Risk Factors Comparison 2024-03-21 to 2023-03-16 Form: 10-K

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Our business involves material and other risks, some of which are summarized and described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Annual Report on Form 10- K, including" Management' s Discussion and Analysis of Financial Condition and Results of Operations" and the condensed financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Annual Report on Form 10- K also contains forward- looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward- looking statements as a result of factors that are described below and elsewhere in this Annual Report. Risks Related to Our Business, Technology and Industry Risks Related to Clinical Development We are early in our development efforts. If we are unable to advance our product candidates through clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed. We are early in our development efforts and we have not yet completed any clinical trials. Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of one or more of our product candidates. Even if we are able to develop and commercialize a marketable product, we may face challenges generating revenue from product sales. The success of our product candidates will depend on several factors, including the following: • successful completion of preclinical studies resulting in data that is supportive of advancing to an IND submission; • successful submission and acceptance of INDs or comparable applications; • successful initiation of clinical trials; • demonstration of adequate safety to progress to a therapeutic dose level; • successful patient enrollment in and completion of clinical trials; • receipt and related terms of regulatory and marketing approvals and licensures from applicable regulatory authorities; • establishing commercial manufacturing capabilities or making arrangements with third- party manufacturers for clinical supply and commercial manufacturing of our product candidates; • making arrangements with various medical divisions across hospitals for administration of our product candidates, including with cancer treatment centers to conduct leukapheresis and with the relevant hospital divisions to perform infusion; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; • establishing sales, marketing and distribution and patient administration capabilities and launching commercial sales of our products, if and when licensed, whether alone or in collaboration with others; • acceptance of our products, if and when licensed, by patients, the medical community and third- party payors; • effectively competing with established and emerging therapies targeting the same indications as our product candidates; • obtaining and maintaining third- party coverage and adequate reimbursement; and • maintaining a continued acceptable safety profile of our products following licensure. If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or be unable to successfully commercialize our product candidates, which would materially harm our business. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Cellular therapies, including our engineered chimeric antigen receptor T cell, or CAR T, chimeric autoantibody receptor T cell, or CAAR T, product candidates, represent a novel approach to the treatment of autoimmune diseases, which creates significant challenges for us. Negative perception or increased regulatory scrutiny of any product candidates that we develop could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates. Cellular therapies are a novel approach and negative perception or increased regulatory scrutiny of any product candidates that we develop could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates. Cellular therapies remain novel in general, and there are no cellular immunotherapies licensed to date in the United States or the European Union to treat autoimmune diseases or alloimmune responses. CAR T or CAAR T cell therapies for autoimmune or alloimmune diseases may not gain the acceptance of the public or the medical community. For example, CAR Ts and other cellular therapies have in some cases caused severe side effects, including death, and their broader use may therefore be limited. ~~Even if~~ **In the future, in the event such severe side effects are observed with other** CAR T therapies **(including** ~~and other cellular therapies are accepted by the public and medical community in the short term, long- term adverse events observed in these~~ **those** ~~therapies~~ **with a CD19 binder), it** may increase negative perception **of,** and regulatory scrutiny **on, our product candidates. For example, in November 2023, the FDA announced that it would be conducting an investigation into reports of T cell malignancies following treatment with BCMA- directed or CD19- directed autologous CAR T cell immunotherapies. The FDA also stated that patients and clinical trial participants receiving treatment with such approved products should be monitored life- long for new malignancies. In January 2024, the FDA determined that new safety information related to T cell malignancies should be included in the labeling with boxed warning language on these malignancies for all BCMA- and CD19- directed genetically modified autologous T cell immunotherapies** . Public perception may be influenced by claims that gene therapy, including the insertion of a transgene, is unsafe, and products incorporating gene therapy may not gain the acceptance of the public or the medical community. The patient populations targeted by our product candidates are also typically not at risk of near- term death, even if they may suffer life- threatening symptoms, so patients will need to deem the benefits of cell therapy to be worth the risk of unknown potential adverse side effects. Our success will depend upon physicians who specialize in the treatment of autoimmune diseases targeted by our product candidates prescribing treatments that involve the use of our product

candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our product candidates ~~or ,~~ in clinical trials of others developing similar products **or in the post- approval setting** and the resulting publicity, as well as any other adverse events in the field of cellular therapies, could result in a decrease in demand for any product that we may develop. We are developing a pipeline of CAR T and CAAR T product candidates that are intended for use in treating individuals with autoimmune diseases. Advancing these novel product candidates creates significant challenges for us, including: • manufacturing our product candidates to our specifications and in a timely manner to support our clinical trials, and, if licensed, commercialization; • sourcing clinical and, if licensed, commercial supplies for the materials used to manufacture our product candidates; • understanding and addressing variability in the quality and quantity of a subject' s T cells, which could ultimately affect our ability to manufacture clinical supply and, if licensed, commercial supply of our product candidates in a reliable and consistent manner; • educating medical personnel regarding the potential side effect profile of our product candidates, if licensed, such as the potential adverse side effects related to **systemic lupus erythematosus, or SLE flare, idiopathic inflammatory myopathy (IIM), or myositis, worsening, systemic sclerosis, or SSc, worsening,** pemphigus flare, **muscle- specific kinase myasthenia gravis, or** MuSK MG **, generalized myasthenia gravis, or gMG,** flare or myasthenic crisis from infusion of activated T cells or medication taper, cytokine release syndrome, or CRS, or other unexpected adverse effects of therapy with our product candidates **or potential class- wide side effects, such as those related to CD19- directed autologous CAR T cell immunotherapies** ; • facilitating patient access to the limited number of facilities able to administer our product candidates, if licensed; • using medicines to manage adverse side effects of our product candidates that may not adequately control the side effects and / or may have a detrimental impact on the efficacy of the treatment; • utilizing preconditioning agents in patients to enhance engraftment in advance of administering our product candidates, which may increase the risk of adverse side effects and potentially reduce the population eligible for therapy; • obtaining and maintaining regulatory approval for our product candidates, as the FDA and other regulatory authorities have limited or no experience with development of engineered T cell therapies for the treatment of ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** ; • establishing sales and marketing capabilities upon obtaining any regulatory approval to gain market acceptance of a novel therapy; and • managing costs of inputs and other supplies while scaling production. In addition, preclinical murine and other animal models may not exist or be adequate for some or all of the ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** we choose to pursue in our programs, and because we are early in the clinical development process, we are unable to predict whether there may be short- term or long- term effects from treatment with any product candidates that we develop. In developing our product candidates, we have not exhaustively explored different options in the method for manufacturing CAR T or CAAR T cells. We may find our existing manufacturing process may be substantially improved with future design or process changes, necessitating further clinical testing, delaying commercial launch of our first products, and causing us to incur additional expenses. For example, while we have used a lentiviral vector in our manufacturing process, we may in the future find that another viral vector or non- viral vector- based process offers advantages. Switching from one lentiviral vector to another or switching from lentiviral to another delivery system would necessitate additional process development and clinical testing, and this may delay the development of existing product candidates. In addition, we do not know the doses to be evaluated in pivotal trials or, if licensed, commercially. Finding a suitable dose may delay our anticipated clinical development timelines. Our expectations with regard to our scalability and costs of manufacturing may vary significantly as we develop our product candidates and understand these critical factors. We may experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical studies or commercializing our product candidates on a timely or profitable basis, if at all. Moreover, our product candidates may not perform successfully in clinical trials or may be associated with adverse events that distinguish them from the ~~chimeric antigen receptor T, or~~ CAR T ~~,~~ therapies that have previously been licensed. For instance, subjects in our CAAR T clinical trials will be infused with our proposed therapies, and may possess strongly activating soluble antibodies, which, are not present in oncology patients and when they interact with our infused product candidates, could result in potential adverse side effects, such as CRS. Additionally, adverse side effects caused by even one of our **CAR T or** CAAR T product candidates could negatively affect our ability to develop future product candidates based on our CABATM platform. Unexpected side effects or clinical outcomes from any of our products candidates would significantly impact our business ~~. In addition, one of our current product candidates, DSG3 / 1- CAART, and certain of our future product candidates may require introducing large transgenes into T cells, and lentiviral vectors may have too limited a genome capacity to accomplish this process. We currently use lentiviral vector transduction for transgene delivery. However, lentiviral vectors have a limited genome capacity that restricts the size of the transgene that can be delivered using this vector system. For example, designing a lentiviral vector that will have sufficient capacity to introduce DSG3 CAAR and DSG1 CAAR together into T cells may not be possible. In addition to reducing lentiviral vector titers that may substantially increase the cost of gene transfer, it may be entirely unsuccessful, thus necessitating use of alternative strategies for transfer of these larger transgenes into T cells~~ . Further, the clinical study requirements of the FDA and other regulatory agencies and the criteria they use to determine the safety, potency and purity of a product candidate are determined according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates such as ours is less clear, and can be more complex and consequently have higher development risk, be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. Approvals by the FDA for existing cell therapies treating B cell- mediated diseases, such as Kymriah (Novartis Pharmaceuticals Corporation) and Yescarta ® (Gilead Sciences, Inc.) in oncology indications, may not be indicative of what the FDA may require for approval of our therapies in autoimmune indications. Approvals by any regulatory agency may not be indicative of what any other regulatory agency may require for approval or what such regulatory agencies may require for approval in connection with new product

