consuming, and which may result in product candidates that we ~~may~~ develop not receiving approval for commercialization in the applicable jurisdiction. We may be unable to manage multiple late- stage clinical trials for a variety of product candidates simultaneously. As our current clinical trials progress, we may need to manage multiple late- stage clinical trials simultaneously in order to continue developing all of our current product candidates. Typically, early- stage trials involve relatively small numbers of patients in relatively few clinical sites. Late- stage (**e. g.,** Phase 3) trials may involve very large numbers of patients in a larger number of sites and may require facilities in several countries. Therefore, the project management required to supervise and control such an extensive program is substantially larger than **for** early- stage programs. As the need for these resources is not known until some months before the trials begin, it is necessary to recruit large numbers of experienced and talented individuals very quickly. If the labor market does not allow this team to be recruited quickly, the

sponsor is faced with a decision to delay the program or to initiate it with inadequate management resources. This may result in recruitment of inappropriate patients, inadequate monitoring of clinical investigators and inappropriate handling of data or data analysis. Consequently, it is possible that conclusions of efficacy or safety may not be acceptable to permit submission of an NDA for any one of the above reasons or a combination of several. Additionally, any such failure may result in regulatory liability for the sponsor, negative publicity, and other adverse impacts on the business or its operations. Any disruption to our access to the reagents, devices, ~~material~~ **materials** or equipment we are using in the clinical development of our product candidates ~~could~~ **would** adversely affect our ability to perform clinical trials and seek future regulatory submissions. Reagents, devices, materials and systems that we are using in our clinical trials, that we intend to use in our planned clinical trials and that we may need or use in future commercial production, are provided by unaffiliated third parties. Any lack of continued availability of these reagents, devices, materials and systems for any reason would have a material adverse effect on our ability to complete these studies and could adversely impact our ability to achieve commercial manufacture of our planned therapeutic products. Although other available sources for these reagents, devices, materials and systems may exist in the marketplace, we have not evaluated their cost, effectiveness, or intellectual property foundation and therefore cannot guarantee the suitability or availability of such other potential sources. The initiation of pivotal Phase 3 clinical trials for our product candidates requires the validation and establishment of manufacturing controls that may delay product development timelines. To conduct pivotal Phase 3 clinical trials, we are required to have certain validated and established manufacturing controls with respect to the ~~safety and~~ identity **, strength, quality and purity** of our product candidates when administered to patients. If we determine that the results of any Phase 2 clinical trial ~~,~~ we may conduct ~~supports~~ **support** Phase 3 development, we expect to initiate and complete one or more pivotal Phase 3 clinical trials for such programs and would need to address any outstanding chemistry, manufacturing and ~~control~~ **controls** (" CMC ") **requirements of** ~~issues raised by~~ the FDA **or other relevant regulatory authority** prior to initiating such trials. We may not be successful in our efforts to address any CMC issues raised by the FDA **or other relevant regulatory authority** . If we cannot initiate, or if we are delayed in initiating, a pivotal Phase 3 clinical program as a result of our failure to satisfy **regulatory** ~~the FDA' s~~ CMC concerns ~~or otherwise~~ , the timing of completing, developing and making a regulatory submission for commercialization of our product candidates would be delayed, or we may be unable to seek regulatory approval to commercialize our products at all. Product candidates that appear promising in research and development may be delayed or may fail to reach later stages of clinical development. The successful development of pharmaceutical product candidates is highly uncertain. Product candidates that appear promising in research and development and early clinical trials may be delayed or fail to reach later stages of development. Decisions regarding the further development of product candidates must be made with limited and incomplete data, which makes it difficult to ensure or even accurately predict whether the allocation of limited resources and the expenditure of additional capital on specific product candidates will result in desired outcomes. Non- clinical and clinical data can be interpreted in different ways, and negative or inconclusive results or adverse events during a clinical trial could delay, limit or prevent the development of a product candidate. Clinical testing 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 preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials. Exploratory trends and results observed in earlier stage clinical trials, particularly trends and results observed for small subsets that were not pre- specified, may not be replicated in later stage clinical trials. Product candidates in Phase 3 clinical trials may fail to demonstrate sufficient efficacy despite having progressed through initial clinical trials, even if certain exploratory subset analyses of primary or secondary endpoints in those early trials showed trends toward efficacy or, in some analyses, nominal statistical significance. The results of clinical trials in one set of patients or line of treatment may not be predictive of those obtained in another. If serious or unacceptable side effects are identified during the development of any of our product candidates, we may need to abandon or limit our development of that product candidate. All of our product candidates are in clinical development and their risk of failure is high. It is impossible to predict when or if any of our product candidates will prove effective ~~or~~ **and** safe in humans or will receive marketing approval. If our product candidates are associated with undesirable side effects or have other unexpected, unacceptable characteristics, we may need to abandon their development or limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. Many investigational products that initially showed promise in clinical or earlier stage testing have later been found to cause side effects or other safety issues that prevented further development. Even if we receive regulatory approval for a candidate with a known safety risk that is described in the product' s labeling, such an approved product may not achieve market acceptance by physicians, patients, third- party payors or others in the medical community, which would materially and adversely affect our business. A breakthrough therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We may seek " breakthrough therapy " designation for ~~LSTA1~~ **certepetide** and some or all of our current or future product candidates. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including priority review and accelerated approval. Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a

breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non- expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for ~~LSTA1~~ **certepetide** and some or all of our future product candidates, there can be no assurance that we will receive or maintain breakthrough therapy designation. A Fast Track designation by the FDA and other similar regulatory designations may not lead to a faster development, regulatory review or approval process. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We have been granted Fast Track designation for ~~LSTA1~~ **certepetide** for the treatment of pancreatic cancer. We may seek Fast Track designation for other indications or for certain of our other current or future product candidates, but there is no assurance that the FDA will grant this status to any of our other proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program or at any time. Accelerated **or provisional** approval by the FDA **or other relevant regulatory authority**, even if granted for ~~LSTA1~~ **certepetide** or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval. We plan to seek approval of ~~LSTA1~~ **certepetide** and may seek approval of other current or future product candidates using **an** ~~the FDA's~~ accelerated **or provisional** approval pathway **available in many regulatory jurisdictions**. A product candidate may be eligible for accelerated **or provisional** approval if it treats a serious or life- threatening condition and generally provides a meaningful advantage over available therapies. ~~In addition, it must demonstrate an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit.~~ As a condition of **provisional** approval, the ~~FDA~~ **regulatory authority** may require **the** ~~that a~~ sponsor **to** ~~of a drug receiving accelerated approval~~ perform adequate and well- controlled post- marketing clinical trials **for the corresponding product / indication**. ~~FDA~~ **Regulatory authorities** may require that such studies be fully enrolled before the NDA is approved. These confirmatory trials must be completed with due diligence **. Specifically, we may seek an early approval under the Australian Provisional Determination scheme. A product candidate may be eligible for a provisional determination in Australia if it is 1) intended to treat, prevent, or diagnose a life threatening or seriously debilitating condition, 2) for which there is preliminary clinical data demonstrating that the medicine is likely to provide a significant improvement in the efficacy or safety of treating the condition, 3) the preliminary clinical data suggests that the medicine is likely to provide a major therapeutic advance, and 4) sufficient evidence has been provided of a plan to submit comprehensive clinical data confirming the safety and efficacy of the medicine before the end of the 6 years provisional registration**. Failure to conduct required post- approval studies, or to confirm the predicted clinical benefit of the product during post- marketing studies, allows ~~the FDA~~ **a regulatory authority** to withdraw approval of the drug. In addition, **in the United States, a company whose drug product is authorized for commercialization through the accelerated approval pathway must submit** all promotional materials for products approved under the accelerated **or provisional** approval pathway ~~must be submitted~~ to the FDA in advance of dissemination for potential agency comment, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated **or provisional** approval for one or more of our product candidates, we may not experience a faster development or regulatory review or approval process, and receiving accelerated **or provisional** approval does not provide assurance of ultimate full ~~FDA~~ **regulatory** approval. Our clinical trials may fail to demonstrate adequately the safety and efficacy of our product candidates, which would prevent or delay regulatory approval and commercialization. The clinical trials of our product candidates are, and the manufacturing and marketing of our products will be, subject to extensive and rigorous review and regulation by numerous ~~government~~ **governmental** authorities in the United States and in other countries where we intend to test and market our product candidates. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are both safe and effective for use in each target indication. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The risk / benefit profile required for product approval will vary depending on ~~these~~ **multiple** factors and may include adequate duration of response, a delay in the progression of the disease, and / or an improvement in survival ~~. For example, response rates from the use of our product candidates may not be sufficient to obtain regulatory approval unless we can also show an adequate duration of response~~. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. ~~A number of~~ **There are precedents for** companies in the biopharmaceutical industry **experiencing** ~~have suffered~~ significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. Data from earlier studies conducted by third- party research institutions should not be relied upon as evidence that later or larger- scale clinical trials will succeed. Some future trials may have different patient populations than current studies and will test our product candidates in different indications, among other differences. In addition, our proposed manufacturing processes for our

