Risk Factors Comparison 2024-04-16 to 2023-03-28 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this Annual Report Form 10- K entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operation " and our financial statements and related notes, before investing in our common stock. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment. Following is a summary of our Risk Factors: • We require substantial additional funding. If we are unable to raise capital, we **may** ~~expect to~~ be ~~compelled~~ **unable** to **complete the** ~~delay, reduce or eliminate our product candidate~~ development ~~programs~~ and ~~may~~ **commercialization of our product candidates and we could** be ~~unable~~ **required** to ~~further develop~~ **complete a wind down of our operations and /** ~~our~~ - **or** ~~AIM nanoparticle technology~~ **seek bankruptcy protection** . • We have identified conditions and events that raise substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing. • ~~Pursuant to our recently announced strategic realignment announced in November 2022, we have paused clinical trials for our AIM ACT cell therapy product candidates in order to realign our focus on our AIM INJ preclinical programs. If we fail to execute successfully on this realigned strategic focus, our business and prospects may be adversely affected. •~~ Our shares of common stock could be delisted from the Nasdaq ~~Global~~ **Capital** Market which could result in, among other things, a decline in the price of our common stock and less liquidity for holders of shares of our common stock. • We have incurred significant operating losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability. • Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. • If we are unable to successfully obtain approval for and commercialize our product candidates or experience significant delays in doing so, our business will be materially harmed. • Initial success in our ongoing clinical trials may not be indicative of results obtained when these trials are completed. • We plan to initially target a small number of patients with our product candidates, and the market opportunities for these product candidates, if and when approved, may be limited to those patients who are ineligible for established therapies or have failed prior treatments and, accordingly, the opportunities may be small. • Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. • The AIM technology is a novel immunotherapy platform and therapies derived from it have not been tested in humans before. As a result, only limited human study data is available and it remains not fully known as to what kind of cytokines may be released. • If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, if approved, and our ability to generate revenue will be materially impaired. • If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. • Our product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. • Our product candidates are biologics and the manufacturing process for our product candidates is complex, generally more costly than traditional small molecule chemical compounds, and more difficult to reproduce. If we or any of our third- party manufacturers encounter manufacturing difficulties, our ability to provide or secure supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. • We rely on, and expect to continue to rely on, third parties to conduct our clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates, and our business could be substantially harmed. • The third parties upon which we rely for the supply of the source materials, are our sole sources of supply and have limited capacity, and the loss of any of these suppliers could harm our business. • Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. • We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. • If we are unable to obtain and maintain intellectual property protection for our technology and products, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired. A detailed discussion of the above Risk Factors follows below. Risks Related to Our Business and Industry We are a clinical- stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance. We are a clinical- stage biopharmaceutical company that was formed in June 2011. We have no products approved for commercial sale and have not generated any revenue. We are focused on developing immunotherapy products in which the body' s immune system ~~is~~ orchestrates a targeted T cell response against disease- relevant cells. Although there have been significant advances in cell-based immunotherapy, our T cell technologies are new and largely unproven. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking preclinical studies, and conducting clinical trials. If one of our product candidates received

regulatory approval, we will need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. In addition, our limited operating history, particularly in light of the rapidly evolving cancer immunotherapy field, may make it difficult to evaluate our current business and predict our future performance. Our short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early- stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer. We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses in for the foreseeable future and may never achieve or maintain profitability. We are not profitable and have incurred significant losses in each period since our inception, including net losses of $ **32. 3 million and $** 62. 5 ~~million and $ 50. 9~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. We have not commercialized any products and have never generated any revenue from product sales. We expect these losses to increase as we continue to incur significant research and development and other expenses related to our ongoing operations, seek regulatory approvals for our product candidates, scale- up manufacturing capabilities and hire additional personnel to support the development of our product candidates and to enhance our operational, financial and information management systems. A critical aspect of our strategy is to invest significantly in our technology platform to improve the efficacy and safety of our product candidates. To become and remain profitable, we must develop and eventually commercialize products with significant market potential, which we may never achieve. Even if we succeed in commercializing one or more of these product candidates, we will continue to incur losses for the foreseeable future relating to our substantial research and development expenditures to develop our technologies. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. Further, the net losses we incur may fluctuate significantly from quarter- to- quarter and year- to- year, such that a period - to - period comparison of our results of operations may not be a good indication of our future performance. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of the company and could impair our ability to raise capital, maintain our discovery and preclinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute your ownership interest. A decline in the value of our company could also cause you to lose all or part of your investment. We are a clinical- stage biopharmaceutical company. Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in June 2011, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking nonclinical studies and conducting clinical trials. We have not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes several years to develop one new drug from the time it is discovered to when it is available for treating patients. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition. 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. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including: • completing research regarding, and nonclinical and clinical development of, our product candidates; • obtaining regulatory approvals and marketing authorizations for product candidates for which we complete clinical trials; • developing a sustainable and scalable manufacturing process for our product candidates, including establishing and maintaining commercially viable supply relationships with third parties and establishing our own manufacturing capabilities and infrastructure; • 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; • 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. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U. S. Food and Drug Administration, or the FDA, or other regulatory agencies, domestic or foreign, or other comparable foreign authorities, to perform preclinical studies or clinical trials in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and revenue could be further delayed. 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 the FDA or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, nonclinical, 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 be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any

price, and whether w. 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 revenue from the sale of any approved products, we may never become profitable. If we fail to obtain additional financing on acceptable terms or at all, we may be unable to complete the development and commercialization of our product candidates **and we could be required to complete a wind down of our operations and / or seek bankruptcy protection** . Our operations have required substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our product candidates. We would have to spend substantial amounts to conduct research and development and preclinical or nonclinical testing and studies and clinical trials, to build a supply chain, to seek regulatory approvals for any product candidates we may develop. If we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company in the United States. As of December 31, ~~2022~~ **2023** , we had $ ~~34~~ **3** . ~~6~~ **2** million in cash, cash equivalents, and available- for- sale marketable securities. In February 2021, we completed the IPO for net proceeds of $ 114. 6 million after deducting underwriting discounts and commissions and offering expenses. We believe that, based upon our current operating plan, our existing capital resources will **not** be sufficient to meet our anticipated cash requirements for at least twelve months from the issuance of these financial statements. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. In addition, our future capital requirements will depend on many factors, and could increase significantly as a result of many factors, including: • the scope, progress, results and costs of nonclinical development, laboratory testing and clinical trials for our product candidates; • the scope, prioritization and number of our research and development programs; • the costs, timing and outcome of regulatory review of our product candidates; • our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all; • the extent to which we acquire or in- license other product candidates and technologies; • revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval; • the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims; • our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel; and • the costs associated with being a public company. We cannot be certain that additional funding will be available on acceptable terms, or at all. Our ability to raise additional funding will depend on financial, economic and market conditions and other factors, over which we may have no or limited control. **We expect that additional funding will be highly dilutive to holders of our common stock. Such additional funding could involve the issuance and sale of redeemable or convertible preferred stock which terms may include liquidation preferences, price resets or other anti- dilution protections, or other equity or debt securities senior to our common stock, that would provide their holders with significant preferences and other rights over our common stock and which could reduce or eliminate some or all of the value of the common stock and any other securities exercisable for or convertible into our common stock. The additional funding may result in certain governance and other board rights being provided to investors in such a financing.** In addition, our ability to obtain future funding when needed through equity financings, debt financings or strategic collaborations may be particularly challenging in light of the continued uncertainties and circumstances regarding the ~~coronavirus~~ **current market conditions** , **any** ~~or COVID- 19, pandemic~~ **pandemics , regional conflicts, sanctions, labor conditions or geopolitical events** . We have no committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we ~~may have~~ **could be required** to ~~significantly delay, scale back~~ **complete the wind down of** ~~or~~ **our operations and /** ~~discontinue the development or commercialization of our~~ **or** ~~product candidates~~ **seek bankruptcy or similar protection. As a result,** ~~or~~ **our business, financial condition and results of operations would be materially affected and our stockholders would lose all of** ~~other~~ **their investment** ~~research and development initiatives~~ . Our license and collaboration agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. We currently have a shelf registration statement effective ~~and an existing " at- the- market " offering facility~~ , however, our ability to raise capital under this registration statement ~~and through our " at- the- market " offering facility~~ may be limited by, among other things, SEC rules and regulations impacting the eligibility of smaller companies to use Form S- 3 for primary offerings of securities. Based on our public float, as of the date of the filing of this Annual Report on Form 10- K, we are only permitted to utilize a shelf registration statement ~~, including the registration statement under which our " at- the- market " offering facility is operated,~~ subject to Instruction I. B. 6 to Form S- 3, which is referred to as the " baby shelf " rule. For so long as our public float is less than $ 75. 0 million, we may not sell more than the equivalent of one- third of our public float during any 12 consecutive months pursuant to the baby shelf rules. Although alternative public and private transaction structures may be available, these may require additional time and cost, may impose operational restrictions on us, and may not be available on attractive terms. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. Pursuant to our announced strategic realignment announced in November 2022, we have paused clinical trials for our AIM ACT cell therapy product candidates in order to realign our focus on our AIM INJ

preclinical programs. If we fail to execute successfully on this realigned strategic focus, our business and prospects may be adversely affected. In November 2022, we announced that we are pausing our clinical trials for NEXI- 001 and NEXI- 003, and that our clinical trial for NEXI- 002 will remain paused, in order to realign our focus on development of the AIM INJ platform. We believe this realigned strategic focus is the best way to optimize our financial and other resources to advance our business. However, there is no assurance that we will be successful at executing on this strategy, and we cannot currently specify when, if ever, we will be able to resume clinical development of NEXI- 001, NEXI- 002 or NEXI- 003. If we are unable to execute successfully on this realigned strategic focus, our business and prospects may be adversely affected. Our future success depends on our ability to retain our chief executive officer and certain other key executives and to attract, retain and motivate qualified personnel. Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the experience of Kristi Jones, our President and Chief Executive Officer, as well as certain other principal members of our management, scientific and R & D teams. Although we have formal employment agreements with our executive officers, these agreements do not prevent them from terminating their employment with us at any time. In ~~November~~ **October** ~~2022~~ **2023** , ~~we~~ **our board of directors** implemented a ~~strategic realignment~~ **reduction- in- force of substantially all of our employees, other** ~~that~~ **than** ~~reduced~~ **key members of** our ~~workforce by approximately 30 %~~ **management, scientific and R & D teams necessary to implement the wind up and support the efforts to maximize the value of our business and our assets** . The uncertainty inherent in this **reduction- in- force** ~~ongoing restructuring may be difficult to manage, may cause~~ **caused** concerns from third parties with whom we do business, and ~~may increase~~ **increased** the likelihood of turnover of other key officers and employees. If we lose ~~one or more of our executive officers or~~ key ~~employees~~ **members of management** , our ability to implement our business strategy successfully could be seriously harmed. Furthermore, replacing **such members** ~~executive officers and key employees~~ may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. ~~We are have undertaken internal realignment activities that~~ **Our strategic refocus and the associated reduction- in- force** could result in disruptions to our business or otherwise materially harm our results of operations or financial condition. There can be no assurance that our strategic ~~realignment~~ **refocus and the associated reduction- in- force** will achieve the cost savings, operating efficiencies or other benefits that we may initially expect. ~~Realignment activities~~ **Our workforce reductions** may also result in a loss of continuity, accumulated knowledge and inefficiency during transitional periods and thereafter. In addition, ~~internal realignments~~ **our workforce reductions** can require a significant amount of time and focus from management and other employees, which may divert attention from operations. Further, our ~~realignment~~ **workforce reductions** may result in unexpected expenses or liabilities and / or write- offs. If our ~~strategic realignment~~ **workforce reductions** ~~fails~~ **fail** to achieve some or all of the anticipated benefits, our cash resources may not last as long as estimated and our business, results of operations and financial condition could be materially and adversely affected. We ~~expect our costs~~ **have identified conditions** and ~~expenses~~ **events that raise substantial doubt about our ability** to ~~increase~~ **continue** as ~~we continue~~ **a going concern, which may force us** to ~~develop~~ **complete a wind down of our operations and /** ~~our~~ **or seek bankruptcy protections** ~~product candidates and progress our current clinical programs and costs associated with being a public company~~ . We had cash, cash equivalents, and marketable securities of $ ~~34~~ **3** . ~~64~~ **2** million as of December 31, ~~2022~~ **2023** , which we believe that should be sufficient to fund our operating plan into the ~~fourth~~ **second** quarter of ~~2023~~ **2024** . We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Pursuant to the requirements of ASC 205- 40, Presentation of Financial Statements- Going Concern, and as a result of our financial condition and other factors described herein, there is substantial doubt about our ability to continue as a going concern for a period of at least twelve months from the date of the financial statements. Our ability to continue as a going concern will depend on our ability to obtain **substantial** additional funding ~~, as to which no assurances can be given~~ . **Adequate** ~~Our future success depends on our ability to raise capital and / or execute our current operating plan. However, we cannot be certain that these initiatives or raising~~ additional **financing may not** ~~capital, whether through issuing additional debt or equity securities or obtaining a line of credit or other loan, will~~ be available to us ~~or, if available, will be on terms acceptable to us. If we issue additional securities to raise funds, these securities may have rights, preferences, or privileges senior to those of our common stock, and our current shareholders may experience dilution. If we are unable to obtain funds when needed or~~ on acceptable terms, ~~we~~ **or at all. Moreover, the terms of any financing** may **adversely affect the holdings or the rights of our stockholders. In addition, the issuance of additional securities, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities will substantially dilute all of our stockholders. We could also** be required to ~~curtail~~ **seek funds through arrangements with potential collaboration partners, including at an earlier stage than otherwise would be desirable, and we may be required to relinquish rights to some of our technologies** ~~our~~ **or** ~~current development programs~~ **product candidates or otherwise agree to terms unfavorable to us** , ~~cut~~ **any of which may have a material adverse effect on our business,** operating **results** ~~costs, forego future development~~ and ~~other opportunities~~ **prospects. In addition,** ~~or~~ **our** ~~even terminate~~ **board of directors will need to consider the interests of all our constituents and take appropriate action, including to restructure or wind down the business, if it appears that we are insolvent. If we are unable to obtain additional funding on a timely basis, we may resume pursuit of a wind down of** our operations **and / or seek** ~~, which may involve seeking~~ bankruptcy **or similar** protection **. As a result, our business, financial condition and results of operations would be materially affected and our stockholders would lose all of our investment** . The biotechnology and immunotherapy industries are characterized by rapid technological developments and a high degree of competition. We may be unable to compete with more substantial enterprises. The biotechnology and biopharmaceutical industries are characterized by rapid technological developments and a high degree of competition. As a result, our actual or proposed immunotherapies could become obsolete before we recoup any portion of our related research and development and commercialization expenses.