candidates. As we advance our product candidates, we will be required to consult with these regulatory agencies and comply with applicable requirements and guidelines. If we fail to do so, we may be required to delay or discontinue development of such product candidates. These additional processes may result in a review and approval process that is longer than we otherwise would have expected. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. In addition, responses by agencies at the federal and state level to negative public perception or ethical concerns may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. The FDA has expressed interest in further regulating biotechnology products, such as cellular therapies. Agencies at both the federal and state level in the United States, as well as the U. S. Congressional committees and other government entities or governing agencies have also expressed interest in further regulating the biotechnology industry. Such action may delay or prevent commercialization of some or all of our product candidates. Adverse developments in clinical trials of cellular therapy products conducted by others **or in the post- approval setting** may cause the FDA or other oversight bodies to change the requirements for approval of any of our product candidates. These regulatory review agencies and committees and the new requirements or guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post- approval limitations or restrictions. Patients receiving T cell- based immunotherapies, such as our product candidates, may experience serious adverse events, including neurotoxicity, CRS and killing of cells other than the intended B cells that express the autoantibodies. If our product candidates are revealed to have high and unacceptable severity and / or prevalence of side effects or unexpected characteristics, their clinical development, regulatory approval, and commercial potential will be negatively impacted, which will significantly harm our business, financial condition and prospects. Our product candidates are CAR T or CAAR T cell- based immunotherapies. In other similarly designed cellular immunotherapies to treat cancer, there have been life threatening events related to severe neurotoxicity and CRS requiring intense medical intervention, such as intubation or medications to support blood pressure, and in several cases, resulted in death. Severe neurotoxicity is a condition that is currently defined clinically by cerebral edema, confusion, drowsiness, speech impairment, tremors, seizures or other central nervous system side effects, when such side effects are serious enough to lead to intensive care. CRS is a condition that is currently defined clinically by certain symptoms related to the release of cytokines, which can include fever, chills and low blood pressure, when such side effects are serious enough to lead to intensive care with mechanical ventilation or significant medications to support blood pressure. There is a possibility that our product candidates could have similarly life threatening serious adverse side effects, such as neurotoxicity and CRS. Our product candidates may have serious and potentially fatal consequences due to the targeting of cells within the body due to unexpected protein interactions with the CAR or CAAR. Although we have completed multiple preclinical studies designed to screen for toxicity caused by unintended off- target recognition by the cell binding domain of the DSG3 CAAR ~~and ,~~ MuSK CAAR and **CABA- 201 and** intend to screen future **CAR and** CAAR candidates not yet tested in patients through preclinical studies, our product candidates may still recognize and react with one or more proteins unrelated to the intended surface immunoglobin target protein to which it is designed to link. If unexpected binding occurs in normal tissue, our product candidates may target and kill the normal tissue in a patient, leading to serious and potentially fatal adverse events, undesirable side effects, toxicities or unexpected characteristics. Detection of any unexpected targeting may halt or delay any ongoing clinical trials for our product candidates and prevent or delay regulatory approval. While we have developed a preclinical screening process to identify cross- reactivity of our product candidates, we cannot be certain that this process will identify all potential tissue that our product candidates may target. For example, a membrane protein array with DSG3- CAART yielded one weak signal against a protein that is designed to bind to glycoproteins and which was detected in both the test and control conditions. Further analysis of this protein in confirmatory cell- based assays repeatedly demonstrated that DSG3- CAART does not recognize nor activate against this protein. We performed similar preclinical studies for the MuSK CAAR and **CABA- 201 and** did not observe any confirmed off target activity for MuSK- CAART **or CABA- 201** . However, this further analysis may prove to be inaccurate. Any unexpected targeting that impacts patient safety could materially impact our ability to advance our product candidates into clinical trials or to proceed to marketing approval and commercialization. Furthermore, in the event subjects are **re-** ~~retreated~~ -- **treated** , they may respond differently than other subjects given the same dose, and may not tolerate the dose or develop safety concerns. Results of our studies could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA. ~~The FDA has requested and we have agreed to provide data on the subjects dosed in Part A of our DesCAARTesTM trial prior to dosing subjects in Part B. The FDA has communicated that the dosing of patients in Part B1 is not dependent on the review of Part A data and that they will provide feedback, if any, in a timely manner.~~ In some cases, side effects such as neurotoxicity or CRS have resulted in clinical holds of ongoing clinical trials and / or discontinuation of the development of the product candidate **. Our clinical trials of CABA- 201 represent the first evaluation of this product candidate in patients and CABA- 201 is directed against all B cells expressing CD19; therefore, there is a risk for prolonged B cell aplasia and / or hypogammaglobulinemia, which may predispose patients to infections** . Given that the autoimmune and alloimmune diseases we are seeking to treat are, in some cases, less serious than the later stage cancers being treated with other immunotherapy products, we believe the FDA and other regulatory authorities likely will apply a different benefit- risk assessment thresholds such that even if our product candidate demonstrated a similar safety profile as current CAR T therapies, the FDA may ultimately determine that the harmful side effects outweigh the benefits and require us to cease clinical trials or deny approval of our product candidates. We believe

