Risk Factors Comparison 2025-02-28 to 2024-02-27 Form: 10-K

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~~● If we are unable to protect the confidentiality of our proprietary information, trade secrets, and know- how, our competitive position could be impaired and our business, financial condition, results of operations, and prospects could be adversely affected; ● Third- party claims of intellectual property infringement may prevent or delay our product development efforts; and ● Intellectual property rights do not necessarily address all potential threats to our competitive advantage. Risks Related to Regulatory Approval and Other Government Regulations ● If we are not able to successfully develop and commercialize our product candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations; ● We cannot market and sell our product candidates in the U. S. or in other countries if we fail to obtain the necessary regulatory approvals; ● Final marketing approval of our product candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which could adversely affect our ability to generate operating revenues; ● We may not be able to secure and maintain research institutions to conduct our clinical trials; ● Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations; and ● Even if we receive regulatory approval of Lomecel- B ™ or any of our other product candidates, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our therapeutic candidates. Risks Related to Our Dependence on Third Parties ● We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential therapeutic candidates; and ● We may enter into arrangements with third- party collaborators to help us develop our product candidates and commercialize our products, and our ability to commercialize such products may be impaired or delayed if collaborations are unsuccessful. Risks Related to the Discovery, Development and Commercialization of Our Product Candidates ● Interim, " topline " and preliminary data from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. Risks Related to Our Class A Common Stock and the Securities Market ● The price of our Class A common stock has been, and may continue to be, volatile, which could result in substantial or total losses for investors. ● We could lose our listing on the Nasdaq Capital Market if our current share price continues to decrease. The loss of our Nasdaq listing would in all likelihood make our Class A common stock significantly less liquid and adversely affect its value. ● Provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Class A common stock. Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business ● We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators; and ● In order to successfully implement our plans and strategies, we will need to grow our organization, and we may experience difficulties in managing this growth. Item 1A. Risk Factors~~ In addition to the other information in this 10- K, the following risk factors should be considered carefully in evaluating us. You should carefully consider the risks and uncertainties described below and the other information in this report, including our financial statements and related notes appearing elsewhere in this 10- K and in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our Class A common stock or to maintain or change your investment. Our business, financial condition, results of operations or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our Class A common stock could decline and you could lose all or part of your investment. This 10- K also contains forward- looking statements that involve risks and uncertainties. See " Cautionary Note Regarding Forward- Looking Statements. " Our actual results could differ materially and adversely from those anticipated in these forward- looking statements as a result of certain factors, including those set forth below. For a summary of these risk factors, please see " Risk Factors Summary " beginning on page ~~29~~ **23** of this 10- K. Risks Related to our Business We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability. We are a clinical stage biotechnology company with a limited operating history upon which you can evaluate our business and prospects. We have no products approved for commercial sale and have not generated any material revenue from product sales. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, building and equipping our research and development laboratories, building and equipping our manufacturing suites, raising capital, acquiring raw materials for manufacturing, product candidate development and manufacturing, securing related intellectual property rights and conducting clinical trials of **our** Lomecel- B ™ **cellular therapy** . We have not yet demonstrated our ability to 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. As a result, it may be more difficult for you to accurately predict our future success or viability than if we had a longer operating history. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage biotechnology companies in rapidly evolving fields, including but not limited to changes in FDA or foreign body regulatory oversight of products. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. Such a transition may involve substantial additional

capital requirements in order to launch and market a product, changes in the use of proceeds, and significant adjustment to personnel, compared to a clinical- stage development company. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer. If the potential of our product candidates to treat diseases is not realized, the value of our technology and our development programs could be significantly reduced. Our team is currently exploring the potential of our product candidates to treat diseases. We have not yet proven in clinical trials that our product candidates will be a safe and effective treatment for any disease or condition. Our product candidates are susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy, or other characteristics that may prevent or limit their marketing approval or commercial use. We have not yet completed all of the testing necessary to allow us to make a determination that serious unintended consequences will not occur. If the potential of our product candidates to treat disease is not realized, the value of our technology and our development programs could be significantly reduced. Because our product candidates are based on ~~MSCs~~ **mesenchymal stem cells**, any negative developments regarding the therapeutic potential or side effects of our ~~MSCs~~ **mesenchymal stem cells**, or regarding scientific and medical knowledge about ~~MSCs~~ **mesenchymal stem cells** in general, could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our product development programs are based on novel technologies and are inherently risky. We are subject to the risks of failure inherent in the development of product candidates based on new technologies. The novel nature of our product candidates creates significant challenges in regards to product development and optimization, manufacturing, government regulation, third- party reimbursement, and market acceptance. For example, although the FDA has approved several cell therapy products, the FDA has relatively limited experience with regulating these kinds of therapies, and its regulations and policies are still evolving. As a result, the pathway to regulatory approval for our product candidates may be more complex and lengthier. Additionally, stem cells that are taken from one person and transplanted into a different individual may pose additional risks. For example, stem cells that are **allogeneic (i. e., taken from one individual and given to a different person) and** not autologous (i. e., taken from, and given to, the same individual ~~) but are instead allogeneic (i. e., taken from one individual and given to a different person~~) are subject to donor- to- donor variability, which can make standardization more difficult. As a result of these factors, the development and commercialization pathway for our therapies may be more complex and lengthier, and subject to increased uncertainty, as compared to the pathway for new conventional (i. e., new chemical entity) drugs. There are no FDA- approved allogeneic, cell- based therapies for Aging- related ~~frailty~~ **Frailty**, Alzheimer' s disease (AD), or other aging- related conditions, nor HLHS or other cardiac- related indications. This could complicate and delay FDA approval of our product candidate for these indications, or other indications we study or will study. Although **the** FDA has approved several cell therapy products, there are no allogeneic cell- based or stem cell therapies currently approved by the FDA for the treatment of Aging- related ~~frailty~~ **Frailty** ~~or our~~ **or the** other indications **we are studying**. There are also no conventional drugs or therapies currently approved by the FDA with stated indications for Aging- related ~~frailty~~ **Frailty**, Aging, or Frailty. According to the FDA, " Aging- related ~~frailty~~ **Frailty** " does not have a definition that is acceptable for characterizing the conditions for regulatory purposes, and there are no precedents for regulatory approvals ~~in these~~ **of this** ~~indications~~ **indication**. This could prevent, complicate and / or delay regulatory approval of our product candidate for these indications to the extent that the Company may continue to pursue ~~these~~ **this** ~~indications~~ **indication**. The FDA and the Japanese PMDA have both indicated that the concept of " Frailty " as an indication will require additional clinical data and discussion before future pivotal trials and marketing authorization. Because the condition of Frailty lacks consensus, there is no guarantee that PMDA, FDA or any regulatory agency will agree to an approvable indication, that ~~there~~ **these regulatory authorities** will ~~be~~ **reach a** consensus regarding the definition of the condition **,** or **that they** will agree on clinical endpoints that would be considered acceptable for demonstrating clinically meaningful benefit. More specifically, our ability to begin Phase 3 (i. e., pivotal) trials in a " Frailty " or " Aging- related ~~frailty~~ **Frailty** " indication would depend on our subsequent interactions with FDA where we would discuss the size and scope of the next program, the appropriate target patient population (i. e., defining the indication), and agreement on one or more primary endpoints that demonstrate clinically meaningful outcome. It is possible that the FDA may never recognize " aging " as a disease and may never agree to a definition of " Aging- related ~~frailty~~ **Frailty** " primarily due to a lack of consensus on the definitions amongst clinicians, researchers and regulators, an insufficient understanding of the underlying pathophysiologic mechanisms that cause any or all of the manifestations, or both. To obtain FDA approval for any indication for the disease states we are studying, we will have to demonstrate, among other things, that our product candidates are safe and effective for that indication in the target population. The results of our clinical trials must be statistically significant, meaning that there must be sufficient data to indicate that it is unlikely the outcome occurred by chance. The FDA will also require us to demonstrate an appropriate dose (i. e., number of cells) and dosing interval for our product candidates, and to identify and define treatment responders, which may require additional clinical trials. As a result, the clinical endpoints, the criteria to measure the intended results of treatment, and the correct dosing for our cell- based therapeutic approaches for ~~these indications~~ **" Aging- related Frailty"** may be difficult to determine. To the extent **we** ~~the Company decides~~ **decide** to pursue ~~these~~ **this** ~~indications~~ **indication**, these challenges may prevent us from developing and commercializing products on a timely or profitable basis, or at all. If we are not able to recruit and retain qualified management and scientific personnel, we may fail in developing our technologies and product candidates. Our future success depends to a significant extent on the skills, experience, and efforts of the principal members of our scientific and management personnel. These members include Joshua M. Hare, M. D. and our staff of scientific consultants. Our co- founder, Dr. Hare, remains employed by UM, and provides services to us as a consultant on a limited basis. The loss of Dr. Hare or any or all of these individuals could harm our business and might significantly delay or prevent the achievement of research, development or business objectives. Competition for regulatory, clinical manufacturing and management personnel in the pharmaceutical industry is intense. We may be unable to recruit or retain personnel with sufficient management skills in the area of cell therapeutics or attract or integrate other qualified management and scientific personnel in the future. Our product candidates

represent new classes of therapy that the marketplace may not understand or accept. Even if we successfully develop and obtain regulatory approval for our product candidates, the market may not understand or accept them. We are developing product candidates that represent novel treatment approaches and will compete with a number of more conventional products and therapies manufactured and marketed by others, including major pharmaceutical companies. The degree of market acceptance of any of our future developed and potential products will depend on a number of factors, including: ● the clinical safety and effectiveness of our products and their perceived advantage over alternative treatment methods; ● our ability to demonstrate that our cell- based products ~~can~~ have a clinically significant effect, initially for Aging- related ~~frailty~~ **Frailty** , AD, HLHS, and other disease states for which we may seek marketing approval; ● ethical controversies that may arise regarding the use of stem cells or human tissue of any kind, including adult stem cells, adult bone marrow, and other adult tissues derived from donors; ● adverse events involving our product candidates or candidates of others that are cell based; ● our ability to supply a sufficient amount of our products to meet regular and repeated demand in order to develop a core group of medical professionals familiar with and committed to the use of our products; and ● the cost of our products and the reimbursement policies of government and third- party payors. If the health care community does not accept our product candidates or future approved products for any of the foregoing reasons, or for any other reason, it could affect our sales or have a material adverse effect on our business, financial condition, results of operations, and prospects. Our dependence upon a limited supply of bone marrow donors and biologic growth media may impact our ability to produce sufficient quantities of our product candidates as needed to complete our clinical trials, and if our trials are successful **and our products are approved** , to meet product demand. The population of acceptable bone marrow donors is limited to volunteers between the ages of 18 and 45. In addition, potential donors are prescreened for a variety of health conditions and are only allowed to donate bone marrow a total of six times in their lifetime, further limiting the total number of potential donors. The amount of bone marrow donated may be insufficient for us to mass produce our product candidates at a scale sufficient to meet our clinical trial needs or to produce a product **, if approved,** to meet future commercial demand at an acceptable cost. In addition, the expansion of ~~MSCs~~ **mesenchymal stem cells** through our proprietary manufacturing methods utilizes biologic growth media that may be in limited supply. Our product candidates will be inherently more difficult to manufacture at commercial- scale than conventional pharmaceuticals, which are manufactured using precise chemical formulations and operational methods. Cost- effective production at clinical trial or commercial scale quantities may not be achievable. Future government regulation or health concerns may also reduce the number of donors or otherwise limit the amount of bone marrow available to us. If we cannot secure quantities of bone marrow or biologic growth media sufficient to meet the manufacturing demands for our clinical trials, we might not be able to complete our clinical trials and obtain marketing approval for our product candidates. Moreover, even if our clinical trials are successful and we obtain marketing approval for our product candidates, our inability to secure enough bone marrow or biologic growth media to meet **commercial** product demand could limit our potential revenues. ~~MSCs~~ **Mesenchymal stem cells** are biological entities derived from human bone marrow and therefore have the potential for disease transmission and can pose risks to the recipient. MSC therapies require many manufacturing steps. Cells must be harvested from donor tissue, isolated, and expanded in cell culture to produce a sufficient number of cells for use. Each step carries risks for contamination by other cells, microbes, or adventitious agents. The transfer of cells into a recipient can also carry risks and complications associated with the procedure itself, and a recipient may reject the transplanted cells. Further, the utilization of donated bone marrow creates the potential for transmission of cancer and communicable disease, including but not limited to human immunodeficiency virus (“ HIV ”), viral hepatitis, syphilis, Creutzfeldt- Jakob disease, and other viral, fungal, or bacterial pathogens. Although we and our suppliers are required to comply with federal and state regulations intended to prevent communicable disease transmission, we or our suppliers may fail to comply with such regulations. Further, even with compliance, our products might nevertheless be viewed by the public as being associated with transmission of disease, and a clinical trial subject or patient who contracts an infectious disease might assert that the use of our product candidate or products resulted in disease transmission, even if the individual became infected through another source. Any actual or alleged transmission of communicable disease could result in clinical trial subject or patient claims, litigation, distraction of management’ s attention, increased expenses, and adverse regulatory authority action. Further, any failure in screening, whether by us or other manufacturers of similar products, could adversely affect our reputation, the support we receive from the medical community, and overall demand for our products. As a result, such actions or claims, whether or not directed at us, could have a material adverse effect on our reputation with our customers and our ability to market our products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. If our processing and storage facility or our clinical manufacturing facilities are damaged or destroyed, our business and prospects could be negatively affected. Our processing and storage facility is located in a region which experiences severe weather, notably hurricanes, from time to time. If this facility in Miami, Florida or the equipment in the facility were to be significantly damaged or destroyed, we could suffer a loss of some, or all of the stored units of our product candidates and it could force us to halt our clinical trial processes. The risk of tropical storm and hurricane activity historically rises on or about June 1st each year ~~,~~ and subsides on or about November 30th each year. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major hurricane or tornado, flood, fire, earthquake, power loss, terrorist activity or other disasters and do not currently have a recovery plan for such disasters. If we underestimate our insurance needs, we will not have sufficient insurance to cover losses above and beyond the limits on our policies. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Ethical and other concerns surrounding the use of stem cell therapy or human tissue may negatively affect public perception of us or our future products or product candidates, or may negatively affect regulatory approval of our future products or product candidates, thereby reducing demand for our future products. The commercial success of our product candidates will depend in part on