Competition in the biopharmaceutical industry is based significantly on scientific and technological factors. These factors include the availability of patent and other protection for technology and products, the ability to commercialize technological developments and the ability to obtain governmental approval for testing, manufacturing and marketing. We compete with specialized biopharmaceutical firms in the United States, Europe and elsewhere, as well as a growing number of large pharmaceutical companies that are applying biotechnology to their operations. Many biopharmaceutical companies have focused their development efforts in the human therapeutics area, including cancer. Many major pharmaceutical companies have developed or acquired internal biotechnology capabilities or made commercial arrangements with other biopharmaceutical companies. These companies, as well as academic institutions, governmental agencies and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical field will also depend to a considerable degree on the continuing availability of capital to us. We are aware of certain investigational new drugs under development or approved products by competitors that are used for the prevention, diagnosis, or treatment of certain diseases we have targeted for drug development. Various companies are developing biopharmaceutical products that have the potential to directly compete with our immunotherapies even though their approach may be different. The competition comes from both biotechnology firms and from major pharmaceutical companies. Many of these companies have substantially greater financial, marketing, and human resources than us. We also experience competition in the development of our immunotherapies from universities, other research institutions and others in acquiring technology from such universities and institutions. In addition, certain of our immunotherapies may be subject to competition from investigational new drugs and / or products developed using other technologies, some of which have completed numerous clinical trials. The successful development of immunotherapies is highly uncertain. Successful development of biopharmaceuticals is highly uncertain and depends on numerous factors, many of which are beyond our control. Immunotherapies that appear promising in the early phases of development may fail to reach the market for several reasons including: • clinical study results that may show the immunotherapy to be less effective than expected (e. g., the study failed to meet its primary endpoint) or to have unacceptable side effects; • failure to receive the necessary regulatory approvals or a delay in receiving such approvals. Among other things, such delays may be caused by slow enrollment in clinical studies, length of time to achieve study endpoints, additional time requirements for data analysis, or preparation of Biologics License Application, or BLA, discussions with the FDA, an FDA request for additional preclinical or clinical data, or unexpected safety or manufacturing issues; • manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make the immunotherapy uneconomical; and • the proprietary rights of others and their competing products and technologies that may prevent the immunotherapy from being commercialized. Success in preclinical and early clinical studies does not ensure that large- scale clinical studies will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical studies and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly from one immunotherapy to the next and may be difficult to predict. Even if we are successful in getting market approval, commercial success of any of our product candidates will also depend in large part on the availability of coverage and adequate reimbursement from third- party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations, which may be affected by existing and future health care reform measures designed to reduce the cost of health care. Third- party payors could require us to conduct additional studies, including post- marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other health care payors were not to provide adequate coverage and reimbursement levels for any of our products once approved, market acceptance and commercial success would be reduced. Our technology platform, including our proprietary Artificial Immune Modulation, or AIM, technology is a new approach to treat cancer and other immune- related diseases that presents significant challenges. We have concentrated our research and development efforts on advancing a new generation of immunotherapies based on the AIM technology, and our future success is highly dependent on the successful development of our product candidates, which target cancer and other immune- related diseases. Our technology platform is the foundation for our innovative approach to immunotherapy in which the body' s immune system orchestrates a targeted T cell response against disease- relevant cells. Central to the AIM technology are synthetic dendritic cells that present antigens to T cells eliciting a targeted therapy driven by the patient' s immune system. Because this is a new approach to immunotherapy and for the treatment of cancer and other immune- related diseases generally, developing and commercializing our product candidates subjects us to a number of challenges, including: • educating medical personnel about the administration of the AIM product candidates; • educating medical personnel regarding the potential side effect profile of our product candidates, such as the potential adverse side effects related to cytokine release syndrome, neurotoxicity or autoimmune or rheumatologic disorders. As the AIM technology is a novel immunotherapy platform and therapies derived from it have not been tested in humans before, only limited human study data is available, and it remains not fully known as to what kind of cytokines may be released. Medical personnel will need to continue to monitor on an ongoing basis; • administering chemotherapy to patients in advance of administering our product candidates, which may increase the risk of adverse side effects; • sourcing clinical and, if approved, commercial, supplies for the materials used to manufacture and process our product candidates; • manufacturing the proteins necessary for the cell therapy and injections and issues with our facility, quality control or general production process may arise, which could delay the development of our product candidates; • developing AIM INJ, a direct- injectable modality of the AIM technology that has not previously been demonstrated and may not work as originally contemplated; • potentially moving the development of AIM INJ into the clinic, and addressing uncertainty around the regulatory requirements that may need to be met in connection with such an investigational new drug application, or IND; • managing the risk in relying on one single source for the production of AIM nanoparticles, including the risk that if that source is unable to provide us with the necessary particles that may result in significant delays to our clinical trials; • developing a robust and reliable T cell manufacturing process,

including efficiently managing shipment of patient cells from and to clinical sites, minimizing potential contamination to the cell product and effectively scaling manufacturing capacity to meet demand; • managing costs of inputs and other supplies while scaling production; • using medicines to manage adverse side effects of our product candidates, which may not adequately control the side effects and / or may have a detrimental impact on the efficacy of the treatment; • obtaining and maintaining regulatory approval from the FDA; • addressing the broader uncertainty around the regulatory requirements and pathway for the approval of an adoptive cell therapy; • establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy. We cannot be sure that our AIM technology will yield satisfactory products that are safe and effective, scalable, or profitable. Although we are a cell therapy company our technology could become subject to many of the challenges and risks that gene therapies face, including: • regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. • the FDA could recommend follow- up observation period of up to 15 years for all patients who receive our treatment. We may need to adopt such an observation period for our product candidates. • clinical trials using genetically modified cells conducted at institutions that receive funding for recombinant DNA research from the U. S. National Institutes of Health, or the NIH, are subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee, or the RAC. Although the FDA decides whether individual protocols may proceed, the RAC review process can impede the initiation of a clinical trial, even if the FDA has reviewed the study and approved its initiation. Moreover, public perception of therapy safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, of physicians to subscribe to the novel treatment mechanics. Physicians, hospitals and third- party payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. Physicians may not be willing to undergo training to adopt this novel and personalized therapy, may decide the therapy is too complex to adopt without appropriate training and may choose not to administer the therapy. Based on these and other factors, hospitals and payors may decide that the benefits of this new therapy do not or will not outweigh its costs. Our near- term ability to generate product revenue is dependent on the success of one or more of our product candidates, each of which are at an early- stage of development and will require significant additional clinical testing before we can seek regulatory approval and begin commercial sales. Our near- term ability to generate product revenue is highly dependent on our ability to obtain regulatory approval of and successfully commercialize one or more of our product candidates. All of our product candidates are in the early stages of development and will require additional clinical and nonclinical development, regulatory review and approval in each jurisdiction in which we intend to market the products, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts before we can generate any revenue from product sales. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety, purity, and potency of the product candidates in humans. We cannot be certain that any of our product candidates will be successful in clinical trials and they may not receive regulatory approval even if they are successful in clinical trials. Before we can generate any revenues from sales of our lead product candidates, we must complete the following activities for each of them, any one of which we may not be able to successfully complete: • conduct additional preclinical and clinical development with successful outcomes; • manage preclinical, manufacturing and clinical activities; • obtain regulatory approval from the FDA and other comparable foreign regulatory authorities; • establish manufacturing relationships for the clinical and post- approval supply of the applicable drug candidate in compliance with all regulatory requirements; • build a commercial sales and marketing team, either internally or by contract with third parties; • establish and maintain patent and trade secret protection or regulatory exclusivity for our product candidates; • develop and implement marketing strategies for successful commercial launch of our product candidates, if and when approved; • secure and maintain acceptance of our products, if and when approved, by patients, from the relevant medical communities and from third- party payors; • compete effectively with other therapies; • establish and maintain adequate health care coverage and reimbursement from third- party payors; • ensure continued compliance with any post- marketing requirements imposed by regulatory authorities, including any required post-marketing clinical trials or the elements of any post- marketing Risk Evaluation and Mitigation Strategy, or REMS, that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of the product outweigh its risks; • maintain continued acceptable safety profile of the product candidates following approval; and • invest significant additional cash in each of the above activities. If we are unable to address one or more of these factors in a timely manner or at all, we could experience significant delays in the successful commercialization of, or an inability to successfully commercialize, our product candidates, which would materially harm our business. If we do not receive regulatory approvals for one or more of our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to manufacture and market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved. In addition, because NEXI- 001 and NEXI- 002 are clinical- stage candidates, and because our other product candidates are based on similar technology, if NEXI- 001 and NEXI- 002 were to encounter safety or efficacy problems, developmental delays, regulatory issues, or other problems, our development plans and business could be significantly harmed. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business. We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect. Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation of clinical trials; • delays in reaching a consensus with