tolerance for adverse events in the patient population being pursued with **our** CAAR **T and CAR** T cell therapies **in autoimmune and alloimmune indications** will be lower than it is in oncology, and the risks of negative impact from these toxicities may therefore be higher for us than for CAR T programs in oncology. Furthermore, treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the studies or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell- based immunotherapies are not normally encountered in routine medical care. Medical personnel may need additional training regarding T cell- based immunotherapy product candidates to understand their side effects. Inadequate training in recognizing or failure to effectively manage the potential side effects of T cell- based immunotherapy product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly. In addition to side effects caused by our product candidates, any preconditioning, administration process or related procedures, which we evaluate from time to time as part of our process improvement and optimization efforts, may also cause adverse side effects. For example, prolonged or persistent cytopenias and severe neurotoxicity has been noted to be associated with the use of certain lymphodepleting regimens and CAR T therapies. ~~While we initiated the DesCAARTesTM~~ **Preconditioning regimens, as currently implemented in several of our clinical** ~~trial~~ **trials** ~~without~~ **, may increase the risk of adverse side effects and impact our ability to accurately assess the efficacy of our product candidates. In oncology patients receiving CAR T cell therapy,** a **lymphodepleting** preconditioning regimen **is typically used to condition the patient prior to CAR T cell infusion in order to improve tumor immunogenicity and to promote the expansion of the infused CAR T cells. Together** , ~~we~~ **these effects** have ~~implemented a cohort where a preconditioning~~ **been shown to enhance the clinical activity of CAR T cells in oncology patients. These** ~~regimen~~ **regimens often include cyclophosphamide** ~~with a lymphodepleting agent and an~~ **and** ~~immunomodulatory agent will be~~ **fludarabine and are usually** administered **within the week prior to infusion of CAR T cells** . We have implemented a preconditioning regimen in the DesCAARTesTM trial where **certain** subjects are pre- treated with IVIg and cyclophosphamide **, and other patients are pre- treated with IVIg, cyclophosphamide, and fludarabine** prior to DSG3- CAART infusion, ~~and~~ **have** included ~~a~~ planned dosing ~~cohort~~ **cohorts** in the MusCAARTesTM trial where subjects are pre- treated with cyclophosphamide prior to MuSK- CAART infusion, and we **have incorporated** ~~may in the future use a preconditioning regimen for our other CAR T or CAAR T cell product candidates, which may increase the risk of adverse side effects and impact our ability to accurately assess the efficacy of our product candidates. In oncology patients receiving CAR T cell therapy,~~ a lymphodepleting preconditioning regimen ~~is typically used to condition the patient prior to CAR T cell infusion in order to improve tumor immunogenicity and to promote the expansion~~ of ~~the infused CAR T cells. Together~~ **fludarabine and cyclophosphamide in our CABA- 201 REstoring SElf- Tolerance** , **or RESETTM,** ~~these effects have been shown to enhance the~~ clinical **trials** ~~activity of CAR T cells in oncology patients. These regimens often include cyclophosphamide and fludarabine and are usually administered within the week prior to infusion of CAR T cells~~ . Serious adverse events have been observed in some patients following CAR T cell infusion, and these include infection, cytokine release syndrome and neurotoxicity. The lymphodepleting and immunomodulatory preconditioning regimen may contribute to the occurrence and severity of these adverse events due to its role in inducing **leukopenia, or low levels of white blood cells in the blood, including** lymphopenia, or low levels of lymphocytes in the blood, and regulating the activation and effector functions of other immune cells and antibodies, and enhanced CAR T cell activity ~~. Lymphodepleting preconditioning may not be required in all oncology settings for CAR T cell activity. A clinical trial in multiple myeloma patients published in 2019 in The Journal of Clinical Investigation showed similar clinical activity of CAR T cell infusions in patients with or without a lymphodepleting preconditioning regimen. Furthermore, the requirement for lymphodepleting preconditioning for potentiating engineered T cell therapy outside of oncology has not been well established. Specifically, the effect on tumor immunogenicity is not relevant in settings outside oncology, and therefore the contribution of this aspect to the potential enhancing effect of preconditioning would not apply~~ . In addition, a lymphodepleting regimen may eliminate pathogenic B cells targeted by our CAAR T cell product candidates. As a result, any lymphodepleting regimen for preconditioning that we use may delay or otherwise adversely affect our ability to use DSG3 or MuSK autoantibody titers, a standard clinical assay, to assess the activity of DSG3- CAART and MuSK- CAART, respectively. An inability to use DSG3 or MuSK autoantibody levels to demonstrate the specific activity of our CAAR T cell product candidates may require us to rely on the subjective measurement of blister formation in patients in the DesCAARTesTM trial or muscle weakness in the MusCAARTesTM trial, which can be a less sensitive and accurate measurement of CAAR T cell activity. This therefore could delay a signal of potential biologic activity attributable to CAAR and therefore may slow clinical development. Based on emerging clinical and translational data, in the setting of autoimmune patients, we believe the inclusion of such a regimen in the DesCAARTesTM trial and MusCAARTesTM trial is justified to further evaluate the DSG3- CAART and MuSK- CAART platforms. We will continue to evaluate emerging data from the DesCAARTesTM trial on an ongoing basis, as well as other relevant clinical trials in autoimmune disease, and may make additional modifications to the DesCAARTesTM trial or MusCAARTesTM trial, as appropriate. In addition to lymphodepleting preconditioning, other preconditioning regimens with immunomodulatory effects may be considered to prepare the body for CAR T or CAAR T infusion. For example, if autoantibody is found to reduce or inhibit function of CAAR T in the body, then pretreatment of patients with antibody reducing therapies, such as FcRN inhibitors, IVIg, plasmapheresis, or treatment of post rituximab patients may be considered. Some of these types of preconditioning are standard of care for this autoimmune population and therefore are already considered to have a beneficial risk profile in this patient population. These other preconditioning regimens may cause serious adverse events, including hypotension, thromboembolism, and opportunistic infections. **Subjects in our RESETTM trials will be treated with a standard preconditioning regimen consisting of fludarabine and cyclophosphamide prior to CABA- 201 infusion. In addition, the lymphodepleting regimen may eliminate some of the pathogenic B cells targeted by CABA- 201. As a result, the lymphodepleting regimen may contribute to the initial clinical response that may be observed after CABA- 201,**