general public acceptance of the use of MSC therapy for the prevention or treatment of human diseases. Although we do not use embryonic stem cells or fetal tissue, ~~but~~ the public may not be able to, or may fail to, differentiate our use of adult ~~MSCs~~ **mesenchymal stem cells** from the use of embryonic stem cells or fetal tissue by others, which could result in a negative perception of our company or our future products or product candidates, thereby reducing demand, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may obtain ~~MSCs~~ **mesenchymal stem cells** from volunteer adult bone marrow donors from non- profit organizations that collect and process tissue donations. Bone marrow donors receive payment, but ethical concerns have been raised by some about the use of donated human tissue in a for- profit setting, as we are doing. Future adverse events in the field of stem cell therapy, changes in public policy, or changes to the FDA' s regulatory approval framework for these products could also result in greater governmental regulation of our product candidates or products, and potential regulatory delays relating to their testing or approval. We may eventually compete for product sales with other companies, many of which will have greater resources or capabilities than we have, or may succeed in developing better products or in developing products more quickly than we do, and we may not compete successfully with them. We compete or may eventually compete with other companies and organizations that are marketing or developing therapies for our targeted disease indications, based on traditional pharmaceutical, medical device, or other non- cellular therapy and technologies. In addition, we have other potential competitors developing a variety of therapeutics, and in some cases, such as with AD, there may be tens or hundreds of companies seeking to commercialize therapeutics. We also face competition in the cell therapy field from academic institutions and governmental agencies. Many of our current and potential competitors have greater financial and human resources than we have, including more experience in research and development and more established sales, marketing, and distribution capabilities. We anticipate that competition in our industry will increase. In addition, the health care industry is characterized by rapid technological change, resulting in new product introductions and other technological advancements. Our competitors may develop and market products that render product candidates under development by us now or in the future, or any products manufactured or marketed by us, non- competitive or otherwise obsolete. Sales of our products may involve a lengthy sales cycle. Many factors are expected to influence the sales cycle for ~~our~~ **products once they are** approved ~~product~~. These factors include the future state of the market, the perceived value of our product candidate (s), the evolution of competing technologies, insurance coverage or prior authorization requirements and changes in medical practices. Any of these may adversely affect our sales cycles and the rate of market acceptance of our approved products. We have ongoing challenges with respect to our liquidity and access to capital. As we advance the preclinical and clinical development of our programs, we expect to continue to incur significant expenses and operating losses, for which we do not have offsetting revenue. We expect that our sales, research and development and general and administrative costs will increase in connection with conducting additional preclinical studies and clinical trials for our current and future programs and product candidates, contracting with contract research organizations (" CROs ") to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources. As of December 31, ~~2023~~ **2024**, we had $ ~~5~~ **19** . ~~4~~ **2** million in cash and cash equivalents ~~and marketable securities~~. To date, we have financed our operations primarily through public and private equity financings, grant awards, and fees generated from clinical trial revenue and contract manufacturing services. There are no assurances that we will be able to continue to finance operations through these means, and our inability to generate sufficient revenue in the near term may have an adverse impact on our business, operations and prospects. We face risks related to health epidemics **, pandemics,** and outbreaks. ~~The global~~ **Global** ~~outbreak~~ **outbreaks** of **epidemics, pandemics, and other public health risks, such as** COVID- 19 **,** ~~continues~~ **continue** to impact countries, communities, supply chains and markets. ~~The~~ **For example, the** COVID- 19 pandemic has impacted ~~and continues to impact~~ our Bahamas Registry Trial business. It is also possible that the COVID- 19 pandemic or other public health risks could adversely affect our business, results of operations, financial condition or liquidity in the future. For example, they could impact the timing and enrollment of our collaborators' planned or ongoing clinical trials, delaying clinical site initiation, regulatory review and the potential receipt of regulatory approvals, payment of milestones under our license agreements and commercialization of one or more of our product candidates, if approved. **Epidemics,** ~~The COVID- 19 pandemic~~ **pandemics ,** and other public health risks could also disrupt the production capabilities of our contract manufacturing facility. Further, the ~~outbreak~~ **continued mutation** of **the virus causing** COVID- 19 **may lead to ongoing illness in** ~~has heightened the risk that a significant portion of~~ our workforce ~~will suffer illness~~ or ~~otherwise be~~ **contracting partners, which may leave individuals** unable to work **for periods of time** . The impact of the **epidemics,** ~~COVID- 19 pandemic~~ **pandemics** ~~is~~ **, and other public health risks are generally** fluid and ~~continues~~ **continue** ~~to~~ evolve **over time** , and therefore, we cannot currently predict the extent to which our business, clinical trials, results of operations, financial condition or liquidity ~~will~~ **would** ultimately be impacted. In addition, ~~COVID- 19 or~~ **epidemics, pandemics, and** other public health risks could materially and adversely impact our operations due to, among other factors: • a general decline in business activity; • difficulty accessing the capital and credit markets on favorable terms, or at all, and a severe disruption and instability in the global financial markets, or deteriorations in credit and financing conditions which could affect our access to capital necessary to fund business operations; • the potential negative impact on the health of our employees, especially if a significant number of them or any of their family members are impacted or if any of our senior leaders are impacted for an extended period of time; • the potential negative impact on our ability to monitor the investigative sites participating in our clinical studies in person or even remotely, which could result in a deviation from pre- pandemic protocols and / or site monitoring and data management plans, and delays in our ability to perform data- related tasks dependent on communications with personnel at the investigative sites, such as resolution of open data queries, the cumulative effects of which could lead to delayed or missed identification of non- compliance with ~~eGCP~~ **cGCPs** , and / or unrecognized data errors; • potential delays in the preparation and submission of applications for regulatory approval of our products, as well as

potential delays in FDA' **s or another regulatory authority'** s ability to review applications in a timely manner consistent with past practices; ~~•~~ **•** potential difficulty in adequately overseeing and / or evaluating the manufacturing process at the facilities that will manufacture future commercial products; and ~~•~~ **•** a deterioration in our ability to ensure business continuity during a disruption. Adverse global conditions, including macroeconomic uncertainty, may negatively impact our financial results. Global conditions, dislocations in the financial markets, or continuing inflation could adversely impact our business. In addition, the global macroeconomic environment has been and may continue to be negatively affected by, among other things, instability in global economic markets, increased U. S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the Russian invasion of the Ukraine, the **Israeli- Palestinian conflict, the** withdrawal of the United Kingdom from the European Union, ~~and~~ other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets, which may adversely affect our business. We **have a history of losses and may not be able to achieve profitability going forward, and** may not be able to raise additional capital necessary to continue as a going concern. ~~As of~~ **We have experienced significant losses since inception and, at** December 31, **2024 and** 2023 **, had an accumulated deficit of approximately $ 109. 6 million and $ 85. 0 million, respectively. We expect to incur additional losses in the future and expect the cumulative losses to increase. We expect our operating expenses to increase and it is not likely that our grant revenues will fully fund our clinical programs. As of December 31, 2024** , we had cash and cash equivalents of $ ~~4~~ **19** . ~~9~~ **2** million ~~and marketable securities of $ 0. 4 million~~ . We ~~have prepared a~~ **currently believe that our** cash **and cash equivalents** ~~flow forecast which indicates that we~~ will **enable us** ~~have sufficient cash~~ to fund our operating expenses and capital expenditure requirements into the ~~second~~ **fourth** quarter of **2025 based on our current operating budget and cash flow forecast. However, as a result of a successful Type C meeting with the U. S. FDA in August** 2024 **with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current ELPIS II trial is successful** . ~~As~~ **Our operating expenses and capital expenditure requirements are expected to accelerate in 2025 as** a result **of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, and there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing / capital raises / non- dilutive funding options to support these activities, and current cash projections may be impacted by these ramped up activities and any financing transactions entered into. There can be no assurance we will be able to attain future financing at terms favorable to us or at all. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect. We currently have no credit facility or committed sources of capital. To continue as a going concern** , we will need **to obtain additional capital, which we will likely obtain through a variety of means, including through public or private equity, debt financings or other sources, including up- front payments and milestone payments from strategic collaborations. There are no assurances that we would be able** to raise additional capital **or on terms favorable** to **us** ~~continue as a going concern~~ . Our recurring losses from operations and negative cash flow raise substantial doubt about our ability to continue as a going concern without sufficient capital resources and we have included an explanatory paragraph in the notes to our financial statements for the year ended December 31, ~~2023~~ **2024** , with respect to this uncertainty **. Further, the report of our independent registered public accounting firm with respect to our audited financial statements for the year ended December 31, 2024 included an emphasis of matter paragraph stating that our recurring losses from operations and continued cash outflows from operating activities raised substantial doubt about our ability to continue as a going concern. Our financial statements do not include any adjustments that might result from the outcome of this going concern uncertainty and have been prepared under the assumption that we will continue to operate as a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. If we are unable to continue as a going concern, we may be forced to liquidate our assets, which would have an adverse impact on our business and developmental activities. In such a scenario, the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements. The reaction of investors to the inclusion of a going concern statement by our independent registered public accounting firm and our potential inability to continue as a going concern may materially adversely affect our stock price and our ability to raise new capital** . Our ability to continue as a going concern is dependent on our available cash, how well we manage that cash, and our operating requirements. If we are unable to raise additional capital when needed, we would be forced to delay, reduce or eliminate our clinical trial programs, commercialization efforts and other business activities ~~. We have a history of losses and may not be able to achieve profitability going forward. We have experienced significant losses since inception and, at December 31, 2023 and 2022, had an accumulated deficit of approximately $ 85. 0 million and $ 62. 8 million, respectively. We expect to incur additional losses in the future and expect the cumulative losses to increase. We expect our operating expenses to increase and it is not likely that our grant revenues will fully fund our clinical programs. In such event, we will not have sufficient cash flow to meet our obligations or make progress in our clinical programs and will need to raise additional capital~~ . We have been funded in part by government and non- profit association grant awards, which is not a guaranteed source of future funding. The funding of government programs is dependent on budgetary limitations, congressional appropriations and administrative allotment of funds, and changes in national health and welfare priorities, all of which are inherently uncertain and may be affected by changes in U. S. government policies resulting from various political and military developments. Our continued receipt of government and non- profit association funding is also dependent on the ability to adhere to the terms and provisions of the original grant and contract documents and other regulations. We can provide no assurance that we will receive or continue to receive funding for the grants and contracts we have been awarded. The loss of government funds or non- profit association grant awards could have a material adverse effect on our clinical programs and on our business, financial condition, and results

of operations. For additional detail regarding the grant awards, we have received from governmental and non- profit associations, see " Management' s Discussion and Analysis of Financial Condition and Results of Operations- Grant Awards " on page ~~79~~ **78** of this report. The use of our product candidates or future products in individuals may expose us to product liability claims, and we may not be able to obtain adequate product liability insurance **coverage** . Because of the nature of our products, we face an inherent risk of product liability claims. None of our product candidates have been widely used over an extended period of time, and therefore our safety data are limited. We derive the raw materials for our product candidates from human donor sources, the manufacturing process is complex, and the handling requirements are specific, all of which increase the likelihood of quality failures and subsequent product liability claims. We will need to increase our insurance coverage if and when we receive approval for and begin commercializing our product candidates. We may not be able to obtain or maintain product liability insurance on acceptable terms with adequate coverage or at all. If we are unable to obtain insurance, or if claims against us substantially exceed our coverage, then our business could be adversely impacted. Whether or not we are ultimately successful in any product liability litigation, such litigation either before or after product approval and marketing could consume substantial amounts of our financial and managerial resources and could result in, among other things: ● significant awards against us; ● substantial litigation costs; ● recall of products or termination of clinical trials; ● FDA withdrawal of marketing approval of products or suspension or revocation of an IND for a product candidate; ● injury to our reputation; ● withdrawal of clinical trial participants; ● withdrawal of clinical trial sites or investigators; or ● adverse regulatory action. Any of these results could have a material adverse effect on our business, financial condition, and results of operations **. We face risks with respect to our contract development and manufacturing business. We provide contract development and manufacturing services to a third- party and may, in the future, provide similar services to a limited number of customers that are developing their own cellular therapy treatments. Losing any customer of our contract development and manufacturing services could have a significant impact on the income generated from this division of our business. Whether we are developing and manufacturing our product candidates or products or product candidates for our customers, similar regulatory, ethical, supply chain, and demand risks apply. Assisting customers in developing a product or product candidate may result in incurring costs and expenses that are not reimbursable by the customer, including, if we are required to obtain regulatory approval that is specific to manufacturing a customer' s product or product candidate. Our success with respect to the contract manufacturing operations of our organization is largely dependent on forces outside of our control as our success in dependent on the success of our customers' products and product candidates. Our customers may have to overcome the same or similar obstacles that we face in bringing their product to market. We must maintain stringent quality control measures, as failure to do so could lead to manufacturing defective products. Failure to manufacture regulatory compliant products or product candidates could result in recalls, legal liabilities, and impact our relationship with current and future customers. The cell therapy development and manufacturing industry is highly competitive. New companies entering the market could result in pricing pressures, reduced margins, and the loss of market share. Our focus has been and will continue to be on developing our own product candidates, while our competitors may only be focused on manufacturing cell therapies for their customers. Splitting our focus may give other contract manufacturing companies a competitive edge. Furthermore, jurisdictions outside of the United States may have other regulatory requirements that we cannot meet without incurring costs and expenses. Customers looking to obtain regulatory approval in the jurisdictions may engage with competitors that already meet the regulatory requirements of such jurisdictions. Our ability to compete effectively depends on our reputation, quality of service, current technology, regulatory approval, and operational efficiency** . Risks Related to Intellectual Property If our trade secret and patent position does not adequately protect our product candidates and their uses, others could compete against us more directly, which could harm our business and have a material adverse effect on our business, financial condition and results of operations. Our success depends, in large part, on our ability to obtain and maintain intellectual property protection for our product candidates. The patent position of biotechnology companies is generally highly uncertain, involves complex legal and factual questions, and continues to be the subject of much litigation. Our trade secrets attempt to bridge the gap that threatens patent exclusivity for the protection of products derived from ~~MSCs~~ **mesenchymal stem cells** . Our trade secrets also **are intended to** remain valid and enforceable without regard to limitations such as term restrictions that are imposed on patents. Our trade secrets and know- how are the subject of various license agreements and confidentiality agreements as further discussed below. The claims of existing U. S. and foreign patent applications and patents, and those patents that may issue in the future, or those to be licensed to us, that are owned by the Company or under an obligation of assignment to the Company, may not confer on us significant commercial protection against competing products **, methods, or processes** . Furthermore, to the extent that the Company owns or is assigned or licenses patent rights covering its business, third parties may challenge or design around those patent rights, such as by asserting that the patents are invalid or arguing that the patent claims should be narrowly construed, and thereby avoid successful infringement actions. Our patent applications on MSC technology, in particular, include claims directed to therapeutic uses and kits comprising ~~MSCs~~ **mesenchymal stem cells** . Patents with such claims tend to be more vulnerable to challenge by other parties than patents with extremely narrow claims. Also, our pending patent applications may not issue, may issue with substantially narrower claims than currently pending claims, or we may not receive any additional patents. Further, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U. S. Our patents might not contain claims that are sufficiently broad to prevent others from practicing our technologies or from competing with us with their own technology in the fields of interest to us. Although the Company has obligations of assignment and has been assigned patents and patent applications concerning stem cell products and their uses, none of those patents or presently pending applications has granted claims or pending claims that, if granted, would **absolutely** prevent a third party from commercializing their own allogeneic stem cell therapy for those indications that we are studying. Consequently, our competitors may independently develop competing products that do not