regulatory agencies on trial design; • the FDA may not allow us to use the clinical trial data from a research institution to support an IND if we cannot demonstrate the comparability of our product candidates with the product candidate used by the relevant research institution in its clinical trials; • our INDs have been approved in a timely manner thus far, however the FDA may not agree with our approach and strategy, which could result in potential delays, and changes to our regulatory strategy; • we may be required to complete additional preclinical studies in HLAs before we can proceed with our INDs; • delays in reaching agreement on acceptable terms with prospective contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; • delays in obtaining required Institutional Review Board, or IRB, approval at each clinical trial site; • imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND application or 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 clinical trial operations or trial sites; developments on clinical trials conducted by competitors for related technology that raises FDA concerns about risk to patients of the technology broadly; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives; • delays in recruiting suitable patients to participate in our clinical trials; • difficulty collaborating with patient groups and investigators; • failure by our CROs, other third parties, or us to adhere to clinical trial requirements; • failure to perform in accordance with the FDA' s current good clinical practice regulations, or cGCPs, requirements, or similar applicable regulatory guidelines in other countries; • delays in having patients complete participation in a trial or return for post- treatment follow- up; • patients dropping out of a trial; • occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • changes in the standard of care on which a clinical development plan was based, which may require new or additional trials; • the cost of clinical trials of our product candidates being greater than we anticipate; • clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; • delays in developing our manufacturing processes and transferring to new third- party facilities to support future development activities and commercialization that are operated by contract manufacturing organizations, or CMOs, in a manner compliant with all regulatory requirements; and • delays in 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. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval for our product candidates. Any inability to successfully complete preclinical 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 additional trials to bridge 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, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of any of our product candidates may be delayed, and our business will be harmed. From time to time, we provide timing estimates regarding the initiation of clinical trials and clinical development milestones, and the expected availability of data resulting from these trials for certain of our product candidates. We expect to continue to estimate the timing of these types of development milestones and our expected timing for the accomplishment of various other scientific, clinical, regulatory and other product development objectives. However, the achievement of many of these milestones and events may be outside of our control. All of these timing estimations are based on a variety of assumptions we make which may cause the actual timing of these events to differ from the timing we expect, including: • our available capital resources and our ability to obtain additional funding as needed; • the rate of progress, costs and results of our clinical trials and research and development activities; • our ability to identify and enroll patients who meet clinical trial eligibility criteria; • our receipt of approvals by the FDA, European Medicines Agency, or EMA, and other regulatory authorities and the timing of these approvals; • our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates; • the efforts with respect to the commercialization of our product candidates; • the securing of, costs related to, and timing issues associated with, manufacturing our therapeutic ; • candidates and, if any of our product candidates are approved, associated with sales and marketing activities and the commercial manufacture of our product candidates; and • circumstances arising from or relating to the COVID- 19 pandemic, including potential effects on the global supply chain, our manufacturers and the availability of raw materials needed for the research and development of our product candidates. If we fail to achieve announced milestones in the timeframes we expect, the commercialization of any of our product candidates may be delayed, and our business and results of operations may be harmed and our stock price may decline. Failure to successfully identify, develop and commercialize additional therapeutics or product candidates could impair our ability to grow. Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of our product candidates in our current pipeline, we expect to continue to innovate and potentially expand our portfolio. Because we have limited financial and managerial resources, research programs to identify product candidates may require substantial additional technical, financial and human resources, whether or not any new potential product candidates are ultimately identified. Our success may depend in part upon our ability to identify, select and develop promising product candidates and therapeutics. We may expend resources and ultimately fail to discover and generate additional product candidates suitable for further development. All product candidates are prone to risks of failure typical of biotechnology product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics indicating that it is unlikely to receive approval by the FDA, the EMA and other comparable foreign regulatory authorities and achieve market acceptance. If we do

not successfully develop and commercialize new product candidates we have identified and explored, our business, prospects, financial condition and results of operations could be adversely affected. We face risks related to health, pandemics, epidemics and outbreaks, including the COVID- 19 pandemic, which could significantly disrupt our **business** ~~preclinical studies and clinical trials~~ . If a pandemic, epidemic or outbreak of an infectious disease occurs in the United States or worldwide, our business may be adversely affected. ~~The~~ **As a recent example, in March 2020, the World Health Organization declared the** COVID- 19 **outbreak a** pandemic ~~has impacted~~ **, and the U. S. government imposed restrictions on travel between the United States, Europe, and certain** ~~the~~ **other** ~~global economy and may continue to impact our operations~~ **countries. In the years following the initial outbreak** , ~~including~~ **numerous state and local jurisdictions imposed quarantines, shelter- in- place orders, executive orders, and similar government orders for** ~~the~~ **their residents to control** ~~potential interruption of our clinical trial activities, regulatory reviews and our supply chain. For example,~~ the **spread of** COVID- 19 ~~pandemic may delay enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak or other factors, and some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services, which would delay our ability to conduct clinical trials or release clinical trial results and could delay our ability to obtain regulatory approval and commercialize our product candidates. Furthermore, the spread of the virus may affect the operations of key governmental agencies, such as the FDA, which may delay the development or approval process for our product candidates. At present, we are not experiencing significant impact or delays from COVID- 19 on our business or operations. However, the enrollment of patients in, and the conduct of, our clinical trials have been, and we expect may continue to be, affected by the COVID- 19 pandemic. In particular, the trial start date for our NEXI- 002 clinical trial was delayed from April to September 2020. We have also experienced delays in transporting blood products from donors to manufacturing sites in California and in planned technology transfer in connection with our manufacturing process. The global outbreak of COVID- 19 may further delay enrollment in our planned or ongoing clinical trials due to prioritization of hospital resources toward the outbreak, the protection of the health of patients and investigators at the clinical trial sites, and restrictions on work and travel. In addition, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. These and other factors could significantly delay our ability to conduct clinical trials or release clinical trial results. We will continue to monitor carefully the situation with respect to each of our clinical trials and follow guidance from local and federal health authorities. COVID- 19 may also affect employees of third- party contract research organizations that we rely upon to carry out our clinical trials. The spread of COVID- 19, or another infectious disease, could also negatively affect the operations at our CMOs, which could result in delays or disruptions in the supply of our product candidates. In addition, we have taken precautionary measures, and may take additional measures, intended to help minimize the risk of the virus to our employees, including temporarily requiring certain employees to work remotely, suspending all non- essential travel worldwide for our employees, and discouraging employee attendance at industry events and in- person work- related meetings, which could negatively affect our business. We cannot presently predict the extent to which current or future business shutdowns and disruptions may impact or limit our ability or the ability of any of the third parties with which we engage to conduct business in the manner and on the timelines presently planned. Any such impacts or limitations could have a material adverse impact on our business and our results of operation and financial condition. While the potential economic impact brought by and the duration of the coronavirus outbreak may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID- 19 could materially affect our business and the value of our common stock~~ . A significant outbreak of other infectious diseases in the future also could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations. The FDA or comparable foreign regulatory authorities may disagree with our regulatory plans **,** and we may fail to obtain regulatory approval of our product candidates. The FDA standard for approval of a biologic generally requires two well- controlled Phase III studies or one large and robust, well- controlled Phase III study in the patient population being studied that provides substantial evidence that a biologic is safe and effective for its proposed indication. Phase III clinical trials typically involve hundreds of patients, have significant costs and take years to complete. Product candidates studied for their safety and effectiveness in treating serious or life- threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well- controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA usually requires a sponsor of a drug or biologic receiving accelerated approval to perform post- marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. Although we intend to request accelerated approval status for NEXI- 001 and NEXI- 002, we can provide no assurance that the FDA will grant such designation for either product candidate, nor can we provide any assurance that even if the FDA grants such designation that it will improve the likelihood that the agency will ultimately approve either product candidate. As part of its marketing authorization process, the EMA may grant marketing authorizations on the basis of less complete data than is normally required, when, for certain categories of medicinal products, doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use, or CHMP, to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may

apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating diseases or life- threatening diseases and those designated as orphan medicinal products. A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met: • the risk- benefit balance of the medicinal product is positive; • it is likely that the applicant will be in a position to provide the comprehensive clinical data; • unmet medical needs will be fulfilled; and • the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required. The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete nonclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public- health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The holder is required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit- risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data. The granting of a conditional marketing authorization allows medicines to reach patients with unmet medical needs earlier than might otherwise be the case and ensure that additional data on a product are generated, submitted, assessed and acted upon. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the EMA or CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied. Our clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or regular approval. The results of preclinical studies and clinical trials may not be predictive of the results of later- stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through preclinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval; • we may be unable to demonstrate that our product candidates' risk- benefit ratios for their proposed indications are acceptable; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; • the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third- party manufacturer' s facilities with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. Further, failure to obtain approval for any of the above reasons may be made more likely due to the novel nature of our AIM technology. Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects. 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 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. In particular, because our product candidates are subject to regulation as biological products, we will need to demonstrate that they are safe, pure, and potent for use in their target indications. 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 licensure will vary depending on these factors and may include not only the ability to show tumor shrinkage, but also 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. 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. The results of studies in one set of patients or line of treatment may not be predictive of those obtained in another. We expect there may be greater variability in results for products processed and administered on a patient- by- patient basis, as anticipated for our product candidates which involve personalized T cell therapy, than for " off- the- shelf " products, like small molecule drugs which are not personalized for each patient. 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 companies in the biopharmaceutical industry 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. In addition, even if our clinical 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. Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences. As with most biological products, use of our product candidates could be associated with side effects or adverse events, which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials. The FDA or comparable foreign regulatory authorities could delay or deny approval of our product candidates for any or all targeted indications and negative side effects could result in a more restrictive label for any product that is approved. Side effects such as toxicity or other safety issues associated with the use of our product candidates could also require us or our collaborators to perform additional studies or halt development or sale of these product candidates. Treatment- related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or could result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, as toxicities resulting from personalized T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using our product candidates to understand their potential side effect profiles, both for our planned clinical trials and upon any commercialization of any product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in adverse effects to patients, including death. Any of these occurrences may materially harm our business, financial condition and prospects. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, including during any long- term follow- up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit their approvals of such products; • regulatory authorities may require the addition of labeling statements, specific warnings or a contraindications; • we may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, plan, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and / or other elements to assure safe use; • we may be required to change the way such products are distributed or administered, or change the labeling of the products; • the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post- marketing testing and surveillance to monitor the safety and efficacy of the products; • we may decide to recall such products from the marketplace after they are approved; • we could be sued and held liable for harm caused to individuals exposed to or taking our products; and • our reputation may suffer. In addition, adverse side effects caused by any therapeutics that may be similar in nature to our product candidates could delay or prevent regulatory approval of our product candidates, limit the commercial profile of an approved label for our product candidates, or result in significant negative consequences for our product candidates following marketing approval. We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including: • the size and nature of the patient population; • the patient eligibility criteria defined in the protocol; • the size of the study population required for analysis of the trial' s primary endpoints; • the proximity of patients to trial sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • competing clinical trials for similar therapies or other new therapeutics not involving T cell based immunotherapy; • clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; • our ability to obtain and maintain patient consents; and • the risk that patients enrolled in clinical trials will not complete a clinical trial. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and hematopoietic cell transplantation, rather than enroll patients in any future clinical trial. Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. Clinical trials are expensive, time- consuming and difficult to design and implement, and our clinical trial costs may be higher than for more conventional therapeutic technologies or drug products. Clinical trials are expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. Because our product candidates are based on new technologies and manufactured on a patient- by- patient basis, we expect that they will require extensive research and development and have substantial manufacturing costs. In addition, costs to treat patients with relapsed / refractory cancer and to treat potential side effects that may result from our product candidates can be significant. Accordingly, our clinical trial costs are likely to be significantly higher per patient than those of more conventional therapeutic technologies or drug products. In addition, one of