which may make interpretation of early efficacy difficult to assess and may also delay our ability to characterize the activity of CABA- 201 independent of the effects of fludarabine and cyclophosphamide. While we initiated the DesCAARTesTM trial without a preconditioning regimen, we have now implemented ~~a cohort~~ **cohorts** ~~where~~ **with** a preconditioning regimen ~~with a lymphodepleting agent and an immunomodulatory agent will be administered~~ . Our clinical patients may experience increased or more severe adverse effects specifically related to the preconditioning ~~regimen~~ **regimens** , such as severe allergic reactions, difficulty breathing, severe headaches, serious infections, low blood counts, inflammation of the colon with bleeding, bladder irritation, blood clots, development of certain cancers, damage to the heart, lung or kidneys, and even death. These undesirable side effects, whether associated with the preconditioning regimen alone or in combination with our **CAR T cell product candidates or** CAAR T cell product candidates, could cause delays in patient enrollment in our clinical trials, could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a change to our clinical trial design, a more restrictive label or the delay or denial of regulatory approval by the FDA. Any of the foregoing may increase the duration and expense of the clinical development of our product candidates or limit market acceptance of such product candidates, if approved, any of which could have a material adverse effect on our business and financial condition. Our business is highly dependent on the success of our initial product candidates targeting ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** ~~, particularly CABA- 201, DSG3- CAART and MuSK- CAART~~ . All of our product candidates will require significant additional preclinical and / or clinical development before we can seek regulatory approval for and launch a product commercially. Our business and future success depend on our ability to obtain regulatory approval of, and then successfully launch and commercialize our initial product candidates targeting ~~B cell- mediated~~ autoimmune diseases **where B cells** ~~, including CABA- 201, DSG3- CAART, MuSK- CAART, DSG3 / 1- CAART, PLA2R- CAART and others that~~ may **play a role** ~~be selected from preclinical and discovery programs. Our product candidates are~~ in **initiating or maintaining disease** ~~the early stages of development and will require additional preclinical studies, clinical trials, regulatory review and licensure, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales~~ . There is no guarantee that we will be able to advance our product candidates through clinical development or obtain marketing approval for any of our product candidates. The process for obtaining marketing approval for any product candidate is very long and risky and there will be significant challenges for us to address in order to obtain marketing approval as planned, if at all. **The** ~~However, the~~ initial clinical results we have observed may not be predictive of results of subsequent cohorts in this clinical trial, or of any future clinical trials. Because DSG3- CAART and MuSK- CAART are the first and second product candidates that we are testing in the clinic, we may experience preliminary complications surrounding trial design, protocol establishment and execution, establishing trial protocols, patient recruitment and enrollment, quality and supply of clinical doses, or safety issues. For example, we did not use pre- infusion lymphodepletion or other preconditioning regimens in the initial dose escalation cohorts of our **DesCAARTesTM** ~~Phase 1~~ trial. However, based on emerging clinical and translational data, we have now implemented a cohort where a preconditioning regimen with ~~a~~ lymphodepleting ~~agent~~ **agents** and an immunomodulatory agent is administered in the DesCAARTesTM trial, and we continue to evaluate whether the use of a lymphodepleting or other **, or any,** preconditioning regimen is necessary for our other product candidates to be successful, and if we determine that it is, it could result in delays in clinical development and will expose patients to the associated risks. Additionally, a failure of our clinical trials of DSG3- CAART ~~or ,~~ MuSK- CAART **or CABA- 201 RESETTM trials** could influence physicians' and regulators' opinions with regard to the viability of our CABATM platform more broadly, particularly if treatment- related side effects are observed. The occurrence of any of these risks could significantly harm our development plans and business prospects. If treatment- related side effects are observed with the administration of DSG3- CAART ~~or ,~~ MuSK- CAART **or CABA- 201** , or if they are viewed as less safe, potent or pure than other therapies, our ability to develop other CAAR **T or CAR** T cell therapies may be significantly harmed. We have never successfully completed any clinical trials, and we may be unable to do so for any product candidates we develop. We have not yet demonstrated our ability to successfully complete any clinical trials, including large- scale, pivotal clinical trials, obtain regulatory 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 commercialization. Although our key employees have significant experience in leading clinical development programs, our experience conducting clinical trials with our product candidates is limited. We may not be able to file INDs for any of our other product candidates on the timelines we expect, if at all. For example, we cannot be certain that the IND- enabling studies for our future product candidates will be completed in a timely manner or be successful or that the manufacturing process will be validated in a timely manner. Even if we submit an IND for a future product candidate, the FDA may not clear the IND and allow us to begin clinical trials in a timely manner or at all ~~. For example, we may not be able to obtain FDA clearance of our IND for CABA- 201 during the first half of 2023~~ . The timing of submissions on future product candidates will be dependent on further preclinical and manufacturing success. Moreover, we cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that require us to suspend or terminate clinical trials. Commencing each of these clinical trials is subject to finalizing the trial design based on discussions with the FDA and other regulatory authorities. Any guidance we receive from the FDA or other regulatory authorities is subject to change. These regulatory authorities could change their position, including, on the acceptability of our trial designs or the clinical endpoints selected, which may require us to complete additional clinical trials or impose stricter approval conditions than we currently expect. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • be delayed in obtaining marketing approval for our product candidates; • not obtain marketing approval at all; • obtain approval for indications or patient populations that are not as broad as intended or desired; • be subject to post- marketing testing requirements; or • have the product removed from the

market after obtaining marketing approval. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates. We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • inability to bring our product candidates to the market; • decreased demand for our product candidates; • injury to our reputation; • withdrawal of clinical trial participants; • initiation of investigations by regulators; • costs to defend the related litigation; • a diversion of management' s time and our resources; • substantial monetary awards to trial participants or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any product candidate; and • a decline in our share price. Since we have not yet commenced marketing of any products, we do not yet hold product liability insurance for commercialization of our product candidates. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop, alone or with corporate collaborators. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. Assuming we obtained clinical trial insurance for our clinical trials, we may have to pay amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. Risks Related to the Industry Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. Undesirable or unacceptable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of subjects and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the drug. Undesirable side effects could also result in an expansion in the size of our clinical trials, increasing the expected costs and timeline of our clinical trials. Additionally, results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Licensed CAR T cell therapies and those under development have shown frequent rates of CRS and neurotoxicity, and adverse events have resulted in the death of patients. Similar adverse events could occur during treatment with our current or future CAR T or CAAR T cell product candidates. For example, activation of CAAR T cells by patient autoantibodies or alloantibodies could stimulate CRS. When CAAR T cells are infused and the CAAR binds to soluble antibodies in the blood or tissues of treated patients, these soluble antibodies may cause the CAAR T cells to proliferate, resulting in an activation of the immune system that is too high, leading to CRS. Further, it is possible that patients will exhibit acute rejection of the CAAR T cells because of preexisting immunity to the antigen within the CAAR. This could render our product candidates ineffective. If unacceptable toxicities or health risks, including risks inferred from other unrelated immunotherapy trials, arise in the development of our product candidates, we could suspend or terminate our trials or the FDA, the Data Safety Monitoring Board, or DSMB, or local regulatory authorities such as institutional review boards, or IRBs, could recommend or order us to cease clinical trials. Regulatory authorities, such as the FDA, could also deny approval of our product candidates for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, as toxicities resulting from T cell therapy are not normally encountered in the general patient population and by medical personnel. We expect to have to train medical personnel using CAR T or CAAR T cell product candidates to understand the side effect profile of our product candidates for both our preclinical studies and clinical trials and upon any commercialization of any of our product candidates, if licensed. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly. Our preclinical studies and clinical trials may fail to demonstrate the safety, potency and purity of any of our product candidates, which would prevent or delay regulatory approval and commercialization. Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product candidates are safe, potent and pure for use in each target indication. Clinical trials are expensive and can take many years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later- stage clinical trials, including in any post- approval studies of our product candidates. In addition, initial success in any clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety, potency and purity profile despite having progressed through preclinical studies and initial clinical trials. **Similarly, while we believe CABA- 201 has a similar overall design to the construct used for the patients in the Nature Medicine, Lancet, Annals of Rheumatic Diseases, and Rheumatology publications, those studies involved a small number of patients, and a different product candidate, and the initial clinical results observed in those**

studies may not be predictive of clinical trial results with CABA- 201 or any of our other product candidates. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of potency or efficacy, insufficient durability of potency or efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical and other nonclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or EMA approval. Most product candidates that commence clinical trials are never approved as products. Any preclinical studies or clinical trials that we may conduct may not demonstrate the safety, potency and purity necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future preclinical studies and clinical trials are inconclusive with respect to evaluations of efficacy, the safety, potency and purity of our product candidates, if we do not meet the clinical endpoints with statistical and clinically meaningful significance, or if there are safety concerns associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for such product candidates. In some instances, there can be significant variability in evaluations of efficacy, safety, potency or purity results between different preclinical studies and clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. For example, because our CAAR T cell product candidates only target approximately 0. 