infringe our patents or other intellectual property. Control over patented technology requires the Company to obtain formal assignment of patents and applications from third parties. Although the Company believes it has contracts requiring formal assignment of the patent properties in its patent portfolio, there is risk that the inventors and research partners now of record as owning these patent properties will refuse to execute documents confirming assignment of their rights to the Company or that litigation will be required to compel the execution of those documents. In the meantime, those inventors and research partners may claim to be co- owners of some of the patent portfolio. Because of the extensive time required for development, testing, and regulatory review of a potential product, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. To the extent our product candidates based on that technology are not commercialized ahead of this patent expiration, to the extent we have no other patent protection on such products, or to the extent that regulatory or patent extensions are not granted, those products might not have the robust protection we currently expect to enjoy. The background technologies used in the development of our product candidates are known in the scientific community, and it may be possible to duplicate the methods we use to create our product candidates, which makes us vulnerable to competition, without the ability to exclude others from potentially commercializing a similar product. If certain license agreements are terminated, our ability to continue clinical trials and commercially market products could be adversely affected. We are a party to various agreements that give us rights to use specified technologies applicable to research, development, and commercialization of our product candidates. If these agreements are voided or terminated, our product development, research, and commercialization efforts may be altered or delayed. Certain aspects of our technology rely on inventions developed using university or other third- party resources. The universities or third parties may have certain rights, as defined by law or applicable agreements, and may choose to exercise such rights. If we fail to comply with any terms or provisions of these agreements, our rights and our access to the universities' or third parties' resources could be terminated. The Exclusive License Agreement with the University of Miami dated November 20, 2014, as amended on December 11, 2017, and on March 3, 2021, **and the additional Exclusive License Agreement with the University of Miami, signed and effective as of July 18, 2024,** ~~requires~~ **require** the Company to pay fees and royalties and to make commercially reasonable efforts to achieve milestones. The University of Miami may terminate the **Exclusive License Agreement and the additional** Exclusive License Agreement for material breach if the fees and royalties are not paid, or if the milestones are not met and an extension to achieve the milestones is not agreed upon. Some of our employees, including but not limited to Dr. Hare, are employed by third party employers in addition to being employed or engaged as a consultant by the Company. Such employees and consultants may owe obligations to the third- party employers related to that employment. Those third- party employers may assert that they are entitled to assignment of some or all rights of new inventions made by such employees or consultants. If we are unable to conclusively prove that we are entitled to assignment of those rights, we may be required to negotiate co- ownership to or a license of those rights, if such an arrangement is available at all. If we are unable to protect the confidentiality of our proprietary information, trade secrets, and know- how, our competitive position could be impaired and our business, financial condition, results of operations, and prospects could be adversely affected. As disclosed above, some aspects of our technology, especially regarding manufacturing processes, are unpatented and maintained by us as trade secrets. In an effort to protect these trade secrets, we require our employees, consultants, collaborators, and advisors to execute confidential disclosure agreements before the commencement of their relationships with us. These agreements require that all confidential information developed by the individual or made known to the individual by us during the course of the individual' s relationship with us be kept confidential and not disclosed to third parties. These agreements, however, may not provide us with adequate protection against improper use or disclosure of confidential information, and these agreements may be breached. A breach of confidentiality could affect our competitive position. In addition, in some situations, these agreements may conflict with, or be subject to, the rights of third parties with whom our employees, consultants, collaborators, or advisors have previous employment or consulting relationships. Also, others may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets. Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information. The disclosure of our trade secrets could impair our competitive position and could have a material adverse effect on our business, financial condition, results of operations, and prospects. Third- party claims of intellectual property infringement may prevent or delay our product 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. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates, methods of making product candidates, and methods of using product candidates may give rise to claims of infringement of the patent rights of others. Third parties may assert that we infringe their patents or are otherwise employing their proprietary technology without authorization and may sue us. We are aware of several U. S. patents held by third parties covering potentially similar or related products and their manufacture and use. Generally, conducting clinical trials and other acts relating to FDA approval are not considered acts of infringement in the U. S. If and when Lomecel- B ™ ~~MSCs~~ **mesenchymal stem cells** are approved by the FDA, third parties may seek to enforce their patents by filing a patent infringement lawsuit against us. Patents issued in the U. S. by law enjoy a presumption of validity that can be rebutted only with evidence that is " clear and convincing, " a heightened standard of proof. We may not be able to prove in litigation that any patent enforced against us is invalid. Additionally, there may be third- party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. Some of those patent applications

may not yet be available for public inspection. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidates unless we obtain a license under the applicable patents, or until such patents expire or they are finally determined to be held not infringed, unpatentable, invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held not infringed, unpatentable, invalid or unenforceable. In either case, 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, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Parties making claims 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. They might seek an exclusion order from the International Trade Commission to prevent import of our product candidates. 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 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. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. We may become involved in lawsuits to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time consuming. Litigation may be necessary to enforce patents issued or licensed to us, to protect trade secrets or know- how, or to determine the scope and validity of the proprietary rights. Litigation, opposition, or other patent office proceedings could result in substantial additional costs and diversion of management focus. If we are ultimately unable to protect our technology, trade secrets, or know- how, we may be unable to operate profitably. Competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file infringement claims to protect our proprietary rights, which can be expensive and time- consuming, particularly for a company of our size. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or is unenforceable, or may refuse to enjoin the other party from using the technology at issue. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly. Litigation or other patent office proceedings may fail and, even if successful, may result in substantial costs and distraction to our management. We may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U. S. Furthermore, though we could seek protective orders where appropriate, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, during the course of this kind of litigation, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our Class A common stock could be significantly harmed. Our industry is highly competitive and subject to significant or rapid technological change. The biotechnology industry, including our fields of therapeutic interest, is highly competitive and subject to significant and rapid technological change. Accordingly, our success may depend, in part, on our ability to respond quickly to such change through the development and introduction of new products. Our ability to compete successfully against currently existing and future alternatives to our product candidates and systems and competitors who compete directly with us in the biopharmaceutical industry may depend, in part, on our ability to attract and retain skilled scientific and research personnel, develop technologically superior products, develop competitively priced products, obtain patent or other required regulatory approvals for our products, be an early entrant to the market and manufacture, market, and sell our products, independently or through collaborations. If a third party were to commercialize a competitive product, there is no assurance that we would have a basis for initiating patent infringement proceedings or that, if initiated, we would prevail in such proceedings. If our product candidates are approved by the FDA, then potential competitors who seek to introduce generic versions of our product candidates may seek to take advantage of the abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with our product candidates. The Biologics Price Competition and Innovation Act of 2009 might permit these potential competitors to enter the market using a shorter and less costly development program for a biosimilar product that competes with our products. As discussed, our ability to obtain one or more types of regulatory exclusivity upon product approval could impact the timing of approval of a competing biosimilar or interchangeable product. If all of the Company' s intellectual property has not been properly assigned to the Company, our business, financial condition, results of operation, and prospects could be adversely affected. While the Company believes that each patent application or patent has already been assigned or, if it has not yet been formally assigned, is under an obligation to be assigned to the Company either through direct employment agreements between the Company and the inventors, or through research agreements with a third party and the Company, if such is not the case, our business, financial condition, results of operations, and prospects could be adversely affected. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because

intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example: ● others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license; ● we or our licensors might not have been the first to make the inventions covered by the issued patents or patent application that we own or license; ● we or our licensors might not have been the first to file patent applications covering certain of our inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ● some or all of our licensors' pending patent applications may not lead to issued patents; ● issued patents that we own or license may be held invalid or unenforceable as a result of legal challenges by our competitors; ● our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets or in commercial markets where we do not have patent rights; ● we may not develop additional proprietary technologies that are patentable; and ● the patents of others may have an adverse effect on our business. Should any of these events occur, it could significantly harm our business, results of operations and prospects. Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline. During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our Class A common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In September 2011, the Leahy- Smith America Invents Act, or Leahy- Smith Act, was signed into law. The Leahy- Smith Act includes a number of significant changes to U. S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy- Smith Act, the U. S. transitioned in March 2013 to a " first inventor to file " system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of that we also made even if we had made the invention before the invention was made independently by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the U. S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications. The Leahy- Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review (PGR), inter partes review (IPR), and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position. Because of a lower evidentiary standard necessary to invalidate a patent claim in USPTO proceedings compared to the evidentiary standard in U. S. federal courts, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a patent claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' patent applications and the enforcement or defense of any resulting issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Changes in U. S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. 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 a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time- consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the U. S. and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third- party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. For example, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our licensors' 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 U. S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future. Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Patents have a limited lifespan. In the U. S., if all maintenance fees are timely paid, the natural expiration of a patent is

generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, are limited. Even if patents directed to our product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents directed to our product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we or our licensors do not obtain patent term extension for our product candidates and / or methods of their use, our business may be materially harmed. Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates and their methods of use, one or more of our U. S. patents may be eligible for limited patent term restoration. These laws permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA- approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Patent term extension may also not be granted because the product candidates and / or methods of use are determined not to be the first permitted marketing or use of those drug candidates in the jurisdiction in question, or patent term extension may not be granted because the product candidates and / or methods of use are determined not to constitute an " active ingredient " or use of an " active ingredient " that is eligible for patent term extension. Moreover, if patent term extension is granted then the additional time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. We may not be able to protect our intellectual property rights throughout the world. Although we have in- licensed issued patents and pending patent applications in the U. S. and certain other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the U. S. can be less extensive than those in the U. S. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the U. S. Consequently, we may not be able to prevent third parties from practicing our in- licensed inventions in all countries outside the U. S. or from selling or importing products made using our in- licensed inventions in and into the U. S. or other jurisdictions. Competitors may use our in- licensed 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 or our licensors have patent protection but enforcement is not as strong as that in the U. S. These products may compete with our product candidates, and our or our licensors ' patents or other intellectual property rights may not be effective or sufficient 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our or our licensors' patents or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our or our licensors' patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our or our licensors' patents at risk of being invalidated or interpreted narrowly and our or our licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our or our licensors' efforts to enforce or defend 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. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and / or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and / or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent ~~office~~ **offices** ~~' s~~ require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and after a patent has been granted. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, 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. If such an event were to occur, it could have a material adverse effect on our business, financial condition, and results of operations. **Risks Related to Regulatory Approval and Other Government Regulations** If we are not able to

successfully develop and commercialize our product candidates and obtain the necessary regulatory approvals, we may not generate sufficient revenues to continue our business operations. To generate sales revenue from our product candidates, we must conduct extensive preclinical studies and clinical trials to demonstrate that our product candidates are safe and effective, and we must obtain required regulatory approvals. Our early- stage product candidates may fail to perform as we expect. Moreover, our product candidates in later stages of development may fail to show the required safety and effectiveness for approval despite having progressed successfully through preclinical or initial clinical testing. We may need to devote significant additional research and development, financial resources, and personnel to develop commercially viable products. If our product candidates do not prove to be safe and efficacious in clinical trials, we will not obtain the required regulatory approvals. If we fail to obtain such approvals, we may not generate sufficient revenues to continue our business operations. In addition, we may experience numerous unforeseen events during, or as a result of, any future clinical trials that could delay or prevent our ability to receive marketing approval for, or to commercialize, ~~of~~ our product candidates, including: ● regulators, IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site; ● the FDA or other regulatory authorities may disagree with our clinical trial protocol, which may delay or prevent us from initiating our clinical trials; ● we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites, prospective CROs, and prospective local representatives which can be subject to extensive negotiation and may vary significantly among different local representatives, CROs and trial sites; ● the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, or subjects may drop out of these clinical trials or fail to return for post- treatment follow- up at a higher rate than we anticipate; ● our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators; ● delays and interruptions to our clinical trials could extend the duration of the trials and increase the overall costs to finish the trials as our fixed costs are not substantially reduced during delays; ● we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks; ● we may not have the financial resources available to begin and complete the planned trials, or the cost of clinical trials of any product candidates may be greater than we anticipate; ● the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our ~~therapeutic~~ **product** candidates may be insufficient or inadequate to initiate or complete a given clinical trial; and ● The FDA or other comparable foreign regulatory authorities may require us to submit additional data such as long- term toxicology studies or may impose other requirements before permitting us to initiate **or complete** a clinical trial. Our product development costs will increase if we experience delays in clinical trials or in obtaining marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. If we do not achieve our product development goals in the time frames we announce and expect, the approval and commercialization of our product candidates may be delayed or prevented entirely. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our ~~product~~ **products** ~~candidates~~ **following approval** and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition, and results of operations significantly. Even if we obtain regulatory approval of a product candidate, that approval may be subject to limitations on the indicated uses for which it may be marketed. Even after granting regulatory approval, the FDA and regulatory ~~agencies~~ **authorities** in other countries continue to review and inspect marketed products, manufacturers, and manufacturing facilities, which may create additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market or a withdrawal of the approved application by the FDA. Furthermore, FDA may require post- approval studies or other post- approval **requirements or** commitments. Failure to comply with or meet those requirements or commitments could result in withdrawal of the approved application by FDA. Regulatory ~~agencies~~ **authorities** may also establish additional regulations, policies, or guidance that could prevent or delay regulatory approval of our product candidates. We cannot market and sell our product candidates in the U. S. or in other countries if we fail to obtain the necessary regulatory approvals. We cannot sell our product candidates until regulatory ~~agencies~~ **authorities** grant marketing approval. The process of obtaining regulatory approval is lengthy, expensive, and uncertain, and the legal requirements for obtaining approval may change. It is likely to take several years to obtain the required regulatory approvals for our lead ~~signaling cell~~ product candidates, or we may never gain the necessary approvals. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our operations. Moreover, because our product candidates are all based on only three platform technologies, any adverse events in any of our clinical trials for one of our product candidates could negatively impact the clinical trials and approval process for our other product candidates. The pathway to regulatory approval for ~~MSCs~~ **mesenchymal stem cells** may be more complex and lengthier than for approval of a new conventional drug. Similarly, to obtain approval to market our cell products outside of the U. S., we, together with our collaborative partners, will need to file appropriate applications and submit clinical data concerning our product candidates and receive regulatory approval from governmental agencies, which in certain countries includes approval of the price we intend to charge for our product. We may encounter delays or rejections if changes occur in regulatory agency regulations, policies or guidance during the period in which we develop a product candidate or during the period required for review of any application for regulatory agency approval. If we are not able to obtain regulatory approvals for use of our product candidates under development, we will not be able to commercialize such products, and therefore may not be able to generate sufficient revenues to support our business. If we are not able to conduct our clinical trials properly and on schedule, marketing approval by FDA and other regulatory authorities may be delayed or denied. The completion of our clinical trials