product candidates include what we believe will be process improvements that are not part of the production processes that were previously used in the earlier conducted clinical trials being conducted by the research institutions. Accordingly, our results with our product candidates may not be consistent with the results of ~~the~~ **those** clinical trials. In addition, even if such trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. We presently rely on contract manufacturing organizations to produce our product candidates at development and commercial scale quantities and have not yet qualified an alternate manufacturing supply, which could negatively impact our ability to meet any future demand for the products. We do not presently have redundant suppliers for any of our product candidates. If the facilities where our product candidates are being manufactured and / or the associated equipment were significantly damaged or destroyed, or if there were other disruptions, delays or difficulties affecting manufacturing capacity, our planned and future clinical trials and commercial production for these product candidates would likely be significantly disrupted and delayed. It would be both time ~~-~~ consuming and expensive to replace this capacity with third parties, particularly since any new facility would need to comply with regulatory requirements. Ultimately, if we are unable to supply our product candidates to meet commercial demand, were commercial approval to be obtained, whether because of processing constraints or other disruptions, delays or difficulties that we experience, our production costs could increase dramatically, and sales of the product and its long- term commercial prospects could be significantly damaged. Also, as a result of the current geopolitical tensions and the conflict between Russia and Ukraine, the governments of the United States, the European Union, Japan and other jurisdictions have **imposed** ~~recently announced the imposition of~~ sanctions on certain industry sectors and parties in Russia, as well as enhanced export controls on certain products and industries. These and any additional sanctions and export controls **involving other countries** , as well as any counter responses by the governments of Russia or other jurisdictions, could adversely affect, directly or indirectly, the global supply chain, with negative implications on the availability and prices of raw materials, energy prices, and our customers, as well as the global financial markets and financial services industry. The commercial potential and profitability of our product candidates are unknown and subject to significant risk and uncertainty. Even if we successfully develop and obtain regulatory approval for some or all of our product candidates, the market may not understand or accept the products, which could adversely affect both the timing and level of future sales. Ultimately, the degree of market acceptance of our product candidates (or any of our future product candidates) will depend on a number of factors, including: • the efficacy and potential advantages compared to alternative treatments or competitive products; • the prevalence and severity of any side effects; • the approval and marketing of other therapeutics against which our product candidates will compete; • physician acceptance of our approach to our target disease indications, include the ease or difficulty of administering the future products; • restrictions on how the product is distributed or used; • the strength of our marketing and distribution support, including whether we receive support from any patient advocacy groups; • the adequacy of product supply in light of complex manufacturing and distribution processes; • the cost of the product, the reimbursement policies of government and third- party payors and our ability to obtain sufficient third- party coverage or reimbursement. Even if we are successful in achieving sales of our product candidates, it is not clear to what extent, if any, the products will be profitable. In addition, changes in manufacturing processes or procedures generally require FDA or foreign regulatory authority review and approval prior to implementation. Thus, we may need to conduct additional non- clinical studies and clinical trials to support approval of any such changes. Furthermore, this review process could be costly and time- consuming and could delay or prevent the commercialization of product candidates. We may enter into collaborations, strategic alliances, additional licensing arrangements, acquisitions, business combinations or other strategic transactions in the future, any of which could require us to incur significant expenses or issue securities that could significantly dilute the shares of our existing stockholders, and we may not realize the benefits of such alliances or licensing arrangements, acquisitions, business combinations or strategic transactions. We may enter into collaborations, strategic alliances, additional licensing arrangements, acquisitions, business combinations or other strategic transactions with third parties that we believe are essential to product commercialization or will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that could significantly dilute the shares of our existing stockholders ~~,~~ or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and / or acquisition candidates and the negotiation process can be time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. Furthermore, there can be no assurance that our exploration of potential acquisitions, business combinations or strategic alternatives will result in us entering or completing any transaction or that such transaction, if completed, will add to stockholder value. Further, collaborations involving our product candidates, such as our collaborations with third- party research institutions, are subject to numerous risks, which may include the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration; • collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products

that compete directly or indirectly with our products or product candidates; • a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution; • collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability; • disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources; • collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and • collaborators may own or co- own intellectual property **and / or critical clinical data** covering our products that results from our collaborating with them, and in such cases, we would not have the **authority or** exclusive right to **utilize, publicly announce or** commercialize such **data or** intellectual property. As a result, if we enter into collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or ~~license~~ **licensing** , we will achieve the **economic return** ~~revenue or specific net income~~ that justifies such **a** transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. If competitors develop and market products that are more effective, safer, or less expensive than our product candidates or offer other advantages, our commercial prospects will be limited. Our development programs now face, and will continue to face, intense competition from pharmaceutical, biopharmaceutical and biotechnology companies, as well as numerous academic and research institutions and governmental agencies engaged in drug discovery **and development** activities or funding, both in the United States and abroad. Some of these competitors are pursuing the development of drugs and other therapies that target the same diseases and conditions that we are targeting with our product candidates. As a general matter, we also face competition from many other companies that are researching and developing **product candidates in** similar **indications** ~~product candidates~~ . Many of these companies have financial and other resources substantially greater than ours. In addition, many of these competitors have significantly greater experience in testing pharmaceutical and other therapeutic products, obtaining FDA and other regulatory approvals, and marketing and selling approved products in highly regulated commercial health care markets. If we ultimately obtain regulatory approval for any of our product candidates, we **will** also ~~will~~ be competing with respect to manufacturing efficiency and marketing capabilities, areas in which we have limited or no commercial- scale experience. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in resources being even more concentrated by our competitors. Competition may increase further as a result of advances made in the commercial applicability of our technologies and greater availability of capital for investment in these fields. We conduct significant operations through our Australian wholly- owned subsidiary. If we lose our ability to operate in Australia, or if the subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations will suffer. We develop certain of our programs in part through our wholly- owned Australian subsidiary, Lisata Therapeutics Australia Pty Ltd. Due to the geographical distance ~~and limited employees currently in Australia,~~ as well as our limited ~~of~~ experience operating in Australia, we may not be able to efficiently or successfully monitor, develop or commercialize our products or programs in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials ~~that it conducts~~ **conducted** for our product candidates in Australia will be accepted by the FDA or foreign regulatory authorities for development and commercialization approvals. In addition, current Australian tax regulations provide for a refundable tax incentive between 43. 5 % to 48. 5 % (depending upon the income tax rate) for qualified research and development activities. If we are ineligible or unable to receive the research and development tax credit, or past credits are determined ineligible upon audit, or if we lose our ability to operate Lisata Therapeutics Australia Pty Ltd. in Australia, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operation would be adversely affected. In the event we determine it advisable to stop operating through this subsidiary, we may be required to migrate such operations ~~, employees and intellectual property~~ from this subsidiary to us. Any such action may be difficult and cause us to incur additional expenses, as well as give rise to tax liabilities for us or erode our tax attributes (such as tax credits or net operating losses). We may be subject to significant product liability claims and litigation, including potential exposure from the use of our product candidates in human subjects, and our insurance may be inadequate to cover claims that may arise. Our business exposes us to potential product liability risks inherent in the testing, processing and marketing of our products. Such liability claims may be expensive to defend and result in large judgments against us. We face an inherent risk of product liability exposure related to the testing of our current and any future product candidates in human clinical trials and will face an even greater risk with respect to any commercial sales of our products should they be approved. **All** ~~None of~~ our product candidates **are in the clinical phase** ~~have been widely used over an extended period~~ of **development** ~~time,~~ and therefore **,** relevant safety data are limited. We will need to increase our insurance coverage ~~when~~ **whenever** we begin commercializing product candidates ~~, if ever~~ . At that time, we may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all, or if claims against us substantially exceed our coverage, then our financial position could be significantly impaired. Whether or not we are ultimately successful in any product liability litigation that may arise, such litigation could consume substantial amounts of our financial and managerial resources, decrease demand for our products and injure our reputation. We seek to maintain errors and omissions, directors and officers, workers ~~'~~ compensation and other insurance at levels we believe to be appropriate to our business activities. If, however, we were subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim from our own limited resources, which ~~could~~ **would** have a material adverse