01 % to 1 % of the B cells in a patient, they may not engage enough of the target to achieve adequate engraftment necessary for elimination of all pathogenic B cells. Insufficient safety or potency in clinical trials may delay product development to enable time to modify the product candidate for next generation approaches or make manufacturing changes or may lead us to discontinue development of the product candidate. Additionally, our ongoing clinical trials utilize, and our planned trials may utilize, an " open- label " trial design. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an active drug or placebo. Most typically, open- label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open- label clinical trial when studied in a controlled environment with a placebo or active control. In addition, we cannot guarantee that the FDA will interpret the results of any of our ongoing or planned clinical trials as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA to support a marketing application, approval of our product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Interim, topline or preliminary data from any preclinical studies or clinical trials that we conduct 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. Our DesCAARTesTM trial **, ~~and our~~** MusCAARTesTM trial **, and RESETTM trials in SLE, myositis, SSc, and gMG** are ~~both~~ designed as open- label trials. From time to time, we may publicly disclose interim, preliminary or topline data from our preclinical studies and clinical trials, including safety data and evaluations of efficacy, which will be based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following our receipt of additional data or a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data ~~. For example, we have disclosed clinical and translational data from the first four cohorts in the DesCAARTesTM trial where we reported no DLTs, serious adverse events or clinically relevant adverse events, within six months of DSG3- CAART infusion. Additionally, we have disclosed that no DLTs were observed through cohort A5, and that no clear trends in antibody levels or disease activity reduction were observed through cohort A4, though one subject in cohort A4 had no disease activity by three months post- infusion while reducing steroid usage during that period, an antibody titer that dropped more than 20 % by three months post- infusion, and was the only patient in the first four cohorts that had detectable DSG3- CAART persistence at the three month time point following initial DSG3- CAART infusion. DSG3- CAART persistence through day 29 in cohort A5 was similar to that observed in cohort A4 and through up to six months post CAART infusion, no clear pattern in antibody levels and disease activity was observed in the first three subjects at the cohort A5 dose. However, the trial is in its early stages and additional data from these initial cohorts, data from subsequent patients and data from patients at higher dosing levels or different dosing regimens, such as our combination sub- study, may not be positive with respect to safety, target engagement or evidence of early signs of biologic activity~~ . As a result, the topline 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 data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from planned interim analyses in our clinical trials. 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 patient enrollment continues and more

patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or our competitors, or by patients or caregivers who are aware that a patient is receiving investigational product, due to the open- label design of the trial, could result in volatility in the price of our common stock. Regulatory agencies, including the FDA, 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 our company in general. 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 harm our business, operating results, prospects or financial condition. 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 product candidates are being developed to treat. We intend to utilize appropriate social media in connection with communicating about our development programs. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business. For example, patients may use social media channels to report an alleged adverse event during a clinical trial. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable adverse event reporting obligations, or 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 investigational products. 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, or a risk that a post on a social networking website by any of our employees may be construed as inappropriate promotion. 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. We may encounter substantial delays in our clinical trials or may not be able to conduct our trials on the timelines we expect or at all. Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Even if these trials begin as planned, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our ongoing and future clinical trials may not be successful. Events that may prevent successful or timely completion of clinical development include: • inability to generate sufficient preclinical, toxicology or other in vivo or in vitro data to support the initiation of clinical trials; • delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for clinical trials; • delays in developing suitable assays for screening patients for eligibility for clinical trials with respect to certain product candidates; • delays in reaching a consensus with the FDA and other regulatory agencies on trial design; • delays in reaching agreement on acceptable terms with prospective CMOs, CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CMOs, CROs and clinical trial sites; • delays in obtaining required institutional review board, or IRB, approval at each clinical trial site; • imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND submission or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical study operations or study sites; developments on trials conducted by competitors for related technology **or by those** that **rely on a similar construct, design and / or third-party research that** ~~raises~~ **raise** FDA concerns about risk to patients of the technology **or construct** broadly **, and / or negative public perception of the same** ; or if FDA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives; • delays in recruiting eligible patients to participate in our clinical trials; • delays in treating one or more patients, once enrolled, due to a patient' s inability to accommodate parts of