may be delayed or terminated for many reasons, including, but not limited to, if: • the FDA does not grant INDs to test the product candidates in humans; • the FDA does not grant, or suspends, permission to proceed **with a clinical trial** and places a trial on clinical hold; • we are not able to identify sufficient clinical trial sites and / or clinical trial investigators to begin or complete a trial; • subjects do not enroll in our trials at the rate we expect; • subjects experience an unacceptable rate or severity of adverse side effects; • third- party clinical investigators do not perform our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, **Current Good Clinical Practices (** ~~cGCP~~ **cGCPs), cGMPs, Current Good Tissue Practices (cGTPs),** and **other** regulatory requirements, or other third parties do not perform data collection and analysis in a timely or accurate manner; • **third- party service providers acting as our local representative in communications with foreign regulatory authorities do not appropriately perform the services required or terminate a service agreement; •** inspections by the FDA or IRBs of clinical trial sites at research institutions participating in our clinical trials find regulatory violations that require us to undertake corrective action, suspend, or terminate one or more sites, or prohibit us from using some or all of the data in support of our marketing applications; or • one or more IRBs suspends or terminates the trial at an investigational site, precludes enrollment of additional subjects, or withdraws its approval of the trial. Our development costs will increase if we have material delays in our clinical trials, or if we are required to modify, suspend, terminate, or repeat a clinical trial. If we are unable to conduct our clinical trials properly and on schedule, marketing approval may be delayed or denied by the FDA. Final marketing approval of our product candidates by the FDA or other regulatory authorities for commercial use may be delayed, limited, or denied, any of which could adversely affect our ability to generate operating revenues. Final marketing approval for our product candidates may be delayed, limited, or denied if, among other factors: • we are unable to satisfy the significant clinical testing required to demonstrate safety and effectiveness of our product candidates before marketing applications can be filed with the FDA **or another regulatory authority** ; • **the** FDA ~~does~~ **or other regulatory authorities do** not agree with our interpretation of data obtained from preclinical and nonclinical animal testing or human clinical trials, even though the data can be interpreted in different ways; • we fail at any stage of the development and testing of our product candidates, which may take years to complete; • we receive negative or inconclusive results or reports of adverse side effects during a clinical trial; **• the FDA does not accept** ~~or~~ **our • application for filing; • the FDA issues us a complete response letter during its review of our filed application; or •** the FDA requires us to expand the size and scope of the clinical trials or to conduct one or more additional trials. If marketing approval for our product candidates is delayed, limited, or denied, our ability to market products, and our ability to generate product sales, could be adversely affected. There has been very little success in gaining FDA approval for an Alzheimer' s disease drug, and we have not had success to date in developing Alzheimer' s disease therapeutics. Despite billions of dollars invested by the biopharmaceutical industry in research programs to develop novel therapeutics for AD, there **are few** ~~have only been two~~ FDA- approved treatments. **For example,** Aduhelm ® (aducanumab- avwa), an amyloid beta- directed antibody, was approved by FDA in **June** 2021 under FDA' s accelerated approval pathway based upon the drug' s effect on a surrogate endpoint. FDA has required confirmatory trials of clinical benefit, and there is ongoing public discussion of the drug' s clinical benefit. Leqembi ™ (lecanemab- irmb), also an amyloid beta- directed antibody, was approved in January 2023 under the accelerated approval pathway as well and will therefore likewise require confirmatory trials. Many new types and classes of drugs have been developed and tested in AD, including monoclonal antibodies, g- secretase modulators and inhibitors, β- site amyloid precursor protein cleaving enzyme (BACE) inhibitors, receptor for advanced glycation end- products (" RAGE ") inhibitors, nicotinic agonists, serotonin subtype receptor (5HT6) antagonists, and others. The vast majority of these scientific programs have failed in clinical testing. Moreover, we have not had any success to date in developing therapeutics for AD, and **we** may never do so. We may not be able to secure and maintain research institutions to conduct our clinical trials. We rely on research institutions to conduct our clinical trials. Specifically, the limited number of bone marrow transplant centers further heightens our dependence on such research institutions for our future Phase 3 clinical trials. Our reliance upon research institutions, including hospitals and clinics, provides us with less control over the timing and cost of clinical trials and the ability to recruit subjects and delays may occur which may result in our incurring additional costs. If we are unable to reach agreement with suitable research institutions on acceptable terms, or if any resulting agreement is breached or terminated, we may be unable to quickly replace the research institution with another qualified institution on acceptable terms. Even if we do replace the institution, we may incur additional costs to conduct the trial at the new institution. We may not be able to secure and maintain suitable research institutions to conduct our clinical trials ~~. Producing and marketing an approved drug or other medical product is subject to significant and costly post- approval regulation. Even if approved for commercial sale, we may be required to conduct Phase 4 (i. e., post- marketing) clinical trials or comply with other post- marketing requirements or commitments for the products. Even if we obtain approval of a product, we can only market the product for the approved indications. After granting marketing approval, the FDA and regulatory agencies in other countries continue to review and inspect marketed products, manufacturers, and manufacturing facilities, creating additional regulatory burdens. Later discovery of previously unknown problems with a product, manufacturer, or facility may result in restrictions on the product or manufacturer, including a withdrawal of the product from the market or withdrawal of product approval. Further, regulatory agencies may establish different or additional regulations that could impact the post- marketing status of our products~~ . Our business involves the use of hazardous materials that could expose us to environmental and other liability. We have contract facilities in Florida that are subject to various local, state, and federal laws and regulations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals, and the use and disposal of hazardous or potentially hazardous substances, including chemicals, micro- organisms, and various radioactive compounds used in connection with our research and development activities. In the U. S., these laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act, and the Resource Conservation and Recovery Act. We cannot guarantee that accidental contamination or injury to our employees and third parties from hazardous materials will not occur. We do not have insurance to cover claims arising from our use and disposal of these hazardous substances other

than limited clean- up expense coverage for environmental contamination due to an otherwise insured peril, such as fire. Even if we receive regulatory approval of Lomecel- B ™ or any of our other product candidates, we will be subject to ongoing regulatory requirements and continued regulatory review, which may result in significant additional expense. We may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our ~~therapeutic~~ **product** candidates. Any regulatory approvals that we receive for Lomecel- B ™ or another product- candidate may require post- marketing surveillance to monitor the safety and efficacy of the product and may require us to conduct post- approval clinical studies. The FDA may also require a **Risk Evaluation and Mitigation Strategy (** REMS **)** program in order to approve our product candidates, which could entail requirements for..... a condition of approval of our therapeutic candidates, which could entail requirements for long- term patient follow- up, a medication guide, physician communication plans or additional elements to ensure safe use **(ETASU)** , 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 ~~therapeutic~~ **product** candidates, ~~we~~ **the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates** will ~~have~~ **be subject** to ~~comply with~~ **extensive and ongoing regulatory** requirements **. These requirements can** ~~including~~ **include** submissions of safety and other post- marketing information and reports ~~and ,~~ registration **,** as well as continued compliance with ~~cGMP~~ **cGMPs** and ~~Good Clinical Practice (" GCP~~ **cGCPs** ~~")~~ ,for any clinical trials that we conduct post- approval and applicable product tracking and tracing requirements.Compliance with ongoing and changing requirements takes substantial resources and,should we be unable to remain in compliance,our business could be materially and adversely affected.Manufacturers and their 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 regulations.As such,we and our contract manufacturers will be subject to continual review and inspections to assess compliance with ~~cGMP~~ **cGMPs** and adherence to commitments made in any 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 4 clinical trials and surveillance to monitor the safety **and efficacy of the product candidate** . 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, or the making of unsupported claims, may result in revisions to the approved labeling to add new safety information; imposition of post- market studies or clinical trials to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things: ~~•~~ • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or product recalls; ~~•~~ • fines **, 483 observations** , warning letters **, untitled letters,** or holds on clinical trials; ~~•~~ • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or withdrawal of approvals; ~~•~~ • product seizure or detention or refusal to permit the import or export of our ~~therapeutic~~ **product** candidates; and ~~•~~ • consent decrees or injunctions or the imposition of civil or criminal penalties **, or the invocation of the FDA' s Application Integrity Policy** . Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. However, companies may share truthful and not misleading information that is not inconsistent with the labeling. ~~The~~ **Companies may also share certain scientific and medical information about off- label uses of products in certain limited circumstances as part of scientific exchange. However, 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. Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example, changes to our manufacturing arrangements; additions or modifications to product labeling; the recall or discontinuation of our products; or additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business. Since the ACA was enacted, other legislative changes have been proposed and adopted in the United States. 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, including aggregate reductions of Medicare payments to providers of 2 % per fiscal year. These reductions went into effect on April 1, 2013, and subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will remain in effect through 2030, unless additional congressional action is taken. However, these Medicare sequester reductions were suspended from May 1, 2020, through December 31, ~~2020~~ **2021** , due to the COVID- 19 pandemic. The BBA also amended the ACA, effective January 1, 2019, by increasing the point- of- sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the " donut hole. " On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Moreover, increasing efforts by governmental and

third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our ~~therapeutic~~ **product** candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been 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. At the federal level, the ~~former~~ **first** Trump ~~administration~~ **Administration** ' s budget for fiscal year 2021 included a $ 135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out- of- pocket drug costs for patients, and increase patient access to lower- cost generic and biosimilar drugs. On March 10, 2020, the ~~former~~ **first** Trump ~~administration~~ **Administration** sent " principles " for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out- of- pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out- of- pocket expenses, and place limits on pharmaceutical price increases. The ~~former~~ **first** Trump ~~administration~~ **Administration** previously released a " Blueprint " to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out- of- pocket costs of drug products paid by consumers. The U. S. Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, Centers for Medicare and Medicaid Services (" CMS ") issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS' s policy change that was effective January 1, 2019. On July 24, 2020, ~~former~~ President Trump signed four Executive Orders aimed at lowering drug prices. The Executive Orders direct the Secretary of HHS to: (1) eliminate protection under an AKS safe harbor for certain retrospective price reductions provided by drug manufacturers to sponsors of Medicare Part D plans or pharmacy benefit managers that are not applied at the point- of- sale; (2) allow the importation of certain drugs from other countries through individual waivers, permit the re- importation of insulin products, and prioritize finalization of the proposed rule to permit the importation of drugs from Canada; (3) ensure that payment by the Medicare program for certain Medicare Part B drugs is not higher than the payment by other comparable countries (depending on whether pharmaceutical manufacturers agree to other measures); and (4) require Federally Qualified Health Centers, or FQHCs, participating in the 340B drug program to provide insulin and injectable epinephrine to certain low- income individuals at the discounted price paid by the FQHC, plus a minimal administrative fee. On October 1, 2020, the FDA issued the final rule allowing importation of certain prescription drugs from Canada. On August 6, 2020, ~~former~~ President Trump signed an additional Executive Order directing U. S. government agencies to encourage the domestic procurement of Essential Medicines, Medical Countermeasures, and Critical Inputs, which include among other things, active pharmaceutical ingredients and drugs intended for use in the diagnosis, cure, mitigation, treatment, or prevention of COVID- 19. The FDA has been directed to release a full list of Essential Medicines, Medical Countermeasures, and Critical Inputs affected by this Order by November 5, 2020. On September 13, 2020, ~~former~~ President Trump signed an Executive Order directing HHS to implement a rulemaking plan to test a payment model, pursuant to which Medicare would pay, for certain high- cost prescription drugs and biological products covered by Medicare Part B, no more than the most- favored- nation price (i. e., the lowest price) after adjustments, for a pharmaceutical product that the drug manufacturer sells in a member country of the Organization for Economic Cooperation and Development that has a comparable per- capita gross domestic product. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump ~~administration~~ **Administration** have each indicated that it will continue to seek new legislative and / or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payors. Additionally, on July 9, 2021, **former** President Biden issued an executive order directing the FDA to, among other things, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition. **It is unclear how other healthcare reform measures of the former Biden Administration, the second Trump Administration, or other efforts, if any, to challenge or repeal the ACA will impact our business. Nor is it clear whether other legislative changes will be adopted, if any, or how such changes would impact healthcare reform efforts of prior Administrations, affect the demand for our product candidates or future products, or otherwise impact our business. Legislative and regulatory agendas, as they relate to the healthcare and pharmaceutical industries and the economy as a whole, of the second Trump Administration and the U. S. Congress currently remain uncertain. Any new laws and initiatives may result in additional reductions in Medicare and other healthcare funding, such as the proposed cap on CRO indirect cost reimbursements by the National Institute of Health (NIH), or impose additional regulatory requirements on drug development or approval, which could have a material adverse effect on our clinical trial sites that rely on collaborations with university hospitals and research institutions funded in whole or in part by NIH grants, our future customers and accordingly, our financial operations.** At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our ~~therapeutic~~ **product** candidates for which we may obtain regulatory approval or the frequency with which any such ~~therapeutic~~ **product** candidate is prescribed or used. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved ~~therapeutic~~ **product** candidates due to the trend toward managed

healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes. Healthcare reform in the U. S. and other countries may materially and adversely affect us. In the U. S. and in many foreign jurisdictions, the legislative landscape continues to evolve. Our revenue prospects could be affected by changes in healthcare spending and policies in our target markets. We operate in a highly regulated industry and new laws or judicial decisions, or new interpretations of existing laws or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could materially and adversely affect us. There is significant interest in promoting healthcare reform, as evidenced by the enactment in the U. S. of the ACA in 2010. It is likely that many governments will continue to consider new healthcare legislation or changes to existing legislation. We cannot predict the initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified, or how they may affect us. The continuing efforts of governments, insurance companies, managed care organizations and other third- party payors to contain or reduce healthcare costs may adversely affect: ● the demand for any products for which we may obtain regulatory approval; ● our ability to set a price that we believe is fair for our products; ● our ability to generate revenues and achieve or maintain profitability; and ● the level of taxes that we are required to pay. Under the ACA, there are many programs and requirements for which details or consequences are still not fully understood. We are unable to predict what healthcare programs and regulations will ultimately be implemented at any level of government in or outside the U. S., but any changes that decrease reimbursement for our approved products, reduce volumes of medical procedures or impose new cost- containment measures could adversely affect us. Prescription Drug Pricing Reduction Act On August 16, 2022, the Inflation Reduction Act of 2022 was passed, which among other things, allows for CMS to negotiate prices for certain single- source drugs and biologics reimbursed under Medicare Part B and Part D, beginning with ten high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The legislation also caps Medicare beneficiaries' annual out- of- pocket drug expenses at $ 2, 000. The effect of Inflation Reduction Act of 2022 on our business and the healthcare industry in general is not yet known. **Additionally, it is not yet known whether, during the second Trump Administration, the Inflation Reduction Act of 2022 will be repealed or otherwise modified. Risks Related to Our Dependence on Third Parties** We rely on third parties to serve as local representatives in foreign jurisdictions where we perform our clinical trials. We rely on third parties to provide us with services related to our clinical trials conducted domestically and in foreign jurisdictions. In foreign jurisdictions, such third parties may serve as our local representative. Such local representative may perform services that include corresponding with the foreign regulatory authority on our behalf. If such third party fails to comply with applicable laws, misrepresents our intentions, fails to adequately provide the necessary services, or terminates its relationship with us, our clinical trial process may be delayed as we engage a new service provider, which would increase our anticipated development and commercialization costs. Any prolonged disruption could have a significant negative impact on our ability to effectively communicate with regulatory authorities, which could delay our pre- clinical and clinical trials. We rely on third parties to provide us with supplies to produce our product candidates. Any problems experienced by these third parties could result in a delay or interruption in the supply of our product candidates for our clinical trials and future approved products to our customers, which could have a material negative effect on our business. We rely on third parties to provide us with supplies to produce our product candidates. If the operations of these third parties are interrupted or if they are unable to meet our delivery requirements due to capacity limitations or other constraints, we may be limited in our ability to fulfill our supply of product candidates. Any prolonged disruption in the operations of third parties could have a significant negative impact on our ability to produce our product candidates for pre- clinical and clinical trials or sell our future approved products, could harm our reputation and could cause us to seek other third- party contracts, thereby increasing our anticipated development and commercialization costs. In addition, if we are required to change third parties for any reason, we will be required to verify that the new third parties maintain facilities and procedures that comply with quality standards required by the FDA and with all applicable regulations and guidelines. The delays associated with the qualification of a new third party could negatively affect our ability to develop product candidates or receive approval for any product candidates in a timely manner. We currently depend upon third parties for services and raw materials needed for the manufacture of our product candidates, and if these products are successfully commercialized, we may become dependent upon third parties for product distribution. If any of these third parties fail or are unable to perform in a timely manner, our ability to manufacture and deliver could be compromised. To produce our product candidates for use in clinical studies, and to produce any of our product candidates that may be approved for commercial sale, we require biologic media, reagents, and other highly specialized materials in addition to the bone marrow aspirate used in the manufacture of our product candidates. These items must be manufactured and supplied to us in sufficient quantities and in compliance with the regulations governing cGMP and ~~Current Good Tissue Practice (" cGTP ")~~ promulgated by the FDA. To meet these requirements, we have entered into supply agreements with firms that manufacture these components to meet cGMP and cGTP standards. Our requirements for these items are expected to increase if and when we transition to the manufacture of commercial quantities of our product candidates. In addition, as we proceed with our clinical trial efforts, we must be able to demonstrate to the FDA that we can manufacture our product candidates with consistent characteristics. While we currently produce our product candidates in our own facility, scaling up the manufacturing process would require us to develop a larger facility, which could require significant time and capital investments to conform to applicable manufacturing standards. Alternatively, we may be required to outsource some or all of our manufacturing, which would cause us to be materially dependent on these suppliers for supply of cGMP- and cGTP- grade components of consistent quality. Our ability to complete ongoing clinical trials may be negatively affected in the event that we are forced to seek and validate a replacement source for any of these critical components. If we are not able to obtain adequate supplies of these items of consistent quality from our third- party suppliers, it

will also be more difficult to manufacture commercial quantities of our product candidates that are approved for commercial sale. In addition, if one or more of our product candidates is approved for commercial sale, we intend to rely on third parties for their distribution. Proper shipping and distribution require compliance with specific storage and shipment procedures (e. g., prevention of damage to shipping materials and prevention of temperature excursions during shipment). Failure to comply with such procedures will necessitate return and replacement, potentially resulting in additional cost and causing us to fail to meet supply requirements. Use of third- party manufacturers may increase the risk that we will not have adequate quantities of our product candidates. We may use a third- party manufacturer to supply our product candidates for clinical trials or other uses at some point. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured ~~such components~~ **the product candidates** ourselves, including reliance on the third party for regulatory compliance and quality assurance, possible breach of the manufacturing agreement by the third party or termination or nonrenewal of the agreement by the third party, based on its own business priorities, at a time that is costly or inconvenient for us. Future contract manufacturers are or will be subject to all of the risks and uncertainties that we would be subject to if we manufactured the product candidates on our own. Similar to us, third- party manufacturers are subject to ongoing, periodic, and unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP and cGTP regulations and other governmental regulations and corresponding foreign standards. Although we do not control compliance by our contract manufacturers with these regulations and standards, we — as the manufacturer — assume the liabilities for our contract manufacturers' non- compliance. Our future contract manufacturers might not be able to comply with these regulatory requirements. If our third- party manufacturers fail to comply with applicable regulations, the FDA or other regulatory authorities could impose penalties on us, including fines, injunctions, civil penalties, consent decrees, invocation of FDA' s Application Integrity Policy, issuance of warning or untitled letters, denial of marketing approval of our product candidates, delays, suspensions, or withdrawals of approvals, license revocation, seizures or recalls of product candidates or our other products, operating restrictions, and criminal prosecutions. Any of these actions could significantly and adversely affect supplies of our product candidates or other products and could have a material adverse effect on our business, financial condition, and results of operations. We rely on third parties to conduct certain aspects of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any potential ~~therapeutic~~ **product** candidates. We depend, or may depend in the future, upon third parties to conduct certain aspects of our preclinical studies and clinical trials, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs. We will rely especially heavily on universities, medical institutions, CROs and other third parties for the conduct of our clinical trials. While we are obligated to ensure compliance ~~by~~ **of** third ~~–~~parties with **our** clinical trial protocols and other aspects of our clinical trials, and to have mechanisms in place to monitor our clinical trials, the sites at which they are conducted, and the investigators and other personnel involved in our clinical trials, we have limited control over these entities and individuals and limited visibility into their day- to- day activities, including with respect to their compliance with the approved clinical protocol. Our reliance on third parties does not relieve us of our regulatory responsibilities for ensuring that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards. We and these third parties are required to comply with ~~GCP~~ **cGCP** requirements, for ~~therapeutic~~ **product** candidates in clinical development. Regulatory authorities enforce ~~GCP~~ **cGCP** requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable ~~GCP~~ **cGCP** requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional preclinical studies 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 ~~GCP~~ **cGCP** requirements. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients meeting requirements for enrollment in the trial 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 violate federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Any third parties conducting aspects of our preclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our preclinical studies and clinical 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 therapeutic 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 preclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory requirements or for other reasons or if, due to federal or state orders ~~or absenteeism due to the COVID- 19 pandemic~~, they are unable to meet their contractual and regulatory obligations, our development timelines, including clinical development timelines, may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our ~~therapeutic~~ **product** candidates. As a result, our financial results and the commercial prospects for our ~~therapeutic~~ **product** candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. 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 may occur, which can materially impact our ability to meet our desired 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. If we decide to use third- party manufacturers

in the future, they will likely be dependent upon their own third- party suppliers, making us vulnerable to supply shortages and price fluctuations, which could harm our business. The operations of any future third- party manufacturers will likely be dependent upon their own third- party suppliers. A supply interruption or an increase in demand beyond a supplier' s capabilities could harm the ability of any future manufacturers to manufacture our product candidates or approved products until the manufacturer identifies and qualifies new sources of supply. Reliance on these third- party manufacturers and their suppliers could subject us to a number of risks that could harm our business, including: • interruption of supply resulting from modifications to or discontinuation of a supplier' s operations; • failure of third- party manufacturers or suppliers to comply with their own legal and regulatory requirements; • delays in product shipments resulting from uncorrected defects, reliability issues, or a supplier' s variation in a component; • a lack of long- term supply arrangements for key components with our suppliers; • inability to obtain adequate supply in a timely manner, or to obtain adequate supply on commercially reasonable terms; • difficulty and cost associated with locating and qualifying alternative suppliers for components in a timely manner; • production delays related to the evaluation and testing of products from alternative suppliers, and corresponding regulatory qualifications; • delay in delivery due to suppliers prioritizing other customer orders over ours or those of our third- party manufacturers; • damage to our brand reputation caused by defective components produced by the suppliers; and • fluctuation in delivery by the suppliers due to changes in demand from us, our third- party manufacturers or their other customers. Any interruption in the supply of components of our product candidates or future products or materials, or our inability to obtain substitute components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demands of our clinical trials or of our future customers, which would have an adverse effect on our business. We will depend on third- party distributors in the future to market and sell our future products which will subject us to a number of risks. We will depend on third- party distributors to sell, market, and service our future products in our intended markets. We are subject to a number of risks associated with reliance upon third- party distributors including: • lack of day- to- day control over the activities of third- party distributors; • failure of the third- party distributors to comply with their own legal and regulatory requirements; • third- party distributors may not commit the necessary resources to market and sell our future products to our level of expectations; • third- party distributors may terminate their arrangements with us on limited or no notice or may change the terms of these arrangements in a manner unfavorable to us; and • disagreements with our future distributors could result in costly and time- consuming litigation or arbitration which we could be required to conduct in jurisdictions with which we are not familiar. If we fail to establish and maintain satisfactory relationships with our future third- party distributors, our revenues and market share may not grow as anticipated, and we could be subject to unexpected costs which could harm our results of operations and financial condition. The successful commercialization of our current or future product candidates will depend on obtaining reimbursement from government and third- party payors, and price controls in foreign markets could adversely affect our future profitability. If we successfully develop and obtain necessary regulatory approvals, we intend to sell our product candidates in countries such as the U. S. and Japan. In the U. S., the market for any pharmaceutical product is affected by the availability of reimbursement from government and third- party payors, such as government health administration authorities, private health insurers, health maintenance organizations, and pharmacy benefit management companies. MSC therapies may be expensive compared with conventional pharmaceuticals, due to the higher cost and complexity associated with the research, development, and production of product candidates, the small size and large geographic diversity of the target patient population for some indications, and the complexity associated with distribution of signaling cell therapies which require special handling, storage, and shipment procedures and protocols. This, in turn, may make it more difficult for us to obtain adequate reimbursement from government and third- party payors, particularly if we cannot demonstrate a favorable cost- benefit relationship. Government and third- party payors may also deny coverage or offer inadequate levels of reimbursement for our potential products if they determine that the product has not received appropriate clearances from the FDA or other government ~~regulators~~ **regulatory authorities** or is experimental, medically unnecessary or inappropriate. In some other countries where we may seek to market our products, such as Japan, the pricing of prescription pharmaceutical products and services and the level of government reimbursement are subject to governmental control. In these countries, pricing negotiations with governmental authorities can take six to twelve months or longer after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our potential future collaborators may be required to conduct one or more clinical trials that compare the cost effectiveness of our product candidates or products to other available therapies. Conducting one or more additional clinical trials would be expensive and could result in delays in commercialization of our product candidates. Managing and reducing health care costs has been of great concern in the U. S. and various foreign governments. Although we do not believe that any recently enacted or presently proposed legislation in any jurisdictions in which we currently operate should impact our business based on our current model, we might be subject to future regulations or other cost- control initiatives that materially restrict the pricing or reimbursement of our products. In addition, payors are continuing to limit reimbursements for newly approved health care products while also challenging the price and cost- effectiveness of medical products and services. In particular, payors may limit the indications for which they will reimburse patients who use any products that we may develop. Finally, cost control initiatives could decrease the price for products that we may develop, which could result in lower product revenues to us. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected. We may enter into arrangements with third- party collaborators to help us develop our product candidates and commercialize our products, and our ability to commercialize such products may be impaired or delayed if collaborations are unsuccessful. We are parties to various collaborations with third parties, and **we** may enter into additional collaborations in the future. We are dependent upon the success of our current and any future collaborators in performing their responsibilities in connection with the relevant collaboration. If we fail to maintain these collaborative relationships for any reason, we would need to perform the activities that we currently anticipate would be performed by our collaborators on our own at our sole expense. This could

substantially increase our capital needs, and we may not have the capability or financial capacity to undertake these activities on our own, or we may not be able to find other collaborators on acceptable terms, or at all. This may limit the programs we are able to pursue and result in significant delays in the development, sale, and manufacture of our product candidates and **future approved** products, and may have a material adverse effect on our business, financial condition, and results of operations. Our dependence upon our current and potential future collaborations exposes us to a number of risks, including that our collaborators (i) may fail to cooperate or perform their contractual obligations, including financial obligations, (ii) may choose to undertake differing business strategies or pursue alternative technologies, or (iii) may take an opposing view regarding ownership of clinical trial results or intellectual property. Due to these factors and other possible events, we could suffer delays in the research, development, or commercialization of our product candidates and future **approved** products or we may become involved in litigation or arbitration, which could be time consuming and expensive. We additionally may be compelled to split revenue with our collaborators, which could have a material adverse effect on our business, 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. From time to time, we may evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products or product candidates, 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; ● the issuance of our equity securities; ● assimilation of operations, intellectual property and products or product candidates of an acquired company, including difficulties associated with integrating new personnel; ● the diversion of our management' s attention from our existing 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 to receive marketing approvals for their existing products or product candidates; and ● our inability to generate revenue from acquired technology, product candidates and / or approved 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 or pursue partnerships in the future, 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. Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct **,** or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the U. S. and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing, patient support and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our preclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a Code of **Business Conduct and** Ethics applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third- 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. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 civil, criminal and administrative penalties, damages, monetary fines, 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. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices ~~may~~ **do** not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it,