effect on our financial condition, results of operations and business. Additionally, liability or alleged liability could harm our business by diverting the attention and resources of our management and damaging our reputation. We may be unable to retain key officers or employees or hire new key officers or employees needed to implement our business strategy and develop our products and businesses. We are substantially dependent on the skills and efforts of current senior management for their management and ~~operations~~ **operation skills**, as well as for the implementation of our business strategy. In addition, our future success depends upon our ability to attract and retain additional qualified personnel (including medical, scientific, technical, commercial, business and administrative personnel) necessary to support our anticipated growth, develop our business, perform our contractual obligations to third parties and maintain appropriate licensure **and compliance to applicable laws and regulations**. There can be no assurance that we will be successful in attracting or retaining personnel required by us to continue to grow our operations. The loss of a key employee, the failure of a key employee to perform in his or her current position or our inability to attract and / or retain skilled employees, as needed, could result in our inability to continue to grow our business or to implement our business strategy, or may have a material adverse effect on our business, financial condition and operating results. Our internal computer systems, or those used by our clinical investigators, clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of development programs for our product candidates. We rely on information technology systems to keep financial records, maintain laboratory and corporate records, communicate with staff and external parties and operate other critical functions. Any significant insufficiency, degradation or failure of these computer systems could cause us to ~~inaccurately calculate or~~ lose our ~~data~~ **ability to operate effectively, accurately and / or efficiently**. Despite the implementation of security measures, these internal computer systems and those used by our clinical investigators, clinical research organizations, and other contractors and consultants are vulnerable to damage from computer viruses **, malware**, unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. The techniques that could be used by criminal elements or foreign governments to attack these computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. Furthermore, there is an increased risk of cybersecurity attacks by state actors. Russian, Chinese, Iranian, North Korean and other ransomware gangs have threatened or enacted increased hacking activity against critical infrastructure of many nations or organizations. Any such increase in such attacks on **us and / or** our third- party ~~provider~~ **providers** or other systems could adversely affect our network systems or other operations. While we have not experienced any such system failure, theft of information, accident or security breach to date, if such an event were to occur and cause interruptions in its operations, it could result in a material disruption of our clinical development activities **and / or business operations**. For example, the loss of clinical trial data from historical or future clinical trials could result in delays in regulatory approval efforts and significantly increase costs to recover or reproduce the data. To the extent that any disruption, theft of information, or security breach were to result in a loss of or damage to data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the clinical development, and the future development of our product candidates could be delayed. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate information about clinical- stage ~~oncology~~ product candidates and the diseases that our therapies are designed to treat. Social media practices in the pharmaceutical industry continue to evolve and regulations related to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients and others may use social media channels to comment on the effectiveness of a product candidate or to report an alleged adverse event. When such disclosures occur, we may fail to monitor and comply with applicable adverse event reporting obligations, or we may not be able to defend against political and market pressures generated by social media due to restrictions on what we may say about our product candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face overly restrictive regulatory actions or incur other harm to our business. RISKS RELATED TO MANUFACTURING OUR DEVELOPMENT PRODUCT CANDIDATES ~~We have no internal capacity to manufacture our development product candidates and have no assurance that we will continue to have access to manufacturers in our industry that can effectively make our development products or make them at an affordable, salable or otherwise commercially reasonable price or quantity.~~ Contract development and manufacturing organizations have a finite manufacturing capacity, which could inhibit the long- term growth prospects of our business. We currently have ~~minimal~~ manufacturing contracts to produce materials for our clinical trials. It is possible that ~~the~~ **future** demand for our products could exceed existing manufacturing capacity. We expect that, as our own development programs progress and demand for therapeutics in the industry ~~expand~~ **expands**, it may become necessary or desirable for us to expand our manufacturing vendors for services and products in the future, which may require us to invest significant amounts of capital and to obtain regulatory approvals. If manufacturers are unable to meet our rising demand for products and services on a timely basis or unable to maintain cGMP compliance standards, then it is likely that the progress of our own programs will be impaired which could materially and adversely affect the overall success of our development programs. Components of therapeutic products approved for commercial sale or used in ~~late- stage~~ clinical trials must be manufactured in accordance with cGMPs. In addition, manufacturers of therapeutic products may be required to modify their manufacturing processes from time to time in response to regulatory requests. We will need to improve manufacturing efficiency at our contract manufacturers in order to establish cost of goods levels that will permit approved products to succeed commercially. CMOs cannot provide assurances that they will be able to develop process enhancements that are acceptable to regulators or other comparable regulatory authorities, on a timely basis, on commercially reasonable terms, or at all, or that any expected improvement in profitability will be realized. If they are unsuccessful in their efforts to develop necessary improvements, we may be unable to develop commercially viable products, which would impair our ability to continue our operations. We will rely on third parties to manufacture our clinical product supplies, and we may rely on third parties to produce and process our ~~product~~ **products** ~~candidates~~, if approved **. We have no**

internal capacity to manufacture our development product candidates and have no assurance that we will continue to have access to manufacturers in our industry that can effectively make our development products or make them at an affordable, salable or otherwise commercially reasonable price or quantity . We do not currently own any facility that may be used as ~~our~~ **a** clinical scale manufacturing facility and expect to rely on outside vendors to manufacture supplies of our product candidates. We will need to negotiate and maintain contractual arrangements with these outside vendors for the supply of our product candidates, and we may not be able to do so on favorable terms. We have not yet caused any product candidates to be manufactured on a commercial scale and may not be able to do so for any of our product candidates. The facilities used by our contract manufacturers to manufacture our ~~product~~ **products** ~~candidates~~ **or future products** must be approved by the FDA or other foreign regulatory authorities following inspections that will be conducted after we submit an application to the FDA or other foreign regulatory authorities. We may not control the manufacturing process of, and may be completely dependent on, our contract manufacturing partners for compliance with cGMPs and any other regulatory requirements of the FDA or other regulatory authorities for the manufacture of our product candidates. Beyond periodic audits and contractual arrangements, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or **products or** if it withdraws any approval in the future, we may need to find alternative manufacturing facilities, which would require the incurrence of significant additional costs and significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Similarly, if any third- party manufacturers on which we will rely fail to manufacture quantities of our product candidates **or products** at quality levels necessary to meet regulatory requirements and at a scale sufficient to meet anticipated demand at a cost that allows us to achieve profitability, our business, financial condition and prospects could be materially and adversely affected. RISKS RELATED TO SALES, MARKETING, AND COMPETITION We currently have no marketing and sales organization and have no experience in marketing products. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, if approved, we may not be able to generate product revenue. We currently have no sales, marketing or distribution capabilities and have no experience in marketing products. We intend to develop an in- house marketing organization and sales force in the future, which will require significant capital expenditure, management resources and time. We will have to compete with other pharmaceutical and biotechnology companies to recruit, hire, train and retain marketing and sales personnel. If we are unable or decide not to establish internal sales, marketing and distribution capabilities, we will pursue arrangements with third- party sales, marketing, and distribution collaborators regarding the sales and marketing of our products, if approved. However, there can be no assurance that we will be able to establish or maintain such arrangements on favorable terms or if at all, or if we are able to do so, that these third- party arrangements will provide effective sales forces or marketing and distribution capabilities. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist with the sales and marketing efforts of our product candidates. There can be no assurance that we will be able to develop in- house sales and distribution capabilities or establish or maintain relationships with third- party collaborators to commercialize any product in the United States or overseas. A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business. We and our partners plan to seek regulatory approval of one or more of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including **but not limited to** : • differing regulatory requirements in foreign countries ~~, for example, no country other than the United States has a pathway for accelerated drug approval and so obtaining regulatory approvals outside of the United States will take longer and be more costly than obtaining approval in the United States~~ ; • unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign taxes, including withholding of payroll taxes; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • difficulties staffing and managing foreign operations; • workforce uncertainty in countries where labor unrest is more common than in the United States; • potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations; • challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geo- political actions, including war and terrorism. These and other risks associated with international operations may materially adversely affect our ability to attain or maintain profitable operations. Even if we obtain regulatory approval of our product candidates, our products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers and others in the medical community. ~~The CendR Platform ® may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers and others in the medical community.~~ Various factors will influence whether our product candidates are accepted in the market, including: • the clinical indications for which our product candidates are approved; • physicians, hospitals, cancer treatment centers and patients considering our product candidates as a safe and effective treatment; • the potential and perceived advantages **and risks** of our product candidates over alternative treatments; • our ability to demonstrate the advantages of our product candidates over other cancer medicines; • ~~the prevalence and severity of any side effects for other precision medicines and public perception of other precision medicines; •~~ product labeling or product insert requirements of ~~the FDA or other regulatory authorities; • limitations or warnings contained in the labeling approved by~~ the FDA or other regulatory authorities; • the timing of market introduction of our product candidates as well as competitive products; • the cost of treatment