our early- stage product candidates that is currently in preclinical development is for a novel class of injectable biologics. Development of the underlying technology may be affected by unanticipated technical, regulatory, manufacturing or other problems, among other research and development issues, and the possible insufficiency of funds needed in order to complete development of this product candidate. Our proposed personalized product candidates involve several complex and costly manufacturing and processing steps, the costs of which will be borne by us. Depending on the number of patients we ultimately enroll in our trials, and the number of trials we may need to conduct, our overall clinical trial costs may be higher than for more conventional treatments. Research and development of biopharmaceutical products is inherently risky. We may not be successful in our efforts to use and enhance our AIM technology platform to create a pipeline of product candidates and develop commercially successful products, or we may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or diseases that may be more profitable or for which there is a greater likelihood of success. If we fail to develop additional product candidates, our commercial opportunity will be limited. We are pursuing clinical development of product candidates developed employing our AIM technology. We are at an early stage of development and our technology platform has not yet led, and may never lead, to approved or commercially successful products. Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing additional product candidates will require substantial additional funding beyond the net proceeds of this transaction and are prone to the risks of failure inherent in medical product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following: • our platform may not be successful in identifying additional product candidates; • we may not be able or willing to assemble sufficient resources to acquire or discover additional product candidates; • our product candidates may not succeed in preclinical or clinical testing; • a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; • competitors may develop alternatives that render our product candidates obsolete or less attractive; • product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights; • the market for a product candidate may change during our program so that the continued development of that product candidate is no longer reasonable; • a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and • a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Even if we receive FDA approval to market additional product candidates, whether for the treatment of cancers or other diseases, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Further, because of our limited financial and managerial resources, we are required to focus our research programs on certain product candidates and on specific diseases. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights. For additional information regarding the factors that will affect our ability to achieve revenue from product sales, see the risk factor above " — 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. " Our product candidates are biologics and the manufacture of our product candidates is complex and we may encounter difficulties in production, particularly with respect to process development or scaling- out of our manufacturing capabilities. If we or any of our third- party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. Our product candidates are biologics and the process of manufacturing our products is complex, highly - regulated and subject to multiple risks. The manufacture of our product candidates involves complex processes, including harvesting T cells from patients, enriching and expanding T cells ex vivo, and ultimately infusing the T cells back into a patient' s body. As a result of the complexities, the cost to manufacture biologics in general, and our modified cell product candidates in particular, is generally higher than traditional small molecule chemical compounds, and the manufacturing process is less reliable and is more difficult to reproduce. Our manufacturing process will be susceptible to product loss or failure due to logistical issues associated with harvesting T cells, or starting material, from the patient, shipping such material to the manufacturing site, shipping the final product back to the patient, and infusing the patient with the product, manufacturing issues associated with the differences in patient starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth, and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If for any reason we lose a patient' s starting material or later- developed product at any point in the process, the manufacturing process for that patient may need to be restarted and the resulting delay may adversely affect that patient' s outcome. Our product candidate relies on donor' s providing their blood, which is used to harvest T- cells. If issues arise with the product candidate, the donor may need to wait three months before they are able to donate again. This could result in the patient not being treated. Additionally, if microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing

facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Because our product candidates are manufactured for each particular patient, we will be required to maintain a chain of identity with respect to materials as they move from the patient to the manufacturing facility, through the manufacturing process, and back to the patient. Maintaining such a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product, or regulatory action including withdrawal of our products from the market. Further, as product candidates are developed through preclinical to late - stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. As a result of the complexities of our manufacturing process, we have in the past encountered difficulties in producing our product candidates. For example, our manufacturer has in prior instances produced batches of the active ingredient in our product candidate that did not meet the dosing requirement of our clinical trial protocol. Our manufacturing strategy involves the use of one or more CMOs, and we expect in the future to establish our own capabilities and infrastructure, including a manufacturing facility. We expect that development of our own manufacturing facility will provide us with enhanced control of material supply for both clinical trials and the commercial market, enable the more rapid implementation of process changes, and allow for better long- term margins. However, we have no experience as a company in developing a manufacturing facility and may never be successful in developing our own manufacturing facility or capability. We may establish multiple manufacturing facilities as we expand our commercial footprint to multiple geographies, which may lead to regulatory delays or prove costly. Even if we are successful, our manufacturing capabilities could be affected by cost- overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. In addition, the manufacturing process for any products that we may develop is subject to FDA and foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA and foreign regulatory authority requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. We rely on third parties to manufacture our clinical product supplies, and we intend to rely on third parties for at least a portion of the manufacturing process of our product candidates, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product or fail to do so at acceptable quality levels or ~~prices~~ **price** , or fail to maintain or achieve satisfactory regulatory compliance. We do not currently own any facility that may be used as our clinical- scale manufacturing and processing facility and currently rely on a single source vendor to manufacture supplies and process our product candidates, which is and will need to be done on a patient- by- patient basis. We have not yet caused our product candidates to be manufactured or processed on a commercial scale and may not be able to do so for any of our product candidates. Although in the future we do intend to develop our own manufacturing facility, we also intend to use third parties as part of our manufacturing process and may, in any event, never be successful in developing our own manufacturing facility. Our anticipated reliance on a limited number of third- party manufacturers exposes us to the following risks: • We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited **,** and the FDA must approve any manufacturers. This approval would require new testing and GMP and current good tissue practices, or cGTP compliance inspections by FDA, as applicable. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products. • Our manufacturers may have little or no experience with autologous cell products, which are products made from a patient' s own cells, and therefore may require a significant amount of support from us in order to implement and maintain the infrastructure and processes required to manufacture our product candidates. • Our third- party manufacturers might be unable to timely manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any. • Contract manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately. • Our future contract manufacturers may not perform as agreed, may not devote sufficient resources to our products, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products. • Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with current cGMP, or cGTP, if applicable and other government regulations and corresponding foreign standards. We do not have control over third- party manufacturers' compliance with these regulations and standards. • We may not own, or may have to share, the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our products. • Our third- party manufacturers could breach or terminate their agreement with us. • Raw materials and components used in the manufacturing process, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects. • Our contract manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man- made disasters. • Our contract manufacturers may have unacceptable or inconsistent product quality success rates and yields. Each of these risks could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in

higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied. In complying with the manufacturing regulations of the FDA and other comparable foreign regulatory authorities, we and our third- party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record- keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. Although our agreements with our CMOs require them to perform according to certain cGMP and, if applicable, cGTP requirements such as those relating to quality control, quality assurance and qualified personnel, we cannot control the conduct of our CMOs to implement and maintain these standards. If any of our CMOs cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA, EMA or other comparable foreign authorities, we would be prevented from obtaining regulatory approval for our drug candidates unless and until we engage a substitute CMO that can comply with such requirements, which we may not be able to do. In addition, our CMOs are subject to inspection and approval by regulatory authorities before we can commence the manufacture and sale of any of our product candidates, and thereafter are subject to ongoing inspection from time to time. Our CMOs may not be able to comply with applicable cGMP or cGTP regulations or similar regulatory requirements outside of the United States. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in regulatory actions, such as the issuance of FDA Form 483 notices of observations, warning letters or sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. Any such failure by us or any of our CMOs would significantly impact our ability to develop, obtain regulatory approval for or market our drug candidates, if approved. Manufacturers of biologic products often encounter difficulties in production, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing process (including the absence of contamination). These problems include logistics and shipping, difficulties with production costs and yields, quality control, including stability of the product, product testing, operator error, availability of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, our manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our manufacturers were to encounter any of these difficulties, or otherwise fail to comply with their contractual obligations, our ability to provide our product candidate to patients in clinical trials would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to begin new clinical trials at additional expense or terminate clinical trials completely. Our third- party manufacturers may be unable to successfully scale up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing any approved product candidates. Our manufacturing partners may be unable to successfully increase the manufacturing capacity for our product candidates in a timely or cost-effective manner, or at all, as needed for our development efforts or, if our product candidates are approved, our commercialization efforts. Quality issues may also arise during scale- up activities. If we, or any manufacturing partners, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing, and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting therapeutic may be delayed or not obtained, which could significantly harm our business. Cell- based therapies rely on the availability of reagents, specialized equipment, and other specialty materials, which may not be available to us on acceptable terms or at all. For some of these reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors, which could impair our ability to manufacture and supply our products. Manufacturing our product candidates will require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of our product candidates. Some of these suppliers may not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill- equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key materials and equipment to support clinical or commercial manufacturing. For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. An inability to continue to source product from any of these suppliers, which could be due to regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands, or quality issues, could adversely affect our ability to satisfy demand for our product candidates, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business. As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or find a suitable substitute, it would have a material adverse effect on our business. We rely and will rely on third parties to conduct our clinical trials. If these third parties do not

successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize our product candidates. We depend and will depend upon independent investigators and collaborators to conduct our clinical trials under agreements with universities, medical institutions, CROs, strategic partners, and others. We expect to have to negotiate budgets and contracts with CROs and trial sites, which may result in delays to our development timelines and increased costs. We rely and will rely heavily on third parties over the course of our clinical trials, and as a result will have limited control over the clinical investigators and limited visibility into their day- to- day activities, including with respect to how they are providing and administering T cell therapy. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with good clinical practices, or GCP, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the applicable GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP, and likely cGTP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical, and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed. Any agreements governing our relationships with CROs or other contractors with whom we currently engage or may engage in the future may provide those outside contractors with certain rights to terminate a clinical trial under specified circumstances. If any of our relationships with these third- party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, and prospects. The market opportunities for our product candidates, if and when approved, may be limited to those patients who are ineligible for established therapies or have failed prior treatments and may be small. Cancer therapies are sometimes characterized as first line, second line, or third line, and the FDA often approves new therapies initially only for third line use. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, usually chemotherapy, hormone therapy, surgery, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of more chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Third line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. We expect to initially seek approval of our product candidates as a third line therapy for patients who have failed other approved treatments. Subsequently, for those products that prove to be sufficiently beneficial, if any, we would expect to seek approval as a second line therapy and potentially as a first line therapy, but there is no guarantee that our product candidates, even if approved, would be approved for second line or first line therapy. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy. Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive third line therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates. For instance, we expect to initially target a small patient population with our product candidates. NEXI- 001 is being developed for the treatment of AML or MDS patients with relapsed disease after an allogeneic hematopoietic cellular transplant and NEXI- 002 is being developed for the treatment of MM patients that have failed at least three prior lines of therapy. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications, including use as a first or second line therapy. Our market opportunities may also be limited by competitor treatments that may enter the market. See the risk factor below " — We face

significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. ” We plan to seek orphan drug status for some or all of our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population greater than 200, 000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if one of our drug candidates receives orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product. We plan to seek orphan drug designation for some or all of our product candidates in specific orphan indications in which there is a medically plausible basis for the use of these products, including AML or MDS and MM, but exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, although we intend to seek orphan drug designation for other product candidates, we may never receive such designations. We plan to seek but may fail to obtain breakthrough therapy designation for some or all of our product candidates. As part of the enactment of Food and Drug Administration Safety and Innovation Act, or FDASIA, in 2012, the Congress established a “ breakthrough therapy ” designation which is intended to expedite the development and review of products that treat serious or life- threatening diseases when “ 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. ” The designation of a product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase I; organizational commitment involving senior managers; and eligibility for rolling review and priority review. Designation as a breakthrough therapy is within the discretion of the FDA, and such designation does not change the standards for product approval. We intend to seek breakthrough therapy designation for some or all of our product candidates for the treatment of AML or MDS and MM, but there can be no assurance that we will receive breakthrough therapy designation. 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 grant 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 product candidates considered for approval under conventional FDA procedures and it would not assure ultimate approval by the FDA. In addition, even after a product candidate qualifies as a breakthrough therapy, the FDA may later decide that the product candidate no longer meets the conditions for qualification or it may decide that the time period for FDA review or approval will not be shortened. The review processes of regulatory authorities are lengthy, time consuming, expensive and inherently unpredictable. If we are unable to obtain approval for our product candidates from applicable regulatory authorities, we will not be able to market and sell those product candidates in those countries or regions and our business could be substantially harmed. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug and biological products are, and will remain, subject to extensive regulation by the FDA in the United States and by the respective regulatory authorities in other countries, where regulatory requirements for such products differ. We are not permitted to market any of our biological product candidates in the United States until we receive approval of a BLA from the FDA, or in any foreign countries until we receive the requisite approval from the respective regulatory authorities in such countries. The time required to obtain approval, if any, by the FDA, EMA and comparable foreign authorities is unpredictable, but typically takes many years following the commencement of clinical trials, if approval is obtained at all, and depends upon numerous factors, including the substantial discretion of the regulatory authorities and the type, complexity and novelty of the product candidates involved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical trials. We have not submitted a marketing application such as a BLA to the FDA, an MAA to the EMA, or any similar application to any other jurisdiction. We have limited experience in planning and conducting the clinical trials required for marketing approvals, and we have and expect to continue to rely on third- party CROs to assist us in this process. Obtaining marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate’ s safety and efficacy. Securing marketing approval also requires the submission of