could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements. The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union **(EU)** . The provision of benefits or advantages to physicians is governed by the national anti- bribery laws of **EU** ~~European Union~~ Member States ~~, such as the U. K. Bribery Act 2010~~ . Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain **EU** ~~European Union~~ Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual **EU** ~~European Union~~ Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the **EU** ~~European Union~~ Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. The collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the **EU** ~~European Union~~ , including personal health data, is subject to the General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third- party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the **EU** ~~European Union~~ , including the U. S., and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to € 20 million or 4 % of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. Compliance with the GDPR is a rigorous and time- intensive process that may increase our cost of doing business or require us to change our business practices and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. **Risks Related to the Discovery, Development and Commercialization of Our Product Candidates** Interim, " topline " and preliminary data from our clinical trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then- available data. These results and related findings and conclusions are based on assumptions, estimations, calculations and conclusions, and are subject to change following the generation of additional data or a more comprehensive review of the data related to the particular study or trial. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data is available. From time to time, we may also disclose interim data from our preclinical studies and clinical trials. For example, we have reported interim data from our ongoing clinical trials elsewhere in this report. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available or as subjects from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Class A common stock. Further, others, including regulatory ~~agencies~~ **authorities** , may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and the value of our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could have a material adverse effect on our business, financial condition, and results of operations. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on other product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. The U. S. FDA, Japanese PMDA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of

their jurisdiction. We are conducting several trials in the U. S., and previously entered into a sponsored clinical research agreement with the National Center for Geriatrics and Gerontology and Juntendo University Hospital in Japan to explore the safety and efficacy of Lomecel- B ™ in older, frail Japanese subjects. This study in Japan **was** ~~has been~~ discontinued by the Company in 2024. The acceptance of study data by the U. S. FDA, Japanese PMDA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the U. S., the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the U. S. population and U. S. medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to cGCP requirements; and (3) the FDA is able to validate the data through an on- site inspection or other appropriate means. The FDA may accept the use of some foreign data to support a marketing approval if the clinical trial meets certain requirements. Additionally, the FDA' s clinical trial requirements, including the adequacy of the subject population studied and statistical powering, must be met. Furthermore, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, PMDA or any applicable foreign regulatory authority will accept data from trials conducted outside of its respective jurisdiction. If the FDA, PMDA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time- consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction. Obtaining and maintaining regulatory approval of a product in one jurisdiction does not mean that we will be successful in obtaining or maintaining regulatory approval in other jurisdictions. Obtaining and maintaining regulatory approval of a product in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or PMDA grants marketing approval of a product, comparable regulatory authorities in **other** foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Moreover, product types or regulatory classifications, as well as approval procedures, vary among jurisdictions and can involve requirements and administrative review periods different from those in the U. S., including different or additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the U. S., a product 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 establishing and maintaining 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 or any future collaborator fails to comply with the regulatory requirements in international markets or fails 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. The FDA and other regulatory ~~agencies~~ **authorities** actively enforce the laws and regulations prohibiting the promotion of off- label uses. If any of our product candidates are approved and we are found to have improperly promoted off- label uses of those products, we may become subject to significant liability. The FDA and other regulatory ~~agencies~~ **authorities** strictly regulate the promotional claims that may be made about **approved** prescription products ~~, such as our product candidates, if approved~~ . In particular, an approved product may not be promoted for uses that are not approved by the FDA or such other regulatory ~~agencies~~ **authorities** as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved ~~label~~ **labeling** , which is within their purview as part of their practice of medicine. If we are found to have promoted such off- label uses, however, we may become subject to significant liability. The U. S. federal government has levied large civil and criminal penalties against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. The FDA may also issue a public warning letter or untitled letter to the company. If we cannot successfully manage the promotion of our future approved products, we could become subject to significant liability, which would materially adversely affect our business and financial condition. If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates, and we do not obtain or face delays in obtaining FDA approval of a diagnostic test, we will not be able to commercialize such future approved product and our ability to generate revenue will be materially impaired. If safe and effective use of any of our product candidates depends on the use of an in vitro diagnostic test that is not otherwise commercially available, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our product candidates if at all. According to FDA guidance, if the FDA determines that a companion diagnostic is essential to the safe and effective use of a novel therapeutic product or indication, then the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to create or obtain one that would be subject to its own regulatory approval requirements. The process of obtaining or creating such a diagnostic is time consuming and costly. Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities. The approval of a companion diagnostic as part of the therapeutic product labeling limits the use of the therapeutic product to only ~~those~~ **certain** patients **for** ~~who~~ **whom** ~~express the specific genetic alteration that~~ the companion diagnostic was developed ~~to detect~~ . If the FDA, PMDA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product candidates, whether before or after it obtains marketing approval, we, and / or future collaborators, may encounter difficulties in developing and obtaining approval for such product candidate. Any delay or failure by us or third- party collaborators to develop or obtain

regulatory approval of a companion diagnostic could delay or prevent approval of a product candidate or continued marketing of an approved product. We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials of a product candidate or commercializing an approved product on a timely or profitable basis, if at all. We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through an expedited review program, and if we are unable to do so, then we could face increased expense to obtain, and delays in the receipt of, necessary marketing approvals. We may in the future seek approval for one or more of our product candidates under one of the FDA' s expedited review programs for serious conditions. These programs are available to sponsors of therapies that address an unmet medical need to treat a serious condition. The qualifying criteria and requirements vary for each expedited program. Prior to seeking review under one of these expedited programs for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive marketing approval through an expedited review program. There can be no assurance that, after our evaluation of the FDA' s feedback and other factors, we will decide to pursue one or more of these expedited review programs. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue one or more of these expedited programs, even if we initially decide to do so. Furthermore, the FDA could decide not to grant our request to use one or more of the expedited review programs for a product candidate, even if the FDA' s initial feedback is that the product candidate would qualify for such program (s). Moreover, the FDA can decide to stop reviewing a product candidate under one or more of these expedited review programs if, for example, the conditions that warranted expedited review no longer apply to that product candidate. Some of these expedited programs (e. g., accelerated approval) also require post- marketing clinical trials to be completed and, if any such required trial fails, the FDA could withdraw the approval of the product. If one of our product candidates does not qualify for any expedited review program, then this could result in a longer time period to approval and commercialization of such product candidate, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace. The FDA' s Rare Pediatric Disease ~~designation~~ **Designation** for Lomecel- B ™ for HLHS does not guarantee that we will receive a priority review voucher if the product is approved for this indication, nor does the receipt of Orphan Drug Designation for Lomecel- B ™ for HLHS guarantee that we will receive seven years of market exclusivity if the product is approved for this indication. As noted elsewhere in this report, the FDA has granted both Rare Pediatric Disease ~~designation~~ **Designation** and Orphan Drug Designation status for the use of Lomecel- B ™ to treat HLHS. These designations were granted following our Phase 1 safety- focused ELPIS trial, However, even though the FDA has granted Lomecel- B ™ Rare Pediatric Disease ~~designation~~ **Designation** for the treatment of HLHS, receipt of Rare Pediatric Disease ~~designation~~ **Designation** does not provide any guarantee that we would or will receive a priority review voucher **(PRV)** upon approval for this indication. This voucher program has been extended **in the past** , but there is no guarantee the Congress will extend it again in the future. **As of December 20, 2024, the rare pediatric disease PRV program has expired and PRVs may no longer be awarded unless the drug has already received a Rare Pediatric Disease Designation as of that date, and the application is approved no later than September 30, 2026.** If we do receive a **PRV** ~~priority review voucher~~ upon approval of Lomecel- B ™ for this indication, then that voucher permits a future application to be treated as a priority review application by the FDA. The FDA does not guarantee that the future application will be reviewed in a particular period of time **, and a future application that redeems a PRV must submit an additional user fee in addition to any regularly assessed user fees** . Vouchers may be transferred, including by sale; accordingly, there is a market for these vouchers at prices that have historically fluctuated. If we receive a voucher, we cannot guarantee that we will use it or that there will be a market to transfer or sell the voucher. Further, receipt of Orphan Drug Designation does not guarantee that we will receive seven years of market exclusivity upon approval for this indication unless all appropriate statutory and regulatory criteria are met, the interpretation of which, as noted, has been in flux. **Orphan Drug designation can also be rescinded in specific circumstances and, if the designation is withdrawn after drug approval, any orphan drug exclusivity awarded would be rescinded as well.** The FDA has also granted Fast Track Designation to Lomecel- B ™ for the treatment of HLHS. A Fast Track designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not necessarily increase the likelihood that our product candidates will receive marketing approval **for this indication. The FDA' s Regenerative Medicine Advanced Therapy (RMAT) and Fast Track designations for Lomecel- B ™ for mild AD does not guarantee that Lomecel- B will be developed or approved faster, or more successfully, than if these designations were not granted, and FDA could rescind these designations if the qualifying criteria are no longer met. FDA has granted two designations to Lomecel- B ™ for the treatment of mild AD based on the completion of certain clinical trials: Regenerative Medicine Advanced Therapy (RMAT) Designation and Fast Track Designation. RMAT Designation may be granted to a regenerative medicine therapy, including a cell therapy, that is intended to treat, modify, reverse, or cure a serious or life- threatening disease or condition when preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such disease or condition. An RMAT Designation can provide earlier and more intensive interactions with FDA during the drug development process. However, these interactions may not lead to a faster or more successful Lomecel- B ™ development program or approval for mild AD because FDA review priorities may change, or the designation could be withdrawn if the qualifying criteria for RMAT Designation are no longer met. FDA has also granted Fast Track Designation to Lomecel- B ™ for the treatment of mild AD. Products are eligible for this designation if they are intended to treat a serious or life- threatening disease or condition, and nonclinical or clinical data demonstrate the potential to address unmet medical needs for the disease or condition. Benefits of a Fast Track Designation can include more frequent interactions with FDA, as well as rolling review of portions of an application before the complete application is submitted. However, a Fast Track Designation does not guarantee that we will have a faster or more successful Lomecel- B ™ development program or approval for mild AD because FDA review priorities may change, or the designation could**

be withdrawn if the qualifying criteria for Fast Track Designation are no longer met . We may face difficulties from changes to current regulations and future legislation, both in the U. S. as well as in other foreign jurisdictions where we may be operating. Existing regulations and regulatory policies may change **,** and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U. S. 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. For example, the ACA substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacted the U. S. pharmaceutical industry. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. Other legislative changes have been adopted since the ACA was enacted, including mandatory sequestration (e. g., aggregate reductions of Medicare payments to providers up to 2 %), which will remain in effect through fiscal year 2031 absent additional Congressional action. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and legislation designed, among other things, to reform government program reimbursement methodologies for pharmaceutical products and bring more transparency to product pricing and the relationship between pricing and manufacturer patient programs. The Inflation Reduction Act of 2022, signed into law by **former** President Biden on August 16, 2022, contains several significant provisions regarding drug pricing, coverage, and reimbursement that could materially impact our business. Among the key provisions related to drug pricing, Title XI of the Social Security Act would be amended to direct the Secretary of the U. S. Department of Health and Human Services to establish a Drug Price Negotiation Program to lower prescription drug costs for people with Medicare and reduce drug spending by the federal government for certain prescription drugs. Each year, under the Drug Price Negotiation Program, the Secretary would identify a small number of single- source brand name drugs or biologics, without generic or biosimilar competition, and for which certain periods of time have elapsed since drug approval, that are covered under Medicare Part D (starting in 2026) and Part B (starting in 2028). These selected drugs would be subject to negotiation to establish a maximum fair price charged to Medicare. Manufacturers that are noncompliant with the drug price negotiation program would be subject to an excise tax and other civil monetary penalties during noncompliance periods. Other important drug pricing provisions include a mandatory rebate for drug manufacturers of certain Medicare Part B and Part D drugs with prices increasing faster than inflation; caps on annual out- of- pocket spending for Medicare beneficiaries; ~~;~~and limits of $ 35 for monthly cost- sharing for insulin products under Medicare Part D and a cap of 20 % of the Medicare- approved amount after reaching the Medicare Part B deductible. In addition, other legislative changes have been proposed and adopted in the U. S. that could impact our future business and operations, including those that may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our product candidates, if approved, and accordingly, our business, financial condition, and results of operations. Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from third- party payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the **future** marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Our relationships with healthcare professionals, clinical investigators, CROs and payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers and payors play a primary role in the recommendation and prescription of any product candidates for which we obtain future marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. **Although our products are not currently reimbursed by government healthcare programs such as Medicare or Medicaid, any future reimbursement from federal and / or state healthcare programs could expose our business to broadly applicable fraud and abuse laws and other healthcare laws and regulations that would regulate the business.** Restrictions under applicable federal and state healthcare laws and regulations include the following: ~~•~~ **Federal**