in relation to alternative treatments; • the availability of adequate coverage, reimbursement and pricing by third- party payors and ~~government~~ **governmental** authorities; • the willingness of patients to pay out- of- pocket in the absence of coverage by third- party payors and ~~government~~ **governmental** authorities; • **the** relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and • the effectiveness of our sales and marketing efforts. If our product candidates are approved but fail to achieve market acceptance among physicians, patients, hospitals, cancer treatment centers or others in the medical community, we will not be able to generate significant revenue. In addition, although our product candidates differ in certain ways from other approaches, serious adverse events or deaths in other clinical trials involving precision medicines, even if not ultimately attributable to our products or product candidates, could result in increased government regulation, unfavorable public perception and publicity, potential regulatory delays in the testing or licensing of our product candidates, stricter labeling requirements for those product candidates that are licensed, and a decrease in demand for any such product candidates. Even if our products achieve market acceptance, it may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The biotechnology and pharmaceutical industries utilize rapidly advancing technologies and are characterized by intense competition. While we believe that our scientific knowledge, technology and development expertise provide us with competitive advantages, we face potential competition from many different sources, including major pharmaceuticals, specialty pharmaceuticals and biotechnology companies, academic institutions and government agencies, and public and private research institutes that conduct research, development, manufacturing and commercialization. Many of our competitors have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, regulatory approvals and product marketing than we do. Our competitors may compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result, our competitors may discover, develop, license or commercialize products before or more successfully than we do. Product candidates that we successfully develop and commercialize may compete with existing therapies and new therapies that may become available in the future. If our drug candidates are approved for the indications for which we are currently planning clinical trials, they will likely compete with existing drugs and other drugs that are currently in development. Key product features that would affect our ability to effectively compete with other therapeutics include the efficacy, safety and convenience of our products. Our competitors may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. The availability of reimbursement from government and other third- party payors will also significantly affect the pricing and competitiveness of our products. Our competitors may also obtain FDA or other regulatory approval for their products more rapidly than we **may** obtain approval for our products, which could result in our competitors establishing a strong market position before we are able to enter the market. RISKS RELATED TO GOVERNMENT REGULATION The development and commercialization of our product candidates are subject to extensive regulation by the FDA and other regulatory agencies in the United States and abroad, **respectively,** and the failure to receive regulatory approvals for our product candidates would likely have a material and adverse effect on our business and prospects. ~~Government~~ **Governmental** authorities in the United States, at the federal, state and local level, and in other countries, extensively regulate, among other things, the research, development, testing, manufacture, including any manufacturing changes, packaging, storage, recordkeeping, labeling, advertising and promotion, distribution, marketing, import and export of pharmaceutical products, such as ~~LSTA1~~ **certepetide**. The process of obtaining required regulatory approvals and the subsequent compliance with appropriate statutes and regulations requires the expenditure of substantial time and money, and there is no guarantee that we will successfully complete the steps needed to obtain regulatory approval of ~~LSTA1~~ **certepetide** or any future product candidates. There also are extensive and ongoing post- marketing compliance obligations to which we would be subject following FDA approval of any of our product candidates. In addition, these federal regulations may change, and our product candidates may be subject to new laws or regulations. To date, we have ~~not~~ **neither applied for nor** received regulatory approval to market any of our product candidates in any jurisdiction. If we seek approval of any of our product candidates, we will be required to submit to FDA and ~~potentially~~ **relevant** other regulatory authorities, extensive non- clinical and clinical data supporting the safety and efficacy of such product candidates, as well as information about the manufacturing process and to undergo inspection of manufacturing facilities, among other things. The process of obtaining FDA and other regulatory approvals is expensive, typically takes many years and is subject to numerous risks and uncertainties. Changes in regulatory approval policies during the clinical research and development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application or may make it easier for our competitors to gain regulatory approval to enter the marketplace. Ultimately, the FDA and other regulatory agencies have substantial discretion in the approval / licensure process and may refuse to accept any application or may decide that our product candidate data are insufficient for approval without the submission of additional non- clinical, clinical or other time- consuming studies. In addition, varying agency interpretations of the data obtained from non- clinical and clinical testing could delay, limit or prevent regulatory approval of a product candidate. Any regulatory approval we ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. Any of the following factors, among others, could cause regulatory approval for our product candidates to be delayed, limited or denied: • the product candidates require further clinical testing to demonstrate safety and effectiveness before applications for marketing approval can be submitted to the FDA and other regulatory authorities; • data obtained from animal testing and other non- clinical testing and clinical trials can be interpreted in different ways, and regulatory authorities may not agree with our respective interpretations or may require us to conduct additional testing; • negative or inconclusive results or the occurrence of serious or unexpected adverse events during a clinical trial could cause us

to delay and / or terminate development efforts for a product candidate; and / or • the FDA and other regulatory authorities may require expansion of the size and scope of the clinical trials. Any difficulties or failures that we encounter in securing regulatory approval for our product candidates would likely have a substantial adverse impact on our ability to generate product sales and could make any search for a collaborative partner more difficult. Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems ~~with our product candidates~~. Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety and efficacy of the product ~~candidate~~. The FDA may also require a REMS in order to approve ~~our~~ **a** product ~~candidates~~ **candidate**, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our ~~product~~ **products** ~~candidates~~ will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with applicable cGMP, GLP and GCP requirements ~~, for any clinical trials that we conduct post- approval~~. Later discovery of previously unknown problems with our product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: • restrictions on the marketing or manufacturing of our ~~product~~ **products** ~~candidates~~, withdrawal of the product from the market or voluntary or mandatory product recalls; • manufacturing delays and supply disruptions where regulatory inspections identify observations of noncompliance requiring remediation; • revisions to the labeling, including limitation on approved uses or the addition of warnings, contraindications or other safety information, including boxed warnings; • imposition of a REMS, which may include distribution or use restrictions; • requirements to conduct additional post- market clinical trials to assess the safety of the product; • fines, warning letters or holds on clinical trials **or product distribution and sale**; • refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals; • product seizure or detention, or refusal to permit the import or export of our product candidates; and • injunctions or the imposition of civil or criminal penalties. The FDA' s and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. If any of our product candidates are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products ~~, if approved~~. In particular, while the FDA permits the dissemination of truthful and non- misleading information about an approved product, a manufacturer may not promote a product for uses that are not approved by the FDA or other regulatory agencies as reflected in the product' s approved labeling. If we are found to have promoted such off- label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The DOJ and FDA have also requested that companies enter into consent decrees, corporate integrity agreements or permanent injunctions under which specified promotional conduct must be changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. We may be unsuccessful in our efforts to comply with applicable federal, state and international laws and regulations, which could result in government enforcement actions or impact our ability to secure regulatory approval of our product candidates. Although we seek to conduct our business in compliance with applicable laws and regulations, these laws and regulations are exceedingly complex and often subject to varying interpretations. The biopharmaceutical industry is a topic of significant government interest, and thus the laws and regulations applicable to our business are subject to frequent change and / or reinterpretation. As such, there can be no assurance that we will be able, or will have the resources, to maintain compliance with all applicable biopharmaceutical and health care laws and regulations. Failure to comply with such biopharmaceutical and health care laws and regulations could result in significant enforcement actions, civil or criminal penalties, which along with the costs associated with such compliance or with enforcement of such biopharmaceutical and health care laws and regulations, may have a material adverse effect on our operations or may require restructuring of our operations or impair our ability to operate profitably. cGMP regulations govern the manufacture, processing, packaging and holding of biopharmaceutical products. Any third- party manufacturers that prepare our products must comply with cGMP requirements including quality control, quality assurance and the maintenance of **relevant** records and documentation ~~for certain products~~. They may be unable to comply with these cGMP requirements and with other national regulators and state and local regulatory requirements. These requirements may change over time and we or third- party manufacturers may be unable to comply with the revised requirements. We may be subject to numerous and varying privacy and security laws, and our failure to comply could result in penalties and reputational damage. We are subject to laws and regulations covering data privacy and the protection of personal information including health information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues which may affect our business. In the United States, we may be subject to state security breach