information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP compliance by us or by our CMOs that could result in the candidate not being approved. Moreover, we have not obtained regulatory approval for any drug candidate in any jurisdiction and it is possible that none of our existing drug candidates or any drug candidates we may seek to develop in the future will ever obtain regulatory approval. Our biological product candidates could fail to receive, or could be delayed in receiving, regulatory approval for many reasons, including any one or more of the following: • the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication; • the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States or elsewhere; • upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate; • the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies may fail to meet the requirements of the FDA, EMA or comparable foreign regulatory authorities; • the FDA, EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing internally or with partners; and • the change of the medical standard of care or the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner that renders our clinical data insufficient for approval. The time and expense of the approval process, as well as the unpredictability of future clinical trial results and other contributing factors, may result in our failure to obtain regulatory approval to market, in one or more jurisdictions, any drug candidates we are developing or may seek to develop in the future, which would significantly harm our business, results of operations and prospects. In such case, we may also not have the resources to conduct new clinical trials and / or we may determine that further clinical development of any such product candidate is not justified and may discontinue any such programs. In addition, even if we were to obtain regulatory approval in one or more jurisdictions, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve prices we may propose to charge for our products, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that drug candidate. Any of the foregoing circumstances could materially harm the commercial prospects for our drug candidates. 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, we may not be able to generate product revenue. We currently have no sales, marketing, or commercial product distribution capabilities and have no experience in marketing products. We intend to develop an in- house marketing organization and sales force, which will require significant capital expenditures, 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 commercial distribution capabilities for any or all products we develop, we will likely pursue collaborative arrangements regarding the sales and marketing of our products. However, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if we are able to do so, that they will have effective sales forces. 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 us 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 commercial distribution capabilities or establish or maintain relationships with third- party collaborators to successfully commercialize any product in the United States or overseas, and as a result, we may not be able to generate product revenue. A variety of risks associated with operating our business internationally could materially adversely affect our business. We may 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 and reimbursement regimes in foreign countries; • 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 laws; • 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; • business interruptions resulting from geo- political actions, including war and terrorism; and • deteriorating relations between the United States and Russia resulting from the current situation involving Russia and Ukraine, including tariffs, economic sanctions and import- export restrictions imposed by either nation, and

retaliatory actions by other nations. These and other risks associated with our planned international operations may materially adversely affect our ability to attain or maintain profitable operations. The biopharmaceutical industry, and the rapidly evolving market for developing T cell therapies in particular, is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations as well as established sales forces. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. Specifically, we face competition from companies developing T cell therapies such as Cue Biopharma, Atara Biotherapeutics, Iovance Biotherapeutics and Parvus Therapeutics. Even if we obtain regulatory approval of our product candidates, we may not be the first to market and that may affect the price or demand for our product candidates. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor' s product. If such competitor product is determined to be the same product as one of our product candidates, that may prevent us from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances. We are highly dependent on our key personnel, and if we are not successful in attracting, motivating and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, particularly our chief executive officer, Kristi Jones, who is an at- will employee, and our scientific and medical personnel. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in product development and harm our business. We conduct our operations at our facility in Gaithersburg, Maryland, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of our region, and doing so may be costly and difficult. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided restricted stock and stock option grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in our stock price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain " key man " insurance policies on the lives of all of these individuals or the lives of any of our other employees. We will need to grow the size and capabilities of our organization, and we may experience difficulties in managing this growth. As of March 1, ~~2023~~ **2024** , we had ~~50~~ **6** employees, ~~most~~ **all** of whom are full- time. As our development and commercialization plans and strategies develop ~~, and as we transition into operating as a public company~~ , we must add a significant number of additional managerial, operational, sales, marketing, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining, and motivating additional employees; • 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 • 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 its 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. There can be no assurance that the services of these 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, if at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, 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. 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 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 and efficacy. 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 covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such 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, 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. If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks. We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including: • increased operating expenses and cash requirements; • the assumption of additional indebtedness or contingent liabilities; • assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel; • our inability to achieve desired efficiencies, synergies or other anticipated benefits from such acquisitions or strategic partnerships; • the diversion of our management' s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition; • retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and • our inability to generate revenue from acquired technology and / or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. Until such time as we can generate substantial revenue from product sales, if ever, we expect to finance our cash needs through a combination of public and private equity offerings, debt financings, strategic partnerships, and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us. If we are unable to raise additional capital through equity or debt financings when needed ~~(including if we are unable to do so as a result of the COVID- 19 pandemic)~~, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant

rights to develop and market product candidates that we would otherwise develop and market ourselves. If we, our CROs or our CMOs 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 us or third parties, such as CROs and CMOs. We and such third parties 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 and such third parties' 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. Our internal computer systems, or those used by our third- party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third- party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. We also engage third- party vendors and service providers to store and otherwise process some of our data, including sensitive and personal information. Our vendors and service providers may also be the targets of the risks described above, including cyberattacks, ransomware, malicious software, phishing schemes, and fraud. From time to time, we get notifications that such vendors experienced cyber security breaches. Our ability to monitor our vendors and service providers' data security is limited, and, in any event, third parties may be able to circumvent those security measures, resulting in the unauthorized access to, misuse, disclosure, loss or destruction of our data, including sensitive and personal information, and disruption of our or third- party service providers' systems. We and our third- party service providers may face difficulties in identifying, or promptly responding to, potential security breaches and other instances of unauthorized access to, or disclosure or other loss of, information. Any hacking or other attack on our or our third- party service providers' or vendors' systems, and any unauthorized access to, or disclosure or other loss of, information suffered by us or our third- party service providers or vendors, or the perception that any of these have occurred, could result in legal claims or proceedings, loss of intellectual property, liability under laws that protect the privacy of personal information, negative publicity, disruption of our operations and damage to our reputation, which could divert our management' s attention from the operation of our business and materially and adversely affect our business, revenues and competitive position. Moreover, we may need to increase our efforts to train our personnel to detect and defend against cyber- or phishing- attacks, which are becoming more sophisticated and frequent, and we may need to implement additional protective measures to reduce the risk of potential security breaches, which could cause us to incur significant expenses. Although we take reasonable steps to help protect confidential and other sensitive information from unauthorized access or disclosure, we also could be the target of phishing attacks seeking confidential information regarding our employees. Furthermore, while we have implemented data privacy and security measures in an effort to comply with applicable laws and regulations relating to privacy and data protection, some PHI and other PII or confidential information may be transmitted to us by third parties, who may not implement adequate security and privacy measures, and it is possible that laws, rules and regulations relating to privacy, data protection, or information security may be interpreted and applied in a manner that is inconsistent with our practices or those of third parties who transmit PHI and other PII or confidential information to us. To the extent we or these third parties are found to have violated such laws, rules or regulations or that any disruption or security breach were to result in a loss of, or damage to, our or our third- party vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position could be harmed and the further development and commercialization of our product candidates could be delayed. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of our third- party research institution collaborators, CROs, CMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured. In addition, we rely on our third- party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third- party manufacturers to produce and process our product candidates on a patient- by- patient basis. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these

suppliers are affected by a man- made or natural disaster or other business interruption. All of our operations including our corporate headquarters are located in a single facility in Gaithersburg, Maryland. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. We may become involved in securities litigation that could divert management' s attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages. In the past, securities litigation has often followed certain significant business events, such as the announcement of a strategic restructuring or ~~realighment~~ **realignment** . We may be exposed to such litigation even if no wrongdoing occurred. Litigation is usually expensive and diverts management' s attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential partnership or other opportunities, or the ultimate value our stockholders receive in any such partnership or other opportunity **.** 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 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. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing any approved products, these claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities (or the manufacturing processes and facilities of our third- party manufacturer) or our marketing programs, a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in: • decreased demand for our products; • injury to our reputation; • withdrawal of clinical trial participants and inability to continue clinical trials; • 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 our share price. Our inability to obtain 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 collaborators. Although we currently carry $ 10, 000, 000 of clinical trial insurance, the amount of such insurance coverage may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may 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. Legislation or other changes in U. S. tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many changes have been made to applicable tax laws and changes are likely to continue to occur in the future. For example, legislation enacted in 2017 informally titled, the Tax Cuts and Jobs Act, or the TCJA, made significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %, the limitation of the tax deduction for net interest expense to 30 % of adjusted taxable income (except for certain small businesses), the limitation of the deduction for net operating losses from taxable years beginning after December 31, 2017 to 80 % of current year taxable income and the elimination of net operating loss carrybacks generated in taxable years ending after December 31, 2017 (though any such net operating losses may be carried forward indefinitely) and the modification or repeal of many business deductions and credits. In addition, on March 27, 2020, former President Trump signed into law the " Coronavirus Aid, Relief, and Economic Security Act " or the CARES Act, which included certain changes in tax law intended to stimulate the U. S. economy in light of the COVID- 19 public health emergency, including providing temporary relief from certain aspects of the TCJA that had imposed limitations on the utilization of certain losses, interest expense deductions, and minimum tax credits and provided temporary deferral of certain payroll taxes. It cannot be predicted whether, when, in what form or with what effective dates new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our or our ~~shareholders~~ **stockholders** ' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof. Our ability to use our U. S. net operating loss carryforwards and certain other U. S. tax attributes may be limited. Our ability to use our U. S. federal and state net operating losses 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 net operating losses. Unused losses for the tax year beginning before January 1, 2018, and prior tax years will carry forward to offset future taxable income, if any, until such unused losses expire. Unused losses generated in tax years beginning after

December 31, 2017, under the TCJA will not expire and may be carried forward indefinitely, and generally may not be carried back to prior taxable years, except that, under the CARES Act, net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such U. S. federal net operating losses generated in tax years beginning after December 31, 2017, is limited to 80 % of our taxable income. In addition, both our current and our future unused losses and other tax attributes may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if we undergo an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future, some of which are outside our control. In addition, at the state level, there may be periods during which the use of net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. Risks Related to Government Regulation The FDA regulatory approval process is lengthy, time- consuming, and inherently unpredictable, and we may experience significant delays in the clinical development and regulatory approval, if any, of our product candidates. The research, testing, manufacturing, labeling, approval, selling, import, export, adverse event reporting, record keeping, advertising, promotion, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive a Biologics License from the FDA. We have not previously submitted a BLA to the FDA, or similar approval filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure, potent, and effective for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre- license inspection. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, the FDA has limited experience with commercial development of T cell therapies for cancer. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained. In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to: • obtaining regulatory approval to begin a trial, if applicable; • the availability of financial resources to begin and complete the planned trials; • reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • obtaining approval at each clinical trial site by an independent institutional review board, or IRB; • recruiting suitable patients to participate in a trial in a timely manner; • having patients complete a trial or return for post- treatment follow- up; • clinical trial sites deviating from trial protocol, not complying with GCP, or dropping out of a trial; • addressing any patient safety concerns that arise during the course of a trial; • addressing any conflicts with new or existing laws or regulations; • adding new clinical trial sites; or • manufacturing qualified materials under cGMP for use in clinical trials. Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. See the risk factor above " — If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected " for additional information on risks related to patient enrollment. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Safety Monitoring Committee for such trial, or the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Our third- party research institution collaborators may also experience similar difficulties in completing ongoing clinical trials and conducting future clinical trials of product candidates. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we 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 we will be able to obtain or maintain regulatory approval in any other jurisdiction, but 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 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 those in the United States, including additional preclinical studies or clinical trials as 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. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or to receive

applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed. 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. If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record- keeping, conduct of post- marketing studies, and submission of safety, efficacy, and other post- market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities. Manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority, requirements, including ensuring that quality control and manufacturing procedures conform to cGMP, and in certain cases cGTP, regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and cGTP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Any regulatory approvals that we receive for our product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase IV clinical trials and surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a REMS program as a condition of approval of our product candidates, which could entail requirements for long- term patient follow- up, 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, we will have to comply with requirements including submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP, cGTP, and GCP 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 the following among other things: • restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • withdrawal of the product from the market; • product recalls; • warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities; • refusal of the FDA or other applicable regulatory authority to approve pending applications or • supplements to approved applications; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • suspension of any of our ongoing clinical trials; • product seizure or detention or refusal to permit the import or export of products; and • consent decrees, injunctions or the imposition of civil or criminal penalties. The FDA strictly regulates marketing, labeling, advertising, and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant liability. Non- compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union' s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. The policies of the FDA and of other regulatory authorities 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. In addition, if we were able to obtain accelerated approval of any of our product candidates, the FDA would require us to conduct a confirmatory study to verify the predicted clinical benefit and additional safety studies. The results from the confirmatory study may not support the clinical benefit, which would result in the approval being withdrawn. While operating under accelerated approval, we will be subject to certain restrictions that we would not be subject to upon receiving regular approval. Even if we obtain regulatory approval of our product candidates, the products may not gain market acceptance among physicians, patients, hospitals, cancer treatment centers, and others in the medical community. The use of modified T cells as a potential cancer treatment is a recent development and may not become broadly accepted by physicians, patients, hospitals, cancer treatment centers, and others in the medical community. For example, certain of the product candidates that we will be developing target a cell surface marker that may be present on cancer cells as well as non- cancerous cells. It is possible that our product candidates may kill these non- cancerous cells, which may result in unacceptable side effects, including death. Additional 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 of our product candidates over alternative treatments; • the prevalence and severity of any side effects; • any restrictions on concomitant us of other medications ; • product labeling or product insert requirements of the FDA or other regulatory authorities; • limitations or warnings contained in the labeling approved by the FDA; • the size of the market for such drug candidate, based on the size of the patient subsets that we are targeting, in their territories for which we gain regulatory approval and have commercial rights; • the safety of the drug candidate as demonstrated through broad commercial rights; • the adequacy of supply of our product candidates; • the timing of market introduction of our product candidates as well as competitive products; • the cost of treatment in relation to alternative treatments; • the amount of upfront