Stark Law. If in the future some of our revenues are derived from federal healthcare programs, we may be subject to the federal self- referral prohibitions, commonly known as the Stark Law. Where applicable, this law prohibits a physician from referring Medicare patients to an entity providing " designated health services " such as laboratory and other diagnostic services and prescription drugs that are furnished at an entity if the physician or a member of such physician' s immediate family has a " financial relationship " with the entity, unless an exception applies. A determination of liability under the Stark Law could have a material adverse effect on our business, financial condition and results of operations; • Federal Anti- Kickback Statute. We will also be subject to the federal Anti- Kickback Statute **if any of our services become reimbursable by government healthcare programs. The Anti- Kickback Statute is broadly worded and** prohibits ~~, among other --~~ **the** ~~things, persons and entities from knowingly --~~ **knowing** and ~~willfully --~~ **willful offer, payment,** ~~soliciting -~~ **solicitation** ~~, offering, receiving~~ or ~~providing~~ **receipt of any form of** remuneration ~~, directly or indirectly, in cash or in kind, to induce or reward, or~~ in return for, ~~either~~ **or to induce, (i)** the referral of ~~an individual~~ **a person covered by Medicare, Medicaid or other governmental programs, (ii) the furnishing or arranging** for ~~,~~ **the furnishing of items** or **services reimbursable under Medicare, Medicaid or** ~~the~~ **other governmental programs or (iii) the** ~~purchase~~ **purchasing** , **leasing or** ~~order~~ **ordering** or **arranging or** ~~recommendation ---~~ **recommending** ~~of~~ **purchasing** , **leasing or ordering of** any ~~good~~ **item** or service **reimbursable** ~~, for which payment may be made~~ under ~~a federal healthcare program such as~~ Medicare ~~and ,~~ Medicaid ~~. A person~~ or **other governmental programs. Violations** ~~entity does not need to have actual knowledge~~ of the federal Anti- Kickback Statute **may result** ~~or specific intent to violate it~~ in ~~order to~~ **civil monetary penalties, criminal penalties and exclusion from participation in government healthcare programs, including Medicare and Medicaid. Imposition of any of these remedies could** have ~~committed~~ a ~~violation. In addition~~ **material adverse effect on our business** , **financial condition and results of operations, if in** the **future we provide services reimbursable by** government **healthcare programs** ~~may assert that a claim including items or services resulting from a violation of the U~~ . ~~• S. federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil~~ False Claims Act **. Both federal and state government agencies have continued civil and criminal enforcement efforts as part of numerous ongoing investigations of healthcare companies and their executives and managers. Although there are a number of civil and criminal statutes that can be applied to healthcare providers, a significant number of these investigations involve the FCA. These investigations can be initiated not only by the government but also by a private party asserting direct knowledge of fraud. These " qui tam " whistleblower lawsuits may be initiated against any person or entity alleging such person or entity has knowingly or recklessly presented, or caused to be presented, a false or fraudulent request for payment from the federal government or has made a false statement or used a false record to get a claim approved. In addition, the improper retention of an overpayment for 60 days or more is also a basis for an FCA action, even if the claim was originally submitted appropriately. Penalties for FCA violations include fines and may provide the basis for exclusion from federally funded healthcare programs** ; ~~● the federal~~ **• State Fraud and Abuse Laws. Several states have also adopted or may adopt similar self- referral, anti- kickback, fraud, whistleblower and** false claims ~~and civil monetary penalties~~ laws ~~, including~~ **as described above. The scope of these laws and the interpretations of** ~~the~~ **them vary by jurisdiction and are** ~~civil False Claims Act, which can be~~ enforced by **local courts** ~~private citizens through civil whistleblower or qui tam actions, prohibit individuals or entities from, among other things, 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~~ **and regulatory authorities** ~~obligation to pay money to the federal government; the federal Health Insurance Portability and Accountability Act of 1996~~ , **each with broad discretion** ~~or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters~~ . **A determination** ~~Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge~~ of ~~the~~ **liability under such** ~~statute --~~ **state fraud and abuse laws could result in fines and penalties and restrictions on** ~~or~~ **our ability** ~~specific intent~~ to **operate** ~~violate it~~ in **these jurisdictions. •** ~~order to have committed a violation; ●~~ HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ~~● the~~ **• Physician Payments Sunshine Act. The** federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to annually report to CMS starting in 2022 information regarding payments and other transfers of value to physicians, certain other healthcare providers and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported will be publicly available on a searchable website, with disclosure required annually; and **• Other Healthcare** ~~● analogous state and foreign laws~~ **Laws** ~~and regulations, such as state anti- kickback and~~ **. The FCA established several separate criminal penalties for making** false **or fraudulent** claims ~~laws, may apply~~ to **insurance companies** ~~sales or marketing arrangements~~ and **other** ~~claims involving healthcare items or services reimbursed by~~ non- governmental ~~third- party payors~~ **payers of healthcare services. Under FCA, these two additional federal crimes are: " Healthcare Fraud " and " False Statements Relating to Healthcare Matters. " The Healthcare Fraud statute prohibits knowingly and recklessly executing a scheme or artifice to defraud any healthcare benefit program** , including private ~~insurers~~ **payers. A violation of this statute is a felony and may result in fines, imprisonment, or exclusion from government sponsored programs. The False Statements Relating to Healthcare Matters statute prohibits knowingly and willfully falsifying, concealing, or covering up a material fact by any trick, scheme or device or making any materially false, fictitious, or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items, or services. A violation of this statute is a felony and may result in fines or imprisonment. This statute could be used by the government to assert criminal liability if a healthcare provider knowingly fails to refund an overpayment. In addition,**

the Civil Monetary Penalties Law imposes civil administrative sanctions for, among other violations, inappropriate billing of services to federally funded healthcare programs and employing or contracting with individuals or entities who are excluded from participation in federally funded healthcare programs. Moreover, a person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration, including waivers of copayments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary' s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable for civil monetary penalties. Furthermore, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries can also be held liable under the Anti- Kickback Statute and civil False Claims Act, which can impose additional penalties associated with the wrongful act. The routine waivers of copayments and deductibles offered to patients covered by commercial payers may also implicate applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts, and statutory or common law fraud. Additionally, pharmaceutical and device manufacturers may be subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business, including, without limitation, the Consumer Fraud Act, fee splitting, patient brokering, and other state and federal laws and regulations, as well as similar foreign laws in jurisdictions outside the U. S., where applicable involving various pharmaceutical regulation issues, fraud and abuse, price reporting, data privacy and security, and transparency . Some state laws require biotechnology companies to comply with the biotechnology industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. ~~Some~~ **Further** state laws require biotechnology companies to report information on the pricing of certain drug products. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, **as previously stated,** the collection and use of health data in the **EU** ~~European Union~~ is governed by the ~~General Data Protection Regulation, or the~~ GDPR, which extends the geographical scope of **EU** ~~European Union~~ data protection law to non- **EU** ~~European Union~~ entities under certain conditions, tightens existing **EU** ~~European Union~~ data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. 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. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states. Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on- going substantial costs. It is possible that governmental authorities will conclude that our business practices ~~may~~ **do** not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, temporary or permanent debarment, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. A variety of factors, including inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel, **collection** ~~accept payments~~ of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result of these and other factors. In particular, the FDA has relatively limited experience with regulating novel ~~regenerative medicines~~ **product candidates** like ours, and this may add to its already fluctuating review times. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times, and certain regulatory ~~agencies~~ **authorities** , such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. Separately, since March 2020 when foreign and domestic inspections of facilities were largely placed on hold in connection with the COVID- 19 pandemic, the FDA has been working to resume pre- pandemic levels of inspections, including routine surveillance, bioresearch monitoring and pre- approval inspections on a prioritized basis. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel or for other reasons, and the FDA does not determine that a remote interactive evaluation will be adequate, the agency has stated that it generally intends

to issue, depending on the circumstances, a complete response letter or defer action on the application until an inspection can be completed. During the COVID- 19 public health emergency, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. Regulatory authorities outside the U. S. may adopt similar restrictions or other policy measures in response to a pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition, and results of operations. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. We may not be successful in our efforts to identify or discover additional product candidates in the future. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield **viable** product candidates for clinical development for a number of reasons, including: ~~•~~ **•** our inability to design such product candidates with the pharmacological properties that we desire or **that result in** attractive pharmacokinetics; ~~•~~ **•** our inability to design and develop a suitable manufacturing process; or ~~•~~ **•** potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to ~~be regenerative medicines that will~~ receive marketing approval and achieve market acceptance. Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify other suitable treatments for preclinical and clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position and adversely impact our stock price. Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing. Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, or if the laws and regulations regarding animal testing otherwise change, our research and development activities may be interrupted, delayed or become more expensive. Our business activities may be subject to the U. S. Foreign Corrupt Practices Act, or the FCPA, and similar anti- bribery and anti- corruption laws of other countries in which we operate, as well as U. S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them. If we further expand our operations outside of the U. S., we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. Our business activities may be subject to the FCPA and similar anti- bribery or anti- corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third- party intermediaries from offering, promising, giving or authorizing the provision of anything of value, either directly or indirectly, to a non- U. S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non- U. S. governments. Additionally, in many other countries, hospitals owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. ~~Recently~~ **In recent years,** the ~~Securities and Exchange Commission (~~SEC ~~)~~ and Department of Justice (DOJ) have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. **On February 10, 2025, President Trump signed an executive order titled " Pausing Foreign Corrupt Practices Act Enforcement to Further American Economic and National Security. The executive order ordered the Attorney General of the United States to (i) review in detail all existing FCPA investigations or enforcement actions, (ii) to take appropriate action to restore proper bounds on FCPA enforcement, and (iii) cease initiation of any new FCPA investigations or enforcement actions unless the Attorney General determines that an individual exception should be made.** There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws **. It is additionally uncertain whether our employees, agents, or contractors, or those of our affiliates, would meet the requirements of any individualized exception to the FCPA**

enforcement moratorium imposed by President Trump' s executive order . Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition. In addition, our products and technology may be subject to U. S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products and technology, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U. S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U. S. sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and / or denial of certain export privileges. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell access to our products would likely adversely affect our business. **Risks Related to Our Class A Common Stock and the Securities Market** The price of our Class A common stock has been, and may continue to be, volatile, which could result in substantial or total losses for investors. The trading price of our Class A common stock has been ~~,~~ and may continue to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our Class A common stock, regardless of our actual operating performance. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this report, these factors include: ~~•~~ the timing and results, or perception of the results, of preclinical studies and clinical trials of our product candidates or those of our competitors; ~~•~~ the success of competitive products or announcements by potential competitors of their product development efforts; ~~•~~ regulatory actions with respect to our or our competitors' product candidates or approved products; ~~•~~ actual or anticipated changes in our growth rate relative to our competitors; ~~•~~ regulatory or legal developments in the U. S. and other countries; ~~•~~ developments or disputes concerning patent applications, issued patents or other proprietary rights; ~~•~~ the recruitment or departure of key personnel; ~~•~~ announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, or capital commitments; ~~•~~ actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts; ~~•~~ fluctuations in the valuation of companies perceived by investors to be comparable to us; ~~•~~ market conditions in the pharmaceutical and biotechnology sector; ~~•~~ changes in the structure of healthcare payment systems; ~~•~~ Class A common stock price and volume fluctuations attributable to inconsistent trading volume levels of our Class A common stock; ~~•~~ announcement or expectation of additional financing efforts; ~~•~~ sales of our Class A common stock by us, our insiders, or our other stockholders; ~~•~~ expiration of market stand- off or lock- up agreements; and ~~•~~ general economic, industry and market conditions. The realization of any of the above risks or any of a broad range of other risks, including those described in this " Risk Factors " section, could have a dramatic and adverse impact on the market price of our Class A common stock. Additionally, in the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources. There may not be sufficient liquidity in the market for our securities in order for investors to sell their shares. We are a small company that is relatively unknown to stock analysts, stockbrokers, institutional investors and others in the investment community that generate or influence sales volume, and even if we came to the attention of such persons, they tend to be risk- averse and may be reluctant to follow an unproven company such as ours or purchase or recommend the purchase of our shares until such time as we became more seasoned and viable. There may be periods of several days or more when trading activity in our shares is minimal as compared to a mature issuer which has a large and steady volume of trading activity that will generally support continuous sales without an adverse effect on share price. It is possible that a broader or more active public trading market for our common stock will not develop or be sustained, or that trading levels will not continue. These factors may materially adversely affect the market price of our Class A common stock, regardless of our performance. We will need to raise substantial additional funding. If we are unable to raise capital when needed, we could be forced to delay, scale back or discontinue some of our ~~therapeutic~~ **product** candidate development programs or commercialization efforts. The development of pharmaceutical drugs is capital intensive. We are currently advancing Lomecel- BTM into clinical development. Our current cash resources are insufficient to fund our planned operations or development plans beyond the **fourth** ~~beginning of the second~~ quarter of ~~2024~~ **2025 , based on our current operating budget and cash flow forecast** . We will require additional funds to advance further. If we are capital constrained, we may not be able to meet our obligations. If we are unable to meet our obligations, or we experience a disruption in our cash flows, it could limit or halt our ability to continue to develop our current product candidate or even to continue operations, either of which occurrence would have a material adverse effect on us. We expect our expenses to continue to increase in connection with our ongoing activities, particularly as we continue the research and development of, advance the preclinical and clinical activities of, and seek marketing approval for, our current product ~~candidate~~ **candidates . As a result of our Type C meeting with the U. S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current**

ELPIS II trial is successful. Our operating expenses and capital expenditure requirements are expected to accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, and there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing / capital raises / non- dilutive funding options to support these activities, and current cash projections may be impacted by these ramped up activities and any financing transactions entered into. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect . In addition, if we obtain marketing approval for any of our current or future product candidates, we expect to incur significant commercialization expenses related to sales, marketing, manufacturing and distribution. We may also need to raise additional funds sooner if we choose to pursue additional indications and / or geographies for our current product ~~candidate~~ **candidates** or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to continue to incur significant costs associated with operating as a public company. If we are unable to raise capital when needed, we could be forced to delay, scale back or discontinue the development and commercialization of one or more of our ~~therapeutic~~ **product** candidates, delay our pursuit of potential licenses or acquisitions, or significantly reduce our operations. We expect that the net proceeds from recent offerings, together with our existing cash, will be sufficient to fund our operations ~~only for various amounts~~ **into the fourth quarter** of ~~time in 2024~~ **2025** ~~depending on the amount of net proceeds we obtain~~ . Our future capital requirements will depend on and could increase significantly as a result of many factors, including: ~~●~~ • the scope, progress, results and costs of drug discovery, preclinical development, laboratory testing and clinical trials for our current or future ~~therapeutic~~ **product** candidates; ~~●~~ • the potential additional expenses attributable to adjusting our development plans (including any supply- related matters) **in response** to ~~the COVID- 19 pandemic~~ **global geopolitical conditions and / or future public health crises** ; ~~●~~ • the scope, prioritization and number of our research and development programs; ~~●~~ • the costs, timing and outcome of regulatory review of our current or future ~~therapeutic~~ **product** candidates; ~~●~~ • our ability to establish and maintain collaborations on favorable terms, if at all; ~~●~~ • the achievement of milestones or occurrence of other developments that trigger payments under any additional collaboration agreements we obtain; ~~●~~ • the extent to which we are obligated to reimburse, or are entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any; ~~●~~ • the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims; ~~●~~ • the extent to which we acquire or license other current or future ~~therapeutic~~ **product** candidates and technologies ~~:~~ ~~●~~ **;** • the costs of securing manufacturing arrangements for commercial production; and ~~●~~ • the costs of establishing or contracting for sales and marketing capabilities if we obtain regulatory approvals to market our current or future ~~therapeutic~~ **product** candidates. Identifying potential current or future product candidates and conducting preclinical testing and clinical trials is a time- consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve drug sales. In addition, our current or future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of drugs that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to continue to rely on additional funding to achieve our business objectives. Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our current or future ~~therapeutic~~ **product** candidates. Disruptions in the financial markets in general have made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms favorable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our Class A common stock to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or current or future ~~therapeutic~~ **product** candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to obtain funding on a timely basis, we may be required to significantly delay, scale back or discontinue one or more of our research or development programs or the commercialization of any ~~therapeutic~~ **product** candidates or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. ~~We~~ **Failure to maintain our share price above the minimum bid price requirement established by Nasdaq** could ~~lose our result in the listing~~ **delisting of our Class A common stock** on the Nasdaq Capital Market ~~if our current share price continues to decrease~~ . The loss of our Nasdaq listing would in all likelihood make our Class A common stock significantly less liquid and adversely affect its value. As of February ~~23~~ **18** , ~~2024~~ **2025** our Class A common stock closing bid price was $ ~~0~~ **1** . ~~518~~ **58** . In **January 2025,** the ~~event~~ **SEC approved Nasdaq' s proposal to modify its listing standards governing minimum bid price compliance periods and delisting processes, such** that ~~our~~ **, among other matters, if a company fails to maintain a** closing bid price ~~falls below~~ **of at least** $ 1. 00 per share (the " Minimum Bid Price Requirement ") ~~for more than thirty (30) days~~ , **and had previously executed** ~~as required for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550 (~~ a ~~) (2)~~ **reverse stock split within the prior year** , ~~we it could~~ **would immediately** receive a notification letter from the Nasdaq Listing Qualifications Department ~~,~~ commencing delisting proceedings **, with** ~~. The receipt of a Nasdaq letter does not~~ **no** ~~result in the immediate delisting of~~ **compliance period. As previously disclosed,** the Company ~~' s~~ **undertook a reverse stock split on March 26, 2024. As such, if our** Class A common stock **closing** ~~from the Nasdaq Capital Market. In~~