notification laws, state health information privacy laws and federal and state consumer protections laws which impose requirements for the collection, use, disclosure, and transmission of personal information. If we fail to comply with applicable laws and regulations, we could be subject to penalties or sanctions, including criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. In addition, as various states, such as California, Virginia, Colorado, Connecticut, and Utah implement their own privacy laws and regulations, the interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, which may create complex compliance issues for us and potentially ~~exposing~~ **expose** us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify. Numerous other countries have, or are developing, laws governing the collection, use and transmission of personal information as well. EU member states and other jurisdictions have adopted data protection laws and regulations, which impose significant compliance obligations. In May 2016, the European Union formally adopted the General Data Protection Regulation (" GDPR "), which applies to all EU member states from May 25, 2018, and replaced the EU Data Protection Directive. The regulation ~~introduces~~ **introduced** stringent new data protection requirements in the European Union and substantial fines for breaches of the data protection rules. It has increased our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new EU data protection rules. The GDPR is a complex law and the regulatory guidance is still evolving, including with respect to how the GDPR should be applied in the context of clinical studies. Furthermore, many of the countries within the European Union are still in the process of drafting supplementary data protection legislation in key fields where the GDPR allows for national variation, including the fields of clinical study and other health-related information. These variations in the law may raise our costs of compliance and result in greater legal risks. Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to: **a)** comply with the regulations of the FDA and foreign regulatory authorities, provide true, complete and accurate information to the FDA and foreign regulatory authorities, **b)** comply with manufacturing standards we have established, **c)** comply with ~~healthcare~~ ---- **health care** fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws **,** or **d)** report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products, our potential exposure under such laws and regulations will increase significantly, and our costs associated with compliance with such laws and regulations are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing, and education programs. In particular, the promotion, sales and marketing of ~~healthcare~~ ---- **health care** items and services, as well as certain business arrangements in the ~~healthcare~~ ---- **health care** industry, are subject to extensive laws designed to prevent fraud, kickbacks, self- dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate include, but are not limited to: • the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal ~~healthcare~~ ---- **health care** program, such as the Medicare and Medicaid programs. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government ~~healthcare~~ ---- **health care** programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the Federal False Claims Act. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; • federal civil and criminal false claims laws and civil monetary penalty laws, including the Federal False Claims Act (the " FCA "), which impose criminal and civil penalties, including through civil " qui tam " or " whistleblower " actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other federal health care programs that are false or fraudulent; knowingly making or causing a false statement material to a false or fraudulent claim or an obligation to pay money to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing such an obligation. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. The FCA also permits a private individual acting as a " whistleblower " to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the Federal False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal ~~healthcare~~ ---- **health care** programs; • HIPAA, which created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any ~~healthcare~~ ---- **health care** benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any ~~healthcare~~ ---- **health care** benefit program, regardless of the payor (e. g., public or

private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, ~~healthcare~~ **health care** benefits, items or services relating to ~~healthcare~~ **health care** matters. Similar to the federal Anti- Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it; • HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose requirements on certain covered ~~healthcare~~ **health care** providers, health plans, and ~~healthcare~~ **health care** clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; • the federal Physician Payment Sunshine Act, created under the ACA and its implementing regulations, which require manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, chiropractors and certain **non- physician** advanced practice practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and • analogous state and foreign laws and regulations, such as state and foreign anti- kickback, false claims, consumer protection and unfair competition laws which may apply to pharmaceutical business practices, including but not limited to, research, distribution, sales and marketing arrangements as well as submitting claims involving ~~healthcare~~ **health care** items or services reimbursed by any third- party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government that otherwise restricts payments that may be made to ~~healthcare~~ **health care** providers and other potential referral sources; state laws that require drug manufacturers to file reports with states regarding pricing and marketing information, such as the tracking and reporting of gifts, compensations and other remuneration and items of value provided to ~~healthcare~~ **health care** professionals and entities; state and local laws requiring the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting it from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements with third parties will comply with applicable ~~healthcare~~ **health care** laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices **, or those of our partners or critical contractors,** may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other ~~healthcare~~ **health care** laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded ~~healthcare~~ **health care** programs, such as Medicare and Medicaid, additional reporting requirements and oversight if it becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm, diminished profits and future earnings, and it may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a ~~healthcare~~ **health care** company may run afoul of one or more of the requirements. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that it will be successful in obtaining regulatory approval of our product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that it will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also **independently** approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional non- clinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we

intend to charge for our products is also subject to approval. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. 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 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. Health care companies have been the subject of federal and state investigations, and we could become subject to such investigations in the future. Both federal and state government agencies have heightened civil and criminal enforcement efforts. There are numerous ongoing investigations of health care companies, including drug, biologic and medical device companies, as well as their executives and managers. In addition, amendments to the Federal False Claims Act, including under health care reform, have made it easier for private parties to bring " qui tam " (whistleblower) lawsuits against companies under which the whistleblower may be entitled to receive a percentage of any money paid to the government. The Federal False Claims Act provides, in part, that an action can be brought against any person or entity that has knowingly presented, or caused to be presented, a false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim approved. The government has taken the position that claims presented in violation of the federal anti- kickback law or other health care- related laws, including laws enforced by the FDA, may be considered a violation of the Federal False Claims Act. Penalties include substantial fines for each false claim, plus three times the amount of damages that the federal government sustained because of the act of that person or entity and / or exclusion from the Medicare program. In addition, a majority of states have adopted similar state whistleblower and false claims provisions. We are not aware of any government investigations involving any of our facilities or management. While we believe that we are in material compliance with applicable governmental health care laws and regulations, any future investigations of our business or executives could cause us to incur substantial costs, and result in significant liabilities or penalties, as well as damage to our reputation. It is uncertain to what extent government, private health insurers, and third- party payors will approve coverage or provide reimbursement for the therapies and products to which our research and development relate. Availability for such reimbursement may be further limited by an increasing uninsured population and reductions in Medicare and Medicaid funding in the United States. To the extent that health care providers cannot obtain coverage or reimbursement for our therapies and products, they may elect not to provide such therapies and products to their patients and, thus, may not need our services. Further, as cost containment pressures are increasing in the health care industry, government and private payors may adopt strategies designed to limit the amount of reimbursement paid to health care providers. Similarly, the trend toward managed health care and bundled pricing for health care services in the United States, could significantly influence the purchase of health care services and products, resulting in lower prices and reduced demand for our therapeutic products under development. We may receive a portion of our revenues from services rendered to patients enrolled in federal health care programs, such as Medicare, and we may also directly or indirectly receive revenues from federal health care programs. Federal health care programs are subject to changes in coverage and reimbursement rules and procedures, including retroactive rate adjustments. These contingencies could materially decrease the range of services covered by such programs or the reimbursement rates paid directly or indirectly for our products and services. To the extent that any health care reform favors the reimbursement of other therapies over our therapeutic products under development, such reform could affect our ability to sell ~~our services~~ **any products for which we are able to obtain regulatory approval** , which may have a material adverse effect on our revenues. The limitation on reimbursement available from private and government payors may reduce the demand for, or the price of, our services, which could have a material adverse effect on our revenues. Additional legislation or regulation relating to the health care industry or third- party coverage and reimbursement may be enacted in the future which could adversely affect the revenues generated from the sale of our products and services. Furthermore, ~~there has been a trend in recent years towards reductions in~~ overall funding for Medicare and Medicaid **remains unpredictable** ~~. There has also been an~~ **and** ~~increase in~~ **at the discretion of the U. S. government. Also,** ~~the~~ **there remain a large** number of people who do not have any form of health care coverage ~~in recent years~~ and who are not eligible for or enrolled in Medicare, Medicaid or other governmental programs. The extent to which **any future** ~~the reforms brought about under~~ health care reform may be successful in reducing the number of such uninsured is unclear, and the reduced funding of governmental programs and increase in uninsured populations could have a negative impact on the demand for our **products and** services **that may be** ~~to the extent they relate to products and services which are~~ reimbursed by government and private payors. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by ~~the~~ CMS, an agency within the U. S. Department of Health and Human Services (" HHS "). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third- party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. It is difficult to predict what CMS will decide with respect to reimbursement for fundamentally novel products such as ours. Reimbursement agencies in Europe may be more conservative than CMS. For example, a number of cancer drugs have been approved for reimbursement in the United States and have not been approved for reimbursement in certain European countries. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drugs, if

applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any approved products we may develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates, and our overall financial condition. Net prices for drugs may be reduced by mandatory discounts or rebates required by government ~~healthcare ----~~ **health care** programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates third- party payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Increasingly, third- party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that ~~it~~ **we are eventually able to** ~~commercializes~~ **commercialize** and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard **-** of **-** care drugs, including lower- priced generic versions of standard **-** of **-** care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates due to the trend toward managed ~~healthcare ----~~ **health care** , the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on ~~healthcare ----~~ **health care** costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. Additionally, we and / or our collaborators may develop companion diagnostic tests for use with our product candidates. We, or our collaborators, may be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. Even if we obtain regulatory approval or clearance for such companion diagnostics, there is significant uncertainty regarding our ability to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates. Medicare reimbursement methodologies, whether under Part A, Part B, or clinical laboratory fee schedule may be amended from time to time, and we cannot predict what effect any change to these methodologies would have on any product candidate or companion diagnostic for which ~~it~~ **we or our collaborators** ~~receives~~ **receive** approval. Our inability to promptly obtain coverage and adequate reimbursement from both third- party payors for the companion diagnostic tests that we develop and for which we **or our collaborators** obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects. Legislation and legislative and regulatory proposals intended to contain health care costs may adversely affect our business. The containment of health care costs has become a priority of federal and state governments and the prices of drug products have been a focus of this effort. For example, there have been several recent U. S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. We expect that federal, state and local governments in the **United States** ~~U. S.~~ will continue to consider legislation directed at lowering the total cost of health care and prescription drugs. Individual **U. S.** states ~~in the U. S.~~ have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate PBMs and other members of the health care and pharmaceutical supply chain, an important decision that has led to more aggressive efforts by states in this area. During the current congressional session, numerous PBM reforms are being considered in both the Senate and the House of Representatives; they include diverse legislative proposals such as eliminating rebates; divorcing service fees from the price of a drug, discount, or rebate; prohibiting spread pricing; limiting administrative fees; requiring PBMs to report formulary placement rationale; promoting transparency. The Federal Trade Commission in mid- 2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. Significant efforts to change the PBM industry as it currently exists in the **United States** ~~U. S.~~ may affect the entire pharmaceutical supply chain and the business of other stakeholders, including medical product developers like us. **On** ~~The Biden Administration has also indicated that lowering prescription drug prices is a priority, and on~~ August 16, 2022, President Biden signed into the law the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the U. S. ~~Starting in 2023~~ **For example, under the IRA** , a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product' s price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting for payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition **, and** ~~. CMS will also negotiate drug prices for a select number of Part B drugs~~ starting for payment year 2028 **, CMS will begin negotiating drug prices for a select number of Part B drugs** . If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities and entered into the first set of agreements with ~~pharmaceutical~~ **drug and biologic product** manufacturers ~~to conduct~~ **for negotiated** ~~price~~ **prices** ~~negotiations in October~~ **of 10 products, which will become applicable for payment year** ~~2023~~ **2026** . ~~However~~ **Ultimately** , the IRA' s impact on the

biopharmaceutical industry in the **United States** ~~U. S.~~ remains uncertain, in part because **of** multiple **ongoing lawsuits against CMS brought by** large pharmaceutical companies and other stakeholders (e. g., the U. S. Chamber of Commerce) ~~have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing~~ . It is uncertain whether and how future legislation or regulatory changes could affect prospects for our product candidates or what actions third- party payors may take in response to any such health care reform proposals or legislation. Adoption of price controls and cost- containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures reforms, may prevent or limit our ability, or the ability of a commercial collaborator, to commercialize any of our future products that receive marketing approval as well as our ability to generate revenue and attain profitability. Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any. In some countries, particularly the member states of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure ~~by~~ **from** governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. In some countries where we may seek to market our product candidates in the future, we may be required to conduct a clinical trial or other studies that compare the cost- effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third- party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected. Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. **Most recently, the U. S. government nearly shutdown at the end of December 2024 due to disagreements in Congress over a continuing resolution package to fund federal government operations.** If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. A variety of risks associated with operating our business internationally could materially adversely affect our business. We plan to seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we, and any potential collaborators in those jurisdictions, will be subject to additional risks related to operating in foreign countries, including: ~~• differing regulatory requirements in foreign countries;~~ • differing coverage and reimbursement requirements in foreign countries; • unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements; • compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad; • potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign laws, such as the U. K. Anti- Bribery Act; • the continued threat of terrorism and the impact of military and other action, including military actions involving Russia and Ukraine **, and others** ; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad, including as a result of pandemics or the military actions involving Russia and Ukraine and the ongoing conflict in Israel and Gaza; and These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations. RISKS RELATED TO OUR INTELLECTUAL PROPERTY We may be unable to obtain or maintain patent protection for our products and product candidates, which could have a material adverse effect on our business. Our commercial success will depend, in part, on obtaining and maintaining patent protection for new technologies, product candidates, products and processes and successfully defending such patents against third- party challenges. To that end, we **have** ~~file~~ **filed** patent applications ~~,~~ and **maintain** ~~have been~~ issued patents ~~, that are~~ intended to cover certain methods ~~and ,~~ uses **and** ~~of human cells as well as~~ compositions ~~and methods~~ relating to ~~hematopoietic stem cells~~ **our products and product candidates** . These patent applications may never result in the issuance of patents. The patent positions ~~of biotechnology companies~~ **in the pharmaceutical industry** can be highly uncertain and involve complex legal, scientific and factual questions and recent court decisions have introduced significant uncertainty regarding the strength of patents in the industry. Moreover, the legal systems of some foreign countries do not favor the aggressive enforcement of patents and may not protect our intellectual property rights to the same extent as the laws of the United States. Any of the issued patents we own or license may be challenged by third parties and held to be invalid, unenforceable or with a narrower or different scope of coverage than what we currently believe, effectively reducing or eliminating protection we believed we had against competitors with similar products or technologies. If we ultimately engage in and lose any such patent disputes, we could be subject to competition and / or significant liabilities, we

could be required to enter into third- party licenses or we could be required to cease using the disputed technology or product. In addition, even if such licenses are available, the terms of any license requested by a third party could be unacceptable or unaffordable to us. Product development and approval timelines in the biotechnology industry are very lengthy. As such, it is possible that any patents that may cover an approved product may have expired at the time of commercialization or only have a short remaining period of exclusivity, thereby reducing the commercial advantages of the patent. In such case, we would then rely solely on other forms of exclusivity, such as regulatory exclusivity provided by the FD & C Act, which may provide less protection to our competitive position. Litigation relating to intellectual property is expensive, time- consuming and uncertain, and we may be unsuccessful in our efforts to protect against infringement by third parties or defend ourselves against claims of infringement. To protect our intellectual property, we may initiate litigation or other proceedings. In general, intellectual property litigation is costly, time- consuming, diverts the attention of management and technical personnel and could result in substantial uncertainty regarding our future viability, even if we ultimately prevail. Some of our competitors may be able to sustain the costs of such litigation or other proceedings more effectively than can we because of their substantially greater financial resources. The loss or narrowing of our intellectual property protection, the inability to secure or enforce our intellectual property rights or a finding that we have infringed the intellectual property rights of a third party could limit our ability to develop or market our products and services in the future or adversely affect our revenues. Furthermore, any public announcements related to such litigation or regulatory proceedings could adversely affect the price of our common stock. Third parties may allege that the research, development and commercialization activities we conduct infringe patents or other proprietary rights owned by such parties. While we do not believe any of our current activities infringe the rights of others, we have not conducted an exhaustive search or analysis of third- party patent rights to determine whether our pre- clinical or clinical research and development or activities may infringe or be alleged to infringe any third- party patent rights. If we are found to have infringed the patents of a third party, we may be required to pay substantial damages; we also may be required to seek from such party a license, which may not be available on acceptable terms, if at all, to continue our activities. A judicial finding or infringement or the failure to obtain necessary licenses could prevent us from commercializing our products, which would have a material adverse effect on our business, operating results and financial condition. If we are unable to maintain our licenses, patents or other intellectual property we could lose important protections that are material to continuing our operations and our future prospects. To obtain and maintain patent protection and licensing rights under certain of our license agreement, we must, among other things, ensure the timely payment of all applicable filing and maintenance fees. Any failure to do so could result in the loss of some or all of our rights to proprietary technology or the inability to secure or enforce intellectual property protection. Additionally, our license agreements require us to meet certain diligence obligations in the development of the licensed products. Our failure to meet these diligence obligations could result in the loss of some or all of our rights, which could materially and adversely affect our business and future prospects. On December 1, 2015, Cend entered into an Exclusive License Agreement (the " SBP License Agreement ") with the Sanford Burnham Prebys Medical Discovery Institute (" SBP "), a California not- for- profit, public benefit corporation based in San Diego, California. Pursuant to the SBP License Agreement, which we assumed in connection with the Merger, SBP licensed to Cend the exclusive right to use certain patents to further Cend' s research and development efforts relating to ~~LSTA1~~ **certepetide** . Because we do not have the right to control the preparation, filing and prosecution of all of the patent applications, or to maintain the patents, covering ~~LSTA1~~ **certepetide** , we cannot be certain that these patents and applications will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our licensors fail to maintain such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated and our right to develop and commercialize any products that are the subject of such licensed rights could be adversely affected. In addition to the foregoing, the risks associated with patent rights that we license from third parties will also apply to patent rights it may own in the future. Further, pursuant to our license agreements, we may be held responsible for bringing actions against infringers. Certain of our license agreements could also require us to meet development thresholds to maintain the license, including establishing a set timeline for developing and commercializing products and minimum yearly diligence obligations in developing and commercializing the product. Disputes may also arise regarding intellectual property subject to a licensing agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we fail to comply with our obligations under these license agreements, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. If we are unable to obtain and maintain patent protection for our products and technology, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully partner and commercialize our products and technology may be adversely affected. Our success depends on our ability to obtain and maintain patent protection in the United States and other countries with respect to proprietary product candidates and manufacturing technology. Our licensors have sought and we intend to seek to protect proprietary position by filing patent applications in the United States and abroad related to the novel technologies and product candidates that are vital to our business. The patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. For example, in some cases, the work of certain academic researchers in the field of oncology could enter the public domain, which may compromise our ability to obtain patent protection for certain inventions related to or building upon such prior work. Consequently, we may not be able to obtain any such patent rights to prevent others from using our technology for, and developing and marketing competing products to treat, these indications. It is also possible that we will fail to identify patentable aspects of our research and development output prior to obtaining adequate patent protection. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and