costs or training required for physicians to administer our product candidates; • the availability of adequate coverage, reimbursement, and pricing by third- party payors and government authorities; • the willingness of patients to pay out- of- pocket in the absence of coverage and reimbursement by third- party payors and government authorities; • support from patient advocacy groups • relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and • the effectiveness of our sales and marketing efforts. In addition, although we are not utilizing embryonic stem cells or replication competent vectors, adverse publicity due to the ethical and social controversies surrounding the therapeutic use of such technologies, and reported side effects from any clinical trials using these technologies or the failure of such trials to demonstrate that these therapies are safe and effective may limit market acceptance our product candidates. 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. Our ability to negotiate, secure and maintain third- party coverage and reimbursement for our product candidates may be affected by political, economic and regulatory developments in the United States, the European Union and other jurisdictions. Governments continue to impose cost containment measures, and third- party payors are increasingly challenging prices charged for medicines and examining their cost effectiveness, in addition to their safety and efficacy. These and other similar developments could significantly limit the degree of market acceptance of any product candidate of ours that receives marketing approval in the future. Even if our products achieve market acceptance, we 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 are and will be subject to stringent privacy laws, cybersecurity laws, regulations, policies and contractual obligations related to privacy and security, and changes in such laws, regulations, policies or how they are interpreted or changes in related contractual obligations could adversely affect our business. We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, processing, storage and use of personally- identifying information including comprehensive regulatory systems in the United States and European Union, which, among other things, impose certain requirements relating to the privacy, security and transmission of personal information. The legislative and regulatory landscape for privacy and data protection continues to evolve worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations by us or third parties to whom we contract certain types of work (like clinical trials) could result in enforcement action against us or such third parties, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. There are numerous U. S. federal and state laws and regulations related to the privacy and security of personal information. In particular, regulations promulgated pursuant to the US federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If we are unable to properly protect the privacy and security of protected health information or other personal, sensitive, or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal and outside resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Some U. S. state governments have enacted or are considering enacting more stringent laws and regulations protecting personal information and data. For instance, California passed the California Data Privacy Protection Act of 2018 (the " CCPA "), which went into effect in January 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. In addition, the California Consumer Rights Act (" CPRA ") was recently enacted to strengthen elements of the CCPA and becomes effective January 1, 2023. A number of other states have considered similar privacy proposals, with states like Virginia and Colorado enacting their own privacy laws (also scheduled to come into effect in January 1, 2023 and July 1, 2023, respectively). These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data. In the EU, we may be subject to the General Data Protection Regulation (GDPR) which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross- border transfer of such data. The GDPR applies to any company established in the European Economic Area, or EEA, (which includes the EU Member States plus Iceland, Liechtenstein, and Norway) and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The GDPR establishes stringent requirements applicable to the processing of personal data, including strict requirements relating to

the validity of consent of data subjects, expanded disclosures about how personal data is used, requirements to conduct data protection impact assessments for " high risk " processing, limitations on retention of personal data, special provisions affording greater protection to and requiring additional compliance measures for " special categories of personal data " including health and genetic information of data subjects, mandatory data breach notification (in certain circumstances), " privacy by design " requirements, and direct obligations on service providers acting as processors. The GDPR also prohibits the international transfer of personal data from the EEA to countries outside of the EEA unless made to a country deemed to have adequate data privacy laws by the European Commission or a data transfer mechanism has been put in place. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to 20 million Euros or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. The GDPR may also impose additional compliance obligations relating to the transfer of data between us and our subsidiaries or other business partners. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU), issued a landmark opinion in the case Maximilian Schrems vs. Facebook (Case C- 311 / 18), called Schrems II. This decision (a) calls into question commonly relied upon data transfer mechanisms as between the EU Member States and the United States (such as the Standard Contractual Clauses) and (b) invalidates the EU- U. S. Privacy Shield on which many companies had relied as an acceptable mechanism for transferring such data from the EU to the United States. The CJEU is the highest court in Europe and the Schrems II decision heightens the burden on data importers to assess U. S. national security laws on their business and future actions of EU data protection authorities are difficult to predict. Some customers or other service providers may respond to these evolving laws and regulations by asking us to make certain privacy or data- related contractual commitments that we are unable or unwilling to make. This could lead to the loss of current or prospective customers or other business relationships. While we continue to address the implications of the recent changes to EU data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EU and elsewhere and carries with it the potential for significant penalties if we are found to be non- compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government- imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects. Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates profitably. Successful sales of our product candidates, if approved, depend on the availability of adequate coverage and reimbursement from third- party payors. In addition, because our product candidates represent new approaches to treat cancer and other immune- related diseases, we cannot accurately estimate the potential revenue from our product candidates. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Additionally, third- party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of our products. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Because our product candidates have a higher cost of goods than conventional therapies, and may require long- term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. We intend to seek approval to market our product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for our product candidates and may be affected by existing and future health care reform measures. Healthcare legislative reform measures may have a material adverse effect on our business

and results of operations. Third- party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and the Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the " ACA ") was enacted, which, among other things, subjected biologic products to potential competition by lower- cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government' s comparative effectiveness research. The ACA continues to significantly impact the United States' pharmaceutical industry. Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the Act. Complying with any new legislation or reversing changes implemented under the ACA could be time- intensive and expensive, resulting in a material adverse effect on our business. In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2 % per fiscal year, which went into effect in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2032, with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. The CARES Act and other COVID- 19 relief legislation suspended the 2 % Medicare sequester from May 1, 2020 through June 30, 2022 (a 1 % sequester will apply from April 1, 2022 through June 30, 2022). In January 2013, the American Taxpayer Relief Act of 2012, was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace from February 15, 2021 through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to health care, including, among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. In addition, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under government payor programs and review the relationship between pricing and manufacturer patient programs. Moreover, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Payment methodologies may also be subject to changes in healthcare legislation and regulatory initiatives. For example, Centers for Medicare and Medicaid Services may develop new payment and delivery models, such as bundled payment models. There also has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. By way of example, in August 2022, the Inflation Reduction Act of 2022, or the IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the Department of Health and Human Services to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated, or the impact of the IRA on our business. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, particularly as a result of the new presidential administration. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our products; • our ability to generate revenue and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. Any denial in coverage or reduction in reimbursement from Medicare or other government programs may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability. 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, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with applicable laws and regulations of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or 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 in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare 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, which could result in significant regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Our relationships with prescribers, purchasers, third- party payors and patients will be subject to applicable anti- kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Although we do not currently have any products on the market, upon commercialization of our drug candidates, if approved, we will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Physicians, other health care providers and third- party payors will play a primary role in the recommendation, prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other health care laws and regulations that may constrain our business or financial arrangements and relationships through which we market, sell and distribute any products for which we may obtain marketing approval. Restrictions under applicable domestic and foreign health care laws and regulations include, but are not limited to, the following: • the U. S. federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal health care program such as Medicare and Medicaid; 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; • U. S. federal false claims, false statements and civil monetary penalties laws, including the U. S. False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal health care programs for items and services which results from a violation of the federal Anti- Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act; • HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any health care benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services; similar to the U. S. federal Anti- Kickback Statute, 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; • analogous state and foreign laws and regulations relating to health care fraud and abuse, such as state anti- kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving health care items or services reimbursed by non- governmental third- party payors, including private insurers; • the FCPA and other anti- corruption laws and regulations pertaining to our financial relationships and interactions with foreign government officials; • the U. S. federal physician payment transparency requirements, sometimes referred to as the " Sunshine Act, " which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to physician payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals as well as the ownership and investment interests of physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be required to report such information regarding its relationships with physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse midwives during the previous year; • analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and / or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other health care providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the health care industry; • the U. S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or

private entities, often as a condition of reimbursement under federal health care programs; • HIPAA, which imposes obligations on certain covered entity health care providers, health plans, and health care clearinghouses and their business associates that perform certain services involving the use or disclosure of individually identifiable health information as well as their covered subcontractors, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; and • state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. 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. In addition, recent health care reform legislation has strengthened these laws. For example, the ACA, among other things, amends the intent requirement of the federal Anti- Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the ACA provides that 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 False Claims Act. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any of our product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. If any of the physicians or other health care providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from federal health care programs. Risks Related to Intellectual Property We depend on intellectual property licensed from third parties, in particular from Johns Hopkins, and termination of any of these licenses could result in the loss of significant rights, which would harm our business. We are dependent on patents, know- how, and proprietary technology, both our own and licensed from others. Any termination of these licenses, in particular from Johns Hopkins, could result in the loss of significant rights and could harm our ability to commercialize our product candidates. See the sections of this Annual Report on Form 10-K captioned " Business — Intellectual Property " and " Business — Johns Hopkins License Agreement " for additional information regarding our license agreements. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to: • 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 on intellectual property of the licensor that is not subject to the license agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates; and • the allocation of ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners. 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. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce patents and patent applications that are material to our business. While we have significant control over the filing, prosecution, and maintenance of our patents licensed from Johns Hopkins, our filing, prosecution, and maintenance of these licensed patents is subject to approval of the licensor. We generally have the first right to enforce our patent rights, although our ability to settle such claims often requires the consent of the licensor. If our licensors or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail to conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. We cannot be certain that such activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of such license agreements, the licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our product development pipeline. We own or license from third

parties certain intellectual property rights necessary to develop our product candidates. The growth of our business may depend in part on our ability to acquire or in- license additional proprietary rights. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. We may be unable to acquire or in- license any relevant third- party intellectual property rights 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 were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non- exclusive, which may allow our competitors access to the same technologies licensed to us. Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, 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 other parties, potentially blocking our ability to pursue our program. 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. The licensing and acquisition of third- party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. 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 we may seek to acquire. We could be unsuccessful in obtaining or maintaining adequate patent protection for one or more of our products or product candidates. We anticipate that we will file additional patent applications both in the United States and in other countries, as appropriate. However, we cannot predict: • if and when any patents will issue; • the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents; • whether others will apply for or obtain patents claiming aspects similar to those covered by our patents and patent applications; or • whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose. Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, physicians may prescribe these products " off- label " for those uses that are covered by our method of use patents. Although off- label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute. Many of our issued patents cover methods for making our cell therapy products. Method of making patents protect the process by which a product is made. This type of patent does not prevent a competitor from marketing a product that is similar to our product, if the competitor' s product is made by a process not covered by our patents. The strength of patents in the biotechnology and pharmaceutical field can be uncertain, and evaluating the scope of such patents involves complex legal and scientific analyses. The patent applications that we own or in- license may fail to result in issued patents with claims that cover our product candidates, methods of making our product candidates, or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing their products to avoid being covered by our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates is threatened, this could dissuade companies from collaborating with us to develop, and could threaten our ability to commercialize, our product candidates. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U. S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For U. S. applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the America Invents Act, which brought into effect significant changes to the U. S. patent laws, including new procedures for challenging pending patent applications and issued patents. Confidentiality agreements with employees and third parties may not prevent unauthorized disclosure of trade secrets and other proprietary information. In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce,