~~accordance with Nasdaq Listing Rule 5810 (c) (3) (A) (the " Compliance Period Rule "), a company is provided an initial period of 180 calendar days (the " Compliance Date ") to regain compliance with the Minimum Bid Price Requirement. If, at any time during this 180- day period, the~~ bid price ~~closes at~~ **drops below** $ 1. 00 **prior** ~~or more per share for a minimum of 10 consecutive business days, as required under the Compliance Period Rule, the Staff would provide written notification~~ to **March 26** ~~the Company that it again complies with the Minimum Bid Price Requirement and the Class A common stock will continue to be eligible for listing on The Nasdaq Capital Market unless other eligibility deficiencies exist. If the Company were to not regain compliance with the Minimum Bid Price Requirement by the Compliance Date~~ , **2025** ~~the Company may be eligible for an additional 180 calendar day compliance period. To qualify~~ , **we** ~~the Company~~ would be ~~required to meet the continued listing requirement for the 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 its intention to cure the deficiency during the additional compliance period. If it appears to the Staff that the Company would not be able to cure the deficiency, the Staff will provide written notice to the Company that its Class A common stock will be subject~~ **subjected** to **immediate** delisting **proceedings** ~~. At that time, the Company may appeal the Staff' s delisting determination to a Nasdaq Hearing Panel (the " Panel "). The Company expects that its Class A common stock would remain listed pending the Panel' s decision, subject to the Company' s ability to regain compliance with the Stockholders' Equity Requirement (as defined below). There can be no assurance that, if the Company does appeal the Staff' s delisting determination to the Panel, such appeal would be successful~~ . In the event of a delisting from the Nasdaq Capital Market, our Class A common stock would likely be traded in the over- the- counter inter- dealer quotation system, more commonly known as the OTC. OTC transactions involve risks in addition to those associated with transactions in securities traded on the securities exchanges, such as the Nasdaq Capital Market, or Exchange- listed stocks. Many OTC stocks trade less frequently and in smaller volumes than Exchange- listed stocks. Accordingly, our Class A common stock would be less liquid than it would be otherwise. Also, the prices of OTC stocks are often more volatile than Exchange- listed stocks. Additionally, many institutional investors are prohibited from investing in OTC stocks, and it might be more challenging to raise capital when needed. The dual- class structure of our common stock may adversely affect the trading market for our **Class A** common stock. We cannot predict whether our dual class structure will result in a lower or more volatile market price of our Class A common stock or in adverse publicity or other adverse consequences. For example, certain index providers have announced restrictions on including companies with dual class or multi- class share structures in certain of their indexes. Our dual class capital structure could make us ineligible for inclusion in certain indices and mutual funds, exchange- traded funds and other investment vehicles that attempt to passively track these indices will not be investing in our stock. These policies are still fairly new, and it is as of yet unclear what effect, if any, they will have on the valuations of publicly traded companies excluded from the indices, but it is possible that they may depress these valuations compared to those of other similar companies that are included. Furthermore, we cannot assure you that other stock indices will not take a similar approach to S & P, Dow Jones or FTSE Russell in the future. Exclusion from indices could make our Class A common stock less attractive to investors and, as a result, the market price of our Class A common stock could be adversely affected. Holders of our Class B common stock **exert considerable** control **over** the direction of our business and their ownership of our **Class B** common stock can prevent other stockholders from influencing significant decisions. ~~As of February 16, 2024, two holders of our Class B common stock, Joshua M. Hare, co- founder, Chief Science Officer and Chairman of the Board of Directors, and Donald M. Soffer, co- founder and former member of our Board of Directors, control voting rights over approximately 84 % of the combined voting power of our Class A common stock and Class B common stock.~~ For so long as holders of Class B common stock continue to hold their **current** shares, they will be able to significantly influence ~~or effectively control~~ the composition of our Board of Directors **(the" Board")** and the approval of actions requiring stockholder approval through their voting power. Accordingly, for such period of time, these holders will have significant influence with respect to our management, business plans and policies. In particular, for so long as the Class B common stock remains outstanding, the holders may be able to cause or prevent a change of control of our Company or a change in the composition of our Board of Directors and could preclude any unsolicited acquisition of our Company. The concentration of ownership could deprive stockholders of an opportunity to receive a premium for shares of Class A common stock as part of a sale of our Company and ultimately might affect the market price of our Class A **common stock. As of February 17, 2025, three holders of our Class B common stock, Joshua M. Hare, co- founder, Chief Science Officer and Chairman of the Board of Directors, Donald M. Soffer, co- founder and former member of our Board of Directors, and Rock Soffer, member of our Board of Directors, control voting rights over approximately 37 % of the combined voting power of our Class A common stock and Class B** common stock. If securities or industry analysts do not publish research or reports, or if they publish negative, adverse, or misleading research or reports, regarding us, our business or our market, our Class A common stock price and trading volume could decline. The trading market for our Class A common stock is influenced by the research and reports that securities or industry analysts publish about us, our business, or our market. We do not currently have significant research coverage and may never obtain significant research coverage by securities or industry analysts. If no or few securities or industry analysts provide coverage of us, the Class A common stock price could be negatively impacted. In the event we obtain significant, or any securities or industry analyst coverage and such coverage is negative, or adverse or misleading regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our Class A common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our Class A common stock price or trading volume to decline. FINRA sales practice requirements may limit a stockholder' s ability to buy and sell our securities. Effective June 30, 2020, the SEC implemented Regulation Best Interest requiring that " A broker, dealer, or a natural person who is an associated person of a broker or dealer, when making a recommendation of any securities transaction or investment strategy involving securities (including account recommendations)

to a retail customer, shall act in the best interest of the retail customer at the time the recommendation is made, without placing the financial or other interest of the broker, dealer, or natural person who is an associated person of a broker or dealer making the recommendation ahead of the interest of the retail customer. " This is a significantly higher standard for broker- dealers to recommend securities to retail customers than before under prior FINRA suitability rules. FINRA suitability rules do still apply to institutional investors and require that in recommending an investment to a customer, a broker- dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending securities to their customers, broker- dealers must make reasonable efforts to obtain information about the customer' s financial status, tax status, investment objectives and other information, and, for retail customers, determine that the investment is in the customer' s " best interest, " and meet other SEC requirements. Both SEC Regulation Best Interest and FINRA' s suitability requirements may make it more difficult for broker- dealers to recommend that their customers buy speculative, low- priced securities. They may affect investing in our Class A common stock, which may have the effect of reducing the level of trading activity in our securities. As a result, fewer broker- dealers may be willing to make a market in our Class A common stock, reducing a stockholder' s ability to resell shares of our Class A common stock. Provisions in our ~~certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** and ~~bylaws~~ **Bylaws** and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Class A common stock. Our ~~certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** and bylaws contain provisions that could depress the market price of our Class A common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things: ~~•~~ establish a classified ~~board~~ **Board** of directors so that not all members of our Board are elected at one time; ~~•~~ permit only the ~~board~~ **Board** of directors to establish the number of directors and fill vacancies on the Board; ~~•~~ provide that directors may only be removed " for cause " and only with the approval of two- thirds of our stockholders; ~~•~~ provide for a dual class common stock structure, which provides certain affiliates of ours, including our co- founder and members of our Board, individually or together, with the ability to significantly influence the outcome of matters requiring stockholder approval, even if they own significantly less than a majority of the shares of our outstanding common stock and Class B common stock; ~~•~~ authorize the issuance of " blank check " preferred stock that our Board could use to implement a stockholder rights plan (also known as a " poison pill "); ~~•~~ eliminate the ability of our stockholders to call special meetings of stockholders; ~~•~~ prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders; ~~•~~ prohibit cumulative voting; ~~•~~ authorize our Board to amend our ~~bylaws~~ **Bylaws** ; ~~•~~ establish advance notice requirements for nominations for election to our ~~board~~ **Board** or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and ~~•~~ require a super- majority vote of stockholders to amend some of the provisions described above. In addition, Section 203 of the General Corporation Law of the State of Delaware prohibits a publicly- held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15 % of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. Any provision of our ~~certificate~~ **Certificate** of ~~incorporation~~ **Incorporation** , ~~bylaws~~ **Bylaws** or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our Class A common stock. We are an emerging growth 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 **currently** an emerging growth company, or EGC, as defined in 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, or Section 404, reduced disclosure obligations regarding executive compensation in 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 completed our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an EGC until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering (i. e., December 31, 2026), (b) in which we have total annual gross revenue of at least $ 1. 235 billion or (c) 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 (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. We may choose to take advantage of some, but not all, of the available exemptions. We cannot predict whether investors will find our **Class A** common stock less attractive if we rely on certain or all of these exemptions. If some investors find our **Class A** common stock less attractive as a result, there may be a less active trading market for our **Class A** 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. The issuance of additional stock in connection with acquisitions or otherwise will dilute all other stockholdings. We are not restricted from issuing additional shares of our Class A common stock, or from issuing securities that are convertible into or exchangeable for, or that represent the right to receive, Class A common stock. As of February ~~16~~ **17** , ~~2024~~ **2025** , we had an aggregate of 84, 295, 000 shares of Class A common stock authorized and of that approximately ~~63~~ **62** , ~~597~~ **902** , ~~015~~ **003** not issued, outstanding or reserved for issuance (for purposes of warrant exercise or under the Company' s current **Second Amended and Restated** 2021 ~~Equity~~ Incentive **Award** Plan). We may issue all of these shares without any action or approval by our stockholders. We may expand our business through complementary or strategic business combinations or acquisitions of

other companies and assets, and we may issue shares of Class A common stock in connection with those transactions. The market price of our Class A common stock could decline as a result of our issuance of a large number of shares of Class A common stock, particularly if the per share consideration we receive for the stock we issue is less than the per share book value of our Class A common stock or if we are not expected to be able to generate earnings with the proceeds of the issuance that are as great as the earnings per share we are generating before we issue the additional shares. In addition, any shares issued in connection with these activities, the exercise of warrants or stock options or otherwise would dilute the percentage ownership held by our investors. We cannot predict the size of future issuances or the effect, if any, that they may have on the market price of our Class A common stock. **Risks Related to Employee Matters, Managing Our Growth and Other Risks Related to Our Business** We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators. We have never commercialized ~~a~~ **an approved** product ~~candidate~~, and we currently have no sales force, marketing or distribution capabilities, nor do any of our current employees have any experience in commercializing a regulated product. To achieve commercial success for our product candidates, **if they are approved,** which we may license to others, we will rely on the assistance and guidance of those collaborators. For **future approved** ~~product~~ **products** ~~candidates~~ for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. Factors that may affect our ability to commercialize our future approved products on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our products and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time- consuming and could delay the launch of our future approved products. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our future approved products, we may not generate revenues from them or be able to reach or sustain profitability. In order to successfully implement our plans and strategies, we will need to grow our organization, and we may experience difficulties in managing this growth. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including: ● identifying, recruiting, integrating, maintaining and motivating additional employees; ● managing our internal development efforts effectively, including preclinical and clinical studies and investigations, as well as FDA, PMDA and other comparable foreign regulatory **authorities** ~~agencies'~~ review process for any current or future product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and ● improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to successfully develop and, if approved, commercialize, any current or future 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, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our current and future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third- party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and / or engaging additional third- party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our current and future product candidates and, accordingly, may not achieve our research, development and commercialization goals. Our computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations. Despite the implementation of security measures, our computer systems and those of our current and any future CROs and other contractors, consultants, collaborators and third- party service providers, are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as HIPAA, **the** Health Information Technology for Economic and Clinical Health Act and GDPR), it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow- up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. 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 lost data. We also rely on third parties to manufacture our product candidates, 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 inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development **, approval,** and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and / or international privacy and security laws. Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention. Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited. Although our first year incurring NOLs **was** ~~will be~~ for the tax year ended 2021, the net operating loss carryforwards, or NOLs, could expire unused and be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U. S. tax law. Under the current Tax Act, federal NOLs generated in tax years ending after December 31, 2017 may be carried forward indefinitely. It is uncertain if and to what extent various states will conform to the Tax Act. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an " ownership change " (generally defined as a cumulative change in our ownership by " 5- percent shareholders " that exceeds 50 percentage points over a rolling three- year period), the corporation' s ability to use its pre- change NOLs and certain other pre- change tax attributes to offset its post- change income and taxes may be limited. Similar rules may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in ownership. Our ability to utilize those NOLs could be limited by an " ownership change " as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes, which could have a material adverse effect on our cash flows and results of operations. A variety of risks associated with marketing our product candidates internationally could materially adversely affect our business. We plan to seek regulatory approval of our product candidates outside of the U. S. ~~, including specifically in Japan,~~ and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including: ~~•~~ 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 U. S.; ~~•~~ potential liability under the FCPA or comparable foreign regulations; ~~•~~ challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the U. S.; ~~•~~ production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and ~~•~~ business interruptions resulting from geo- political actions, including war and terrorism. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations. The increasing use of social media platforms presents new risks and challenges. Social media is increasingly being used to communicate about our clinical development programs and the diseases our therapeutics are being developed to treat, and we intend to utilize appropriate social media in connection with our commercialization efforts following approval of our ~~therapeutic~~ **product** candidates, if any. Social media practices in the biotechnology and biopharmaceutical industries continue to evolve and regulations and regulatory guidance relating to such use are evolving and not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us, along with the potential for litigation related to off- label marketing or other prohibited activities and heightened scrutiny by the FDA, the SEC and other regulators. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical trial or to report an alleged adverse event. If such disclosures occur, there is a risk that trial enrollment may be adversely impacted, that we may fail to monitor and comply with applicable adverse event reporting obligations or that we may not be able to defend our business or the public' s legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our ~~therapeutic~~ **product** candidates. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking ~~website~~ **platform** . In addition, we may encounter attacks on social media regarding our company, management, ~~therapeutic~~ **product** candidates or **future approved** products. Finally, social media may aid in the social reform of current drug prices. For example, CVS' s recently proposed " CostVantage " program is regularly referred to on social media and may have an impact on how pharmaceutical products are priced in the future. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions or incur other harm to our business. ~~Item 1B. Unresolved Staff Comments~~