has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of patent rights remain highly uncertain. Any pending and future patent applications may not result in patents being issued which protect the related technology or product candidates or which effectively prevent others from commercializing competitive technologies and product candidates. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of patents or narrow the scope of patent protection. We may not be aware of all third- party intellectual property rights potentially relating to our targeted product candidates. Publications of discoveries in the scientific literature often lag the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or, in some cases, not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any owned or any licensed patents or pending patent applications, or that it was the first to file for patent protection of such inventions. Even if the patent applications we license or may own in the future do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent key patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and key patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which may impair our ability to stop others from using or commercializing similar or identical technology and products; or limit the duration of the patent protection of our technology and product candidates. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Further, in the event we breach the terms of the SBP License Agreement, we could lose the ability to continue the development and potential commercialization of ~~LSTA1~~ **certepetide**, and our operations and profitability will be significantly negatively impacted. If we fail to comply with our obligations in any future agreements under which we may license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with future licensors, we could lose license rights that are important to our business. In the future, we may be party to license or collaboration agreements with third parties to advance our research or allow commercialization of product candidates. Such future agreements may impose numerous obligations, such as development, diligence, payment, commercialization, funding, milestone, royalty, sublicensing, insurance, patent prosecution, enforcement and other obligations on us and may require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. In spite of our best efforts, future licensors might conclude that we have materially breached future license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technologies covered by these license agreements. Any termination of these licenses, or if the underlying patents fail to provide the intended exclusivity, could result in the loss of significant rights and could harm our ability to commercialize our product candidates, and competitors or other third parties would have the freedom to seek regulatory approval of, and to market, products identical to ours and it may be required to cease our development and commercialization of certain of our product candidates. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. Disputes may also arise between us and our future licensors regarding intellectual property subject to a license agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • whether and the extent to which our technology and processes infringe, misappropriate or otherwise violate intellectual property rights of the licensor that is not subject to the licensing agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; • the priority of invention of any patented technology; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners. In addition, the agreements under which we may license intellectual property or technology from third parties in the future are likely to be complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we may license in the future prevent or impair our ability to maintain future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations and prospects. We may not be successful in obtaining necessary additional rights to our product candidates through acquisitions and in-licenses. We may discover that ~~it~~ **we** ~~needs~~ **need** to obtain additional rights to the foundational IP associated with the product candidates we plan to develop, manufacture and market. If this occurs, we intend to license or purchase the rights to those candidates, which may ~~nor~~ **or** may not prove successful at all, or on acceptable terms. If our programs require the use of proprietary rights held by third parties, such as academic institutions, the growth of our business will critically depend on our ability to acquire, in- license or use these proprietary rights, which may not prove possible on acceptable terms. The licensing or acquisition of third- party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license

rights to us. If we are unable to license or acquire third- party intellectual property rights on terms that would allow us to execute our business plan, your investment may be lost. We may collaborate with non- profit and academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions would provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to it. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our product candidates, identify other candidates, or to develop or license replacement technology, none of which may be feasible on a technical or commercial basis, especially with our limited resources. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could critically harm our business. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and / or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our licensed patents and / or applications and any patent rights we may own in the future. We may rely on our outside counsel or licensing partners to pay these fees due to non- U. S. patent agencies. The USPTO and various non- U. S. government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. We plan to employ reputable law firms and other professionals to help us comply, but we will also be dependent on our licensors to take the necessary action to comply with these requirements with respect to their licensed intellectual property. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could irreparably harm our business. We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. We anticipate that many of our consultants or advisors will currently be, or were previously, employed at universities, industry service providers (e. g., CDMOs, CROs, CDOs, etc.), or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in- licenses. Presently we have ~~three~~ **four** pending patent applications in the United States and fourteen pending patent applications outside the United States. Because additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in- license or use these proprietary rights. Our product candidates may also require specific formulations to work effectively and efficiently and these rights may be held by others. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we are able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be nonexclusive, thereby giving our competitors access to the same technologies licensed to it. In that event, we may be required to expend significant time and resources to develop or license replacement technology. Moreover, the molecules that will be used with our product candidates may be covered by the intellectual property rights of others. Additionally, we sometimes collaborate with academic institutions to accelerate our clinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program and allowing third parties to compete with us. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that it may seek to acquire. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program, and our business, results of operations, financial condition and prospects could suffer. If we do not obtain patent term extension and data exclusivity for any of our current or future product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more U. S. patents we may own or in- license in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch- Waxman Amendments. The Hatch-Waxman Amendments permit a patent term extension of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following expiration of any patents that issue from our patent applications, and our business, financial condition, results of operations, and prospects could be materially harmed. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing on other marks. We intend to rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademarks. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and / or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to obtain a registered trademark or establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. If we are unable to protect the confidentiality of trade secrets, our competitive position could be impaired. A significant amount of our technology, especially regarding manufacturing processes, is unpatented and is maintained as trade secrets and / or know- how. We expend significant energy, resources and know- how in an effort to protect these trade secrets and know- how, including through the use of confidentiality agreements. Even so, improper use or disclosure of our confidential information could occur, and in such case, adequate remedies may not exist. The disclosure of trade secrets and know- how could impair our competitive position. Although we require all of our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information, or technology to enter into confidentiality agreements, trade secrets can be difficult to protect and we have limited the protection of trade secrets used by our collaborators and suppliers. We cannot be certain that we have or will obtain these agreements in all circumstances and cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary information. Moreover, any of these parties might breach the agreements and intentionally or inadvertently disclose our trade secret information and we may not be able to obtain adequate remedies for such breaches. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights and trade secrets to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition, results of operations and future prospects. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements, including aspects of drug manufacturing processes, experiments to validate mechanisms and pharmacology, drug design, and related processes, are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party' s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. Although we require all of our employees to assign their inventions to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may

be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects. In certain countries, patent holders may be required to grant compulsory licenses, which would likely have a significant and detrimental effect on any future revenues in such country. Many countries, including some countries in Europe, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, most countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may be limited to monetary relief and may be unable to enjoin infringement, which could materially diminish the value of the patent. Compulsory licensing of life- saving products is also becoming increasingly common in developing countries, either through direct legislation or international initiatives. Such compulsory licenses could be extended to our product candidates, which may limit our potential revenue opportunities, including with respect to any future revenues that may result from our product candidates. Changes to U. S. patent law may have a material adverse effect on our intellectual property rights. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs, and may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and any licensed patents. Patent reform legislation in the United States and other countries, including the Leahy- Smith America Invents Act (the Leahy- Smith Act), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U. S. Congress, the U. S. courts, the U. S. Patent and Trade Office (the " USPTO ") and the relevant law- making bodies in other countries, 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 patents and patents that we might obtain in the future. Third- party claims of intellectual property infringement may prevent or delay our development and commercialization efforts. Our commercial success depends in part on our avoiding infringement of the patents, trademarks and proprietary rights of third parties. There have been many lawsuits and other proceedings involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, and reexamination proceedings before the USPTO and corresponding foreign patent offices and trademark violations. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products and services. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products and services may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to devices, materials, formulations, methods of manufacture, or methods for treatment related to the use or manufacture of our products and services. We have conducted freedom to operate analyses with respect to only certain of our products and services, and therefore we do not know whether there are any third- party patents that would impair our ability to commercialize these products and services. We also cannot guarantee that any of our analyses are complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the United States and abroad that is relevant or necessary to the commercialization of our products and services. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our products or services may inadvertently infringe upon. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover aspects of our products or services, the holders of any such patents may be able to block our ability to commercialize such products or services unless we obtained a license under the applicable patents, or until such patents expire or are finally determined to be invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products or services. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. RISKS RELATED TO OUR RELIANCE ON THIRD PARTIES We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances, or licensing arrangements. We may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite

potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval. Further, collaborations involving our product candidates are subject to numerous risks, which may include the following: • collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates; **• collaborators may own or co- own critical clinical data or intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the authority or exclusive right to utilize or publicly announce, or commercialize such data or intellectual property, respectively.** As a result, if we enter into additional collaboration agreements and strategic partnerships or licenses our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. Our manufacturing process needs to comply with regulatory authority regulations relating to the quality and reliability of such processes. Any failure to comply with relevant regulations could result in delays in or termination of our clinical programs and suspension or withdrawal of any regulatory approvals. In order to commercially produce our products either at our own facility or at a third party' s facility, we will need to comply **or assure compliance** with the FDA' s and other regulatory authority' s cGMP regulations and guidelines. We **and / or our agents** may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We **and / or our agents** are subject to inspections by the FDA and comparable foreign regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, including leading to significant delays in the availability of our product candidates for our clinical trials or the termination of or suspension of a clinical trial, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant non- compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and business. If our third- party manufacturers use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by our third- party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. RISKS RELATED TO MANAGING GROWTH AND EMPLOYEE MATTERS We may need to grow the size of our organization, and may experience difficulties in managing this growth. As of December 31, ~~2023~~ **2024** , we had ~~25~~ **26** full- time employees. We intend to hire new employees to conduct our research and development ~~activities~~ / administrative / ~~scientific~~ **business activities** in the future. Any delay in hiring such new employees could result in delays in our research and development activities and would harm our business. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial and other personnel, as well as additional facilities to expand our operations. Future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, **managing,** maintaining and motivating additional employees; • ~~advance~~ **advanced and / or expanded** applications of our drug discovery and development platform; • managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and • **maintaining and / or** improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of our attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial ~~management~~ **execution** and manufacturing. There can be no assurance that the services of independent

organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or we are not able to effectively build out new facilities to accommodate this expansion, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. 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 an inherent risk of product liability as a result of the planned clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical 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 or a breach of warranties. 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 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 product candidates or products that we may develop; • injury to our reputation; • withdrawal of clinical trial participants **, clinical investigators and related institutions** ; • initiation of investigations by regulators; • 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; • loss of revenue; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any product candidate; ~~and~~ • a decline in share price **; and • increased insurance costs or the inability to secure sufficient relevant insurance coverage** . Failure to obtain or retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Although we have clinical trial insurance, 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. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. GENERAL RISK FACTORS If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with ~~our~~ storage or disposal of biological, hazardous or radioactive materials. Data collection is governed by restrictive regulations governing the use, storage, processing and transfer of personal information. The collection, use, storage, disclosure, transfer, or other processing of personal data is subject to the California Consumer Privacy Act, or CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies' data collection, use and sharing practices, provide such consumers new ways to opt- out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations beginning July 1, 2020. The CCPA was amended on September 23, 2018, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U. S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, 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 may be unable to adequately protect our

information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure. We rely on information technology systems that we or our third- party providers operate to process, transmit and store electronic information in our day- to- day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as name, mailing address, email addresses, phone number and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial- of- service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e. g., state breach notification laws), federal (e. g., HIPAA, as amended by HITECH), and international law (e. g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business. In addition, the computer systems of various third parties on which we rely, and other contractors, consultants and law and accounting firms, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third- party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third- party providers could have difficulty preventing, detecting and controlling such cyber- attacks and any such attacks could result in losses described above as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. RISKS RELATED TO OUR ~~CAPITAL~~ **COMMON** STOCK Our stock price has been, and will likely continue to be, highly volatile. The market price of our common stock has been, and in the future may continue to be, highly volatile. For example, from January 1, ~~2023~~ **2024** through February ~~29~~ **27**, ~~2024~~ **2025** our common stock traded as low as $ ~~1~~ **2**. ~~95~~ **19** per share and as high as $ 4. ~~53~~ **20** per share. The market price for our common stock is highly dependent on, among other things, stock market conditions in general, **the type and distribution of investors that make up our shareholder base,** our clinical development efforts and the growth of our business in general, the amount of our available cash and investments and our level of cash utilization **as well as the public understanding and perception of public announcements we make**. Future events could increase the volatility seen in our common stock and ultimately cause a significant decline in the price of our common stock and ultimately impact our ability to raise additional capital in the future. These events could include the following, among others: **• positive announcements by competitors;** • low levels of trading volume for our shares; • capital- raising or other transactions that are, or may in the future be, dilutive to existing stockholders or that involve the issuance of debt securities; • delays in our clinical trials, **significant issues associated with any aspect of our development efforts (e. g., failed manufacturing or** negative clinical trial results **)** or adverse regulatory decisions relating to our product candidates; • adverse fluctuations in our revenues or operating results or financial results that otherwise fall below the market' s expectations; • disappointing developments concerning our product candidates; • positive developments concerning our product candidates that lead to the need for additional capital to complete the development process; and • legal challenges, disputes and / or other adverse developments impacting our patents or other proprietary rights that protect our products. In addition, broader external events, such as news concerning economic or market conditions in the general economy or within our industry, the activities of our competitors, changes (or the threat of changes) in U. S. or foreign government regulations impacting the life sciences industry or the movement of capital into or out of our industry, are likely to affect the price of our common stock. Geopolitical events, including the continued threat of terrorism and the impact of military and other action, including **but not limited to** military actions involving Russia and Ukraine as well as Israel and Gaza, could impact our stock price as well. There can be no assurance that the market price of our common stock will not continue to fluctuate or decline significantly in the future. We may fail to comply with the continued listing requirements of the Nasdaq Capital Market, such that our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. Our common stock is listed for trading on the Nasdaq Capital Market. We must satisfy Nasdaq' s continued listing requirements, including, among other things, a minimum closing bid price requirement of $ 1. 00 per share for 30 consecutive business days (the" Minimum Bid Price Requirement"). We have in the past been notified by Nasdaq that we were not in compliance with the Minimum Bid Price Requirement, and while we have regained compliance, there can be no assurance that we will remain compliant with the Minimum Bid Price Requirement or any other Nasdaq continued listing requirements. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting

could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities. In addition to potential dilution associated with potential future fundraising and strategic transactions, we currently have significant numbers of securities outstanding that are exercisable for our common stock, which could result in significant additional dilution and downward pressure on our stock price. As of December 31, ~~2023~~ **2024** , there were 8, ~~149~~ **408** , ~~897~~ **844** shares of our common stock outstanding. In addition, there were outstanding stock options, restricted stock units and warrants representing the potential issuance of an additional ~~2~~ **3** , ~~893~~ **184** , 000 shares of our common stock. The issuance of these shares in the future would result in significant dilution to our current stockholders and could adversely affect the price of our common stock and the terms on which we could raise additional capital. In addition, the issuance and subsequent trading of shares could cause the supply of our common stock available for purchase in the market to exceed the purchase demand for our common stock. Such supply in excess of demand could cause the market price of our common stock to decline. Provisions in our amended and restated certificate of incorporation and by- laws and Delaware law may inhibit a takeover of us, which could limit the price investors might be willing to pay in the future for our common stock and could entrench management. Our amended and restated certificate of incorporation and by- laws contain provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. Our board of directors is divided into three classes, each of which will generally serve for a term of three years with only one class of directors being elected in each year. As a result, at a given annual meeting only a minority of the board of directors may be considered for election. Since our staggered board of directors may prevent our stockholders from replacing a majority of our board of directors at any given annual meeting, it may entrench management and discourage unsolicited stockholder proposals that may be in the best interests of stockholders. Moreover, our board of directors has the ability to designate the terms of and issue new series of preferred stock without stockholder approval. We are also subject to anti- takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make ~~more~~ **the removal of management** difficult ~~the removal of management~~ and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. Failure to maintain effective internal control over financial reporting in accordance with Section 404 of the Sarbanes- Oxley Act could have a material adverse effect on our business and stock price. During the course of testing our disclosure controls and procedures and internal control over financial reporting, we may identify and disclose material weaknesses or significant deficiencies in internal control over financial reporting that will have to be remedied. Implementing any appropriate changes to our internal control may require specific compliance training of our directors, officers and employees, entail substantial costs to modify our existing accounting systems, and take a significant period of time to complete. Such changes may not, however, be effective in maintaining the adequacy of our internal control over financial reporting, and any failure to maintain that adequacy or inability to produce accurate financial statements on a timely basis could result in our financial statements being unreliable, increase our operating costs and materially impair our ability to operate our business. Failure to achieve and maintain effective internal control over financial reporting could result in a loss of investor confidence in our financial reports and could have a material adverse effect on our stock price. Additionally, failure to maintain effective internal control over our financial reporting could result in government investigation or sanctions by regulatory authorities.