and any other elements of our product discovery and development processes that involve proprietary know- how, information, or technology that is not covered by patents. Trade secrets, however, may be difficult to protect. We seek to protect our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, and collaborators. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, outside scientific advisors, contractors, and collaborators might intentionally or inadvertently disclose our trade secret information to competitors. 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 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, or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition. Third- party claims of intellectual property infringement against us or our collaborators may prevent or delay our product discovery and development efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, due to changes in U. S. law referred to as patent reform, procedures including inter parties review and post- grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Although we have conducted analyses of the patent landscape with respect to our product candidates, and based on these analyses, we believe that we will be able to commercialize our product candidates, third parties may nonetheless assert that we infringe their patents, or that we are otherwise employing their proprietary technology without authorization, and may sue us. While we are aware of at least one third- party U. S. patent that is relevant to our planned products, it will expire prior to our currently planned commercial launch. There may be other third- party patents of which we are currently unaware with claims to compositions, methods of manufacture, or methods of use or treatment that cover our product candidates. 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 product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies or the manufacture, use, or sale of our product candidates infringes upon these patents. If any such third- party patents were held by a court of competent jurisdiction to cover our technologies or product candidates, the holders of any such patents may be able to block our ability to commercialize the applicable product candidate unless we obtain a license under the applicable patents, or until such patents expire or are finally determined to be held invalid or unenforceable. Such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Third parties asserting their patent rights against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. 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, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, maintaining and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can have a different scope and strength than do those in the United States. To date, in addition to the United States, we have filed patent applications in Australia, Brazil, Canada, China, Europe (via European Patent Office, or EPO), Hong Kong, India, Israel, Japan, Russian Federation, South Korea, Mexico, and Singapore. In addition, the laws of some foreign countries, such as China, Brazil, Russia, and India, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement against importation of infringing products is challenging or legal remedies are insufficient. These products may compete with our products and our patents or other intellectual property rights may not be effective or adequate to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, such as China, Brazil, Russia, and India, do not favor the enforcement of patents, trade secrets and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore such proceedings could put

our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time- consuming, and unsuccessful. Competitors may infringe our patents or the patents of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding or a declaratory judgment action against us, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceeding could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. 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. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to, or the correct inventorship of, our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation, interference, or derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Issued patents covering our product candidates could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign authority. If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, inter partes review, post- grant review, and equivalent proceedings in foreign jurisdictions, such as opposition or derivation proceedings. Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover and protect our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection could have a material adverse impact on our business. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. 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. In addition, the United States has recently enacted and is currently implementing wide- ranging patent reform legislation. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, 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. For example, in, Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the U. S. Supreme Court held that certain claims to naturally- occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, the U. S. Congress or the USPTO may impact the value of our patents. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means

in accordance with the applicable rules, there are situations in which noncompliance 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non- payment of fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business. The lives of our patents may not be sufficient to effectively protect our products and business. Patents have a limited lifespan. In the United States and most foreign jurisdictions, the natural expiration of a patent is generally 20 years after its first effective filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilars. Our issued patents will expire on dates ranging from 2034 to 2039, subject to any patent extensions that may be available for such patents. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2034 to 2042. In addition, although upon issuance in the United States a patent' s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. If we do not have sufficient patent life to protect our products, our business and results of operations will be adversely affected. We may face competition from biosimilars, which may have a material adverse impact on the future commercial prospects of our product candidates. Even if we are successful in achieving regulatory approval to commercialize a product candidate faster than our competitors, we may face competition from biosimilars. The Patient Protection and Affordable Care Act, which was signed into law in March 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. While certain biosimilar products have been approved by the FDA for use in the United States, none of these have been cell therapy products and none have been interchangeable biosimilars. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidance is expected to be finalized by the FDA in the near term. Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is " biosimilar to " or " interchangeable with " a previously approved biological product or " reference product. " In order for the FDA to approve a biosimilar product, it must find that the product is " highly similar " to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and, for products administered multiple times, that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor' s own non- clinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity, and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed " interchangeable " by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law. If competitors are able to obtain marketing approval for biosimilars referencing our products, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences. We may be subject to claims challenging the inventorship of our patents and other intellectual property. Although we are not currently experiencing any claims challenging the inventorship of our patents or ownership of our intellectual property, we may in the future be subject to claims that former employees, collaborators, or other third parties have an interest in our patents or other intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Risks Related to the Commercialization of Our Product Candidates Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale. Our product candidates have never been manufactured on a commercial scale, and there are risks associated with scaling up manufacturing to commercial scale including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, lot consistency and timely availability of raw materials. There is no assurance that our manufacturers will be successful in establishing a larger- scale commercial manufacturing process for our product candidates that achieves our objectives for manufacturing capacity and cost of goods. Even if we could otherwise obtain regulatory approval for any product candidate, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities of the approved product for commercialization, our commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations. The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are

unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell our biological product candidates would adversely impact our business and future results of operations. Our product candidates for which we intend to seek approval may face generic or biosimilar competition sooner than anticipated. Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products. In the United States, our AIM technology- based product candidates are expected to be regulated by the FDA as biological products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates. We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12- year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow- on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient- provider relationship and a patient' s specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off- label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved. In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class- specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved. If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval. Even if we are able to commercialize any of our product candidates, such products may become subject to unfavorable pricing regulations, third- party reimbursement practices or health care reform initiatives, which would harm our business. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug and biological products vary widely from country to country. Current and future legislation may change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product marketing approval is granted and, in some markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we may obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the United States, reimbursement varies from payor to payor. Reimbursement agencies in Europe may be more conservative than federal health care programs or private health plans in the United States. For example, a number of cancer drugs are generally covered and paid for in the United States, but have not been approved for reimbursement in certain European countries. A primary trend in the U. S. health care industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of payments for particular products. For example, payors may limit coverage to specific drug or biological products on an approved list, also known as a formulary, which might not include all of the FDA- approved drugs or biologics for a particular indication. Payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be

covered. Additionally, payors may seek to control utilization by imposing prior authorization requirements. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Patients are unlikely to use our products, if they are approved for marketing, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such products. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining coverage and reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. 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. Net prices for drugs may be reduced by mandatory discounts or rebates required by federal 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. In the United States, third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. In the European Union, reference pricing systems and other measures may lead to cost containment and reduced prices. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private 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. Further, there have been, and may continue to be, legislative and regulatory proposals at the U. S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. In addition, existing legislation aimed at patient affordability in the United States such as the ~~ACAmay~~ **ACA may** be repealed or replaced. The continuing efforts of the government, insurance companies, managed care organizations and other third- party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability. In some foreign countries, particularly the member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a product candidate. In addition, there can be considerable pressure by 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, we may be required to conduct additional clinical trials that compare the cost- effectiveness of our product candidates to other available therapies in order to obtain 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 in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability for sales of any of our product candidates that are approved for marketing in that country and our business could be adversely affected. We have no experience selling, marketing or distributing products and currently have no internal marketing and sales force. If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our product candidates, we may not be able to effectively market and sell our product candidates, if approved, or generate product revenues. We currently have no sales, marketing or distribution capabilities and have no experience as a company in the sale or marketing of pharmaceutical products. There can be no assurance that we will be able to market and sell our products in the United States or overseas. In order to commercialize any product candidates, we must build on a territory- by- territory basis marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. Therefore, with respect to the commercialization of all or certain of our product candidates, we may choose to collaborate, either globally or on a territory- by- territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If so, our success will depend, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, such collaborators' strategic interest in the products under development and such collaborators' ability to successfully market and sell any such products. If we are unable to enter into such arrangements when needed on acceptable terms or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. Further, to the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our products, we may in the future need to establish an internal sales and marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which could be expensive, time- consuming and requiring significant attention of our executive officers to manage. Further, we may not have sufficient resources to allocate to the sales and marketing of our products. Any failure or delay in the development of sales, marketing and distribution capabilities, through collaboration with one or more third parties or through internal efforts,

would adversely impact the commercialization of any of our products that we obtain approval to market. As a result, our future product revenue will suffer and we may incur significant additional losses. Risks Related to Our Common Stock If we fail to maintain the listing of our common stock with a United States national securities exchange, the liquidity of our common stock could be adversely affected. On ~~October 25~~ **November 30** , ~~2022~~ **2023** , we received a ~~deficiency~~ letter from the Listing Qualifications Department ~~(~~ **, or** the ~~"~~ Staff **,** ~~")~~ of The Nasdaq Stock Market LLC ~~("~~ **, or** Nasdaq **,** ~~")~~ notifying us that, **based** ~~for the last 30 consecutive business days, the bid price for our common stock had closed below the $ 1. 00 per share minimum bid price requirement for continued inclusion~~ on ~~the~~ Nasdaq ~~Global Select Market~~ **' s review of our Company and** pursuant to Nasdaq Listing Rule **5101,** ~~5450 (a) (1) (the " Minimum Bid Price Requirement "). The Nasdaq deficiency letter has no immediate effect on the listing of our~~ **or** ~~common stock, and our common stock will continue to trade on~~ the ~~Nasdaq Global Select Market under the symbol " NEXI " at this time. In accordance with Nasdaq~~ Listing Rule **, Nasdaq believes that we are a** ~~5810 (c) (3) (A) (the~~ " **public shell, " and that the continued listing of our securities is no longer warranted. In response, we timely requested a hearing before a Nasdaq Hearings Panel, or the Panel, which request stayed any further action by the Staff. Subsequent to the hearing, we received notice that the Panel had granted our request for an exception through May 28, 2024 to evidence** ~~Compliance~~ **compliance** ~~Period~~ **with the Listing** Rule **. This** ~~"), we have been provided a period of 180 calendar days, or until April 24, 2023 (the " Compliance~~ **compliance** ~~Date~~ **date** ~~")~~ **represents the full extent of the Panel' s discretion to grant continued listing while we are non- compliant with the Listing Rule. The Panel reserves the right to reconsider the terms of this exception based on any event** , **condition or circumstance that exists or develops that would, in the opinion of the Panel, make our continued listing inadvisable or unwarranted. Accordingly, there can be no assurance that we will be able** to regain compliance with the **Nasdaq listing rules** ~~Minimum Bid Price Requirement. If, at any time ending April 24, 2023, the bid price for~~ **or maintain** ~~our common stock closes at $ 1. 00 or~~ **our** ~~more for a minimum of ten consecutive business days, as required under the Compliance Period Rule, the Staff will provide written notification to us that we have regained compliance with the Minimum Bid Price Requirement and our common stock will continue to be eligible for~~ listing on the ~~Nasdaq Global Select Market, unless the Staff exercises its discretion to extend this ten- day period pursuant to Nasdaq Listing Rule 5810 (c) (3) (H). If we do not regain compliance with the Minimum Bid Price Requirement by the Compliance Date, we may be eligible for an additional 180 calendar day compliance period. To qualify, we would need to transfer the listing of our common stock to The~~ Nasdaq Capital Market ~~, provided that we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price Requirement, and would need to provide written notice to Nasdaq of our intention to cure the deficiency during the additional compliance period. To effect such a transfer, we would also need to pay an application fee to Nasdaq and provide written notice to the Staff of our intention to cure the deficiency during the second compliance period by effecting a reverse stock split if necessary. As part of its review process, the Staff will make a determination of whether it believes we will be able to cure the deficiency. Should the Staff conclude that we will not be able to cure the deficiency, the Staff will provide written notification to us that our common stock will be subject to delisting. At that time, we may appeal the Staff' s delisting determination to a Nasdaq Listing and Hearing Review Panel. However, there can be no assurance that, if we receive a delisting notice and appeal the delisting determination by the Staff to the panel, such appeal would be successful. We intend to monitor the closing bid price of our common stock and may, if appropriate, consider available options to regain compliance with the Minimum Bid Price Requirement, which could include seeking to effect a reverse stock split. However, there can be no assurance that we will be able to regain compliance with the Minimum Bid Price Requirement, secure a second period of 180 days to regain compliance, or maintain compliance with any of the other Nasdaq continued listing requirements~~ . If our common stock is delisted **, it could be more difficult to** ~~by~~ **buy** ~~Nasdaq,~~ **or sell** our common stock ~~may be eligible to trade on the OTC Bulletin Board or another over- the- counter market. Any such alternative would likely result in it being more difficult for~~ **or** ~~us~~ to ~~raise additional capital through the public or private sale of equity securities and for investors to dispose of, or~~ obtain accurate quotations ~~as to the market value of~~ , **and the price of** our common stock ~~. In addition, there can be no assurance that our common stock would~~ **could** ~~be eligible for trading on any such alternative exchange~~ **suffer a material decline. Delisting could also impair** ~~or~~ **our** ~~markets~~ **ability to raise capital** . The price of our stock may be volatile, and you could lose all or part of your investment. The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section and many others beyond our control. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report on Form 10- K, these factors include: • ~~the enrollment, completion or results of our Phase I / II clinical trials for NEXI- 001 and NEXI- 002; •~~ any delay in identifying and advancing a clinical candidate for our other programs; • any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; • adverse results or delays, suspensions or terminations in future preclinical studies or clinical trials; • our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial ~~; • adverse regulatory decisions, including failure to receive regulatory approval of NEXI- 001, NEXI- 002 or any other product candidate or the failure of a regulatory authority to accept data from preclinical studies or clinical trials conducted in other countries~~ ; • changes in laws or regulations applicable to any of our product candidate, including but not limited to clinical trial requirements for approvals; • adverse developments concerning our manufacturers; • our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices; • our inability to establish collaborations, if needed; • our failure to commercialize our product candidates, if approved; • additions or departures of key scientific or management personnel; • unanticipated serious safety concerns related to the use of any of our product candidates; • introduction of new products or services offered by us or our competitors; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • our ability to effectively manage our growth; • actual or anticipated variations in quarterly operating results; • our