the complex study procedures schedule; • difficulty collaborating with patient groups and investigators; • failure by our CROs, other third parties or us to adhere to clinical trial requirements and the potential termination of ongoing agreements with our CROs; • limitations on our recourse in our CRO relationship with Penn as compared to a CRO that is not an academic institution; • failure to perform in accordance with the FDA' s Good Clinical Practice, or GCP, requirements or applicable regulatory guidelines in other countries; • transfer of manufacturing processes to any new CMO or our own manufacturing facilities or any other development or commercialization partner for the manufacture of product candidates; • delays in having patients complete participation in a trial or return for post-treatment follow- up; • patients dropping out of a trial; • occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • changes in the standard of care on which a clinical development plan was based, which may require new or additional trials; • the cost of clinical trials of our product candidates being greater than we anticipate; • clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; • delays or failure to secure supply agreements with suitable raw material suppliers, or any failures by suppliers to meet our quantity or quality requirements for necessary raw materials; and • delays in manufacturing or inability to manufacture sufficient clinical supply (for example, due to capacity constraints, supply interruption, or the need to engineer the process to meet higher dose requirements), testing, releasing, validating or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenue. If we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect to, conduct additional trials to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our product candidates and products, if licensed, have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. We could

also encounter delays if a clinical trial is suspended or terminated by us, the FDA or other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Delays in the initiation, conduct or completion of any clinical trial of our product candidates will increase our costs, slow down our product candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. In the event we identify any additional product candidates to pursue, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin in a timely manner, if at all. In addition, from time to time, we may publicly announce the expected timing of various scientific, clinical, regulatory, manufacturing and other product development milestones. These milestones may include the commencement, completion or development of data from our preclinical studies and clinical trials or the submission of regulatory filings, such as an IND. All of these milestones are, and will be, based on a variety of assumptions. If any of the foregoing events impact our ability to meet the publicly announced timing of our milestones, we may experience adverse effects on our business, financial condition and prospects and the price of our common stock could decline. Monitoring safety of patients receiving our product candidates will be challenging, which could adversely affect our ability to obtain regulatory approval and commercialize our product candidates. For our ~~clinical~~ **RESETTM** trials **and** ~~of CABA- 201,~~ DSG3- CAART, MuSK- CAART and our other product candidates **clinical trials** , we expect to continue to contract with ~~Penn and / or other~~ academic medical centers and hospitals experienced in the assessment and management of toxicities arising during clinical trials. In the future, we may also contract with non- academic medical centers and hospitals with similar capabilities. Nonetheless, these centers and hospitals may have difficulty observing patients, including due to failure by patients to comply with post- clinical trial follow- up programs, and treating toxicities, which may be more challenging due to personnel changes, inexperience, shift changes, house staff coverage or related issues. This could lead to more severe or prolonged toxicities or even patient deaths, which could result in us or the FDA delaying, suspending or terminating one or more of our clinical trials, and which could jeopardize regulatory approval. We also expect the centers using CABA- 201, DSG3- CAART, MuSK- CAART and our other product candidates, if licensed, on a commercial basis could have similar difficulty in managing adverse events. Medicines used at centers to help manage adverse side effects of CABA- 201, DSG3- CAART, MuSK- CAART and our other product candidates may not adequately control the side effects and / or may have a detrimental impact on the efficacy of the treatment. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including: • the size and nature of the patient population; • the patient eligibility criteria defined in the protocol; • the size of the patient population required for analysis of the trial' s primary endpoints; • recruiting an adequate number of suitable patients to participate in a clinical trial; • reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; • obtaining IRB and other required reviewing body approval at each clinical trial site; • the proximity of patients to trial sites; • the design of the trial and whether the FDA agrees to the design and implementation of the trial; • our ability to identify clinical trial sites and recruit clinical trial investigators with the appropriate capabilities, competencies and experience; • clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating **, or with CAR T cell therapies broadly following the FDA' s investigation into reports of T cell malignancies for approved BCMA- and CD19- directed CAR T cell immunotherapies** ; • the occurrence of dose- limiting toxicity in the clinical trial; • the efforts to facilitate timely enrollment in clinical trials; • the patient referral practices of physicians; • the ability to monitor patients adequately during and after treatment; • our ability to obtain and maintain patient consents; • the risk that patients enrolled in clinical trials will drop out of the trials before the infusion of our product candidates or trial completion; and • the ability of patients to meet the complex follow- up requirements of the clinical trial. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, some of our clinical trial sites may also be used by some of our competitors, which may reduce the number of patients who are available for our clinical trials in that clinical trial site. Moreover, because our product candidates represent a departure from more commonly used methods for **autoimmune diseases where** B ~~cell~~ **cells** ~~- mediated autoimmune~~ **