cash position; • our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; • publication of research reports about us or our industry, or product candidates in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts; • changes in the market valuations of similar companies; • changes in the structure of the healthcare payment systems; • overall performance of the equity markets; • sales of our common stock by us or our stockholders in the future; • trading volume of our common stock; • changes in accounting practices; • ineffectiveness of our internal controls; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including patent or stockholder litigation; • general political and economic conditions; • the financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflict between Russia and Ukraine **, Israel and Gaza** , terrorism or other geopolitical events. • sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability; and • other events or factors, many of which are beyond our control. In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management' s attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation. We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Furthermore, future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock. Our executive officers, directors and principal stockholders and their affiliates, if they choose to act together, will continue to have the ability to exercise significant influence over all matters submitted to stockholders for approval. Our executive officers and directors, combined with our stockholders who own more than 5 % of our outstanding common stock, in the aggregate, beneficially own shares representing a majority of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may adversely affect the market price of our common stock by: • delaying, deferring or preventing a change in control; • entrenching our management and the board of directors; • impeding a merger, consolidation, takeover or other business combination involving us that other stockholders may desire; and / or • discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us. We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors. We are an emerging growth company, or EGC, as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in this Annual Report on Form 10- K and our periodic reports and proxy statements and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We could be an EGC for up to five years following the year in which we complete the IPO, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (a) the last day of the fiscal year (i) following the fifth anniversary of the completion of the IPO, (ii) in which we have total annual gross revenue of at least $ ~~1~~ **2** . ~~07~~ **35** billion or (iii) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non- affiliates to exceed $ 700. 0 million as of the prior June 30th, and (b) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. We are also a " smaller reporting company, " meaning that the market value of our stock held by non- affiliates plus the proposed aggregate amount of gross proceeds from the IPO was less than $ 700. 0 million and our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10- K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this Annual Report on Form 10- K. In particular, we have not included all of the executive compensation information that would be required if we were not an EGC. We cannot predict whether investors will find our common stock less attractive if we rely on certain or all of these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Under the JOBS Act, EGCs can also delay adopting new or revised accounting standards until such time as those standards apply to private companies, which may make our financial statements less comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We ~~previously~~ **have** identified a material weakness in our internal control over financial reporting ~~, which has been remediated~~ **related to our control environment** . If we ~~identify additional~~ **do not remediate the** material weaknesses in ~~the future or~~ **our**

~~otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price. A material weakness is a deficiency, or a combination of deficiencies, in~~ internal control over financial reporting, **or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting,** such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented **,** or detected ~~in~~ **and corrected on** a timely basis ~~. We cannot assure you that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent or avoid potential future material weaknesses~~ . In connection with the ~~implementation~~ **preparation** of ~~the necessary procedures and practices related to~~ **this Annual Report on Form 10- K, we identified a material weakness in our** internal control over financial reporting **related to our control environment. More specifically** , we **have determined that we have not maintained adequate segregation of duties as a result of a lack of sufficient finance and accounting staff to maintain policies and procedures intended to ensure appropriate segregation of duties with respect to accounting and financial reporting. This lack of sufficient finance and accounting staff is a consequence of our previously reported reduction- in- force. The process of designing and implementing an effective accounting and financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain an accounting and financial reporting system that is adequate to satisfy our reporting obligations. We** may **determine to take actions to address these control deficiencies, however, we cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weakness we have** ~~identify~~ **identified or avoid potential future material weakness. Any failure to remediate the material weakness we identified or develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to remediate the** material weaknesses ~~that~~ we **identified** ~~may not be able to remediate in time to meet the deadline imposed by the Sarbanes- Oxley Act for~~ - **or** ~~compliance with the requirements of Section 404. In addition, we may encounter problems or delays in completing the implementation~~ ----- **implement** ~~of any improvements~~ and ~~receiving a favorable attestation by our~~ **maintain effective internal control over financial reporting could also adversely affect the results of management reports and** independent registered public accounting firm **audits of** ~~, if and when required. If we are unable to achieve and maintain an effective internal control environment in our disclosure controls or~~ **our** internal control over financial reporting ~~, the accuracy and timing of~~ **that we will eventually be required to include in** our **periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over** financial reporting **could also cause** ~~may be adversely affected; our liquidity, our access to capital markets and our ability to complete acquisitions may be adversely affected; we may be unable to maintain or regain compliance with applicable securities laws, The Nasdaq Stock Market LLC (" Nasdaq ") listing requirements, and the covenants under certain agreements regarding the timely filing of periodic reports; we may be subject to regulatory investigations and penalties;~~ investors ~~may~~ **to** lose confidence in our **reported** financial ~~reporting;~~ and **other information, which would likely have a negative effect on the market price of** our **common** stock ~~price may decline~~ . Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. As of December 31, ~~2022~~ **2023** , there are ~~26~~ **1** , ~~078~~ **066** , ~~451~~ **320** shares of common stock outstanding. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock. We have registered on Form S- 8 all shares of common stock that are issuable under our 2021 Equity Incentive Plan. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation **, or certificate of incorporation,** and amended and restated **bylaws, or** bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: • a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; • a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; • a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office **;** • advance notice requirements for stockholder proposals and nominations for election to our board of directors; • a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two- thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors; • a requirement of approval of not less than two- thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and • the

authority of the board of directors to issue convertible preferred stock on terms determined by the board of directors without stockholder approval and which convertible preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our ~~amended and restated~~ certificate of incorporation and ~~amended and restated~~ bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our ~~company~~ **Company** , the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. Our bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers and employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our ~~amended and restated~~ certificate of incorporation or our bylaws (in each case, as they may be amended from time to time) or (iv) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein; provided, however, that this exclusive forum provision will not apply to any causes of action arising under Exchange Act. Our bylaws further provide that, unless we consent in writing to an alternative forum, the United States District Court for the District of Maryland will be the exclusive forum for resolving any complaint asserting a cause of action arising under **the Securities Act of 1933, as amended, or** the Securities Act. We have chosen the United States District Court for the District of Maryland as the exclusive forum for such Securities Act causes of action because our principal executive offices are located in Gaithersburg, Maryland. In addition, our amended and restated bylaws will provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. We recognize that the forum selection clause in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the State of Maryland, as applicable. Additionally, the forum selection clause in our bylaws may limit our stockholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. The Court of Chancery of the State of Delaware or the United States District Court for the District of Maryland may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Because the applicability of the exclusive forum provision is limited to the extent permitted by applicable law, we do not intend that the exclusive forum provision would apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. We also acknowledge that Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder and that there is uncertainty as to whether a court would enforce an exclusive forum provision for actions arising under the Securities Act. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules, and any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. **Risks Related to the Proposed Dissolution and Liquidation Our proposed dissolution and liquidation may not be completed in a timely manner or at all. As previously disclosed, on November 2, 2023, our board of directors unanimously approved the liquidation and wind up of our Company through a dissolution pursuant to a plan of liquidation and dissolution, or the Plan of Dissolution, subject to stockholder approval, while continuing to pursue alternatives intended to maximize the value of our business and our assets. We called a special meeting of the stockholders, or the Special Meeting, to seek**

approval of the plan of dissolution and filed proxy materials relating to the Special Meeting with the SEC as soon as practicable. As a result of the financing consummated on February 6, 2024 resulting in gross proceeds to us of approximately $ 3. 7 million before deducting the placement agent fee and related offering expenses, we determined to postpone the Special Meeting. Subject to the outcome of our pursuit of alternatives to maximize the value of the business and our assets, we expect to call a new Special Meeting of stockholders to seek approval of the plan of dissolution, set a new record date for the determination of stockholders entitled to vote at the Special Meeting, and file proxy materials relating to the Special Meeting with the SEC. If our stockholders do not approve the Plan of Dissolution, we would not be able to continue our business operations. If we call a new Special Meeting and our stockholders do not approve the Plan of Dissolution, our board of directors will continue to explore what, if any, alternatives are available for the future of our Company in light of its business activities; however, those alternatives are likely limited to seeking voluntary dissolution at a later time with potentially diminished assets or seeking bankruptcy protection (should our net assets decline to levels that would require such action). It is unlikely that these alternatives would result in greater stockholder value than the proposed Plan of Dissolution. Our board of directors may determine not to proceed with the dissolution. If we call a new Special Meeting and the dissolution is approved by our stockholders, our board of directors may determine in its sole discretion not to proceed with the dissolution. If our board of directors elects to pursue any alternative to the Plan of Dissolution, our stockholders may not receive any of the funds that might otherwise be available for distribution to our stockholders. After the Certificate of Dissolution has been filed, revocation of the dissolution would require stockholder approval under Delaware law. Our stockholders of record will not be able to buy or sell shares of our common stock after we close our stock transfer books at the effective time of the dissolution. If our board of directors determines to proceed with the dissolution, we intend to close our stock transfer books and discontinue recording transfers of our common stock at the effective time of the dissolution. After we close our stock transfer books, we will not record any further transfers of our common stock on our books except by will, intestate succession or operation of law. Therefore, shares of our common stock will not be freely transferable after the effective time of the dissolution. As a result of the closing of the stock transfer books, all liquidating distributions in the dissolution, if any, will likely be made pro rata to the same stockholders of record as the stockholders of record as of the final record date. We cannot assure you as to the amount of distributions, if any, to be made to our stockholders. At present, we cannot predict with certainty the amount of distributions to our stockholders if the Plan of Dissolution is implemented. The amount of cash ultimately distributed to our stockholders in any distribution pursuant to the Plan of Dissolution depends on, among other things, the amount of our liabilities, obligations and expenses and claims against us, and the amount of the reserves that we establish during the liquidation process. Estimates of these amounts may be inaccurate. Factors that could impact these estimates include the following: (i) if any of the estimates regarding the Plan of Dissolution, including the expenses to satisfy outstanding obligations, liabilities and claims during the liquidation process, are inaccurate, (ii) if litigation is brought against us or our directors and officers, if unforeseen claims are asserted against us, we will have to defend or resolve such claims or establish a reasonable reserve before making distributions to our stockholders, (iii) if the estimates regarding the expenses to be incurred in the liquidation process, including expenses of personnel required and other operating expenses (including legal, accounting and other professional fees) necessary to dissolve and liquidate the Company, are inaccurate and (iv) if we continue to incur significant expenses related to ongoing reporting obligations. General Risk ~~Factor~~ **Factors** We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, and particularly after we are no longer an " emerging growth company, " we will incur significant legal, accounting and other expenses that we did not incur as a private company. Sarbanes- Oxley, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq ~~Global~~ **Capital** Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Our issuance of additional capital stock in connection with potential future financings, acquisitions, investments, our stock incentive plans or otherwise will dilute all other stockholders. We expect to issue additional capital stock in the future that will result in dilution to all other stockholders. We expect to grant equity awards to employees, directors and consultants under our stock incentive plans. We may also raise capital through equity financings in the future. As part of our business strategy, we may acquire or make investments in complementary companies, products or technologies and issue equity securities to pay for any such acquisition or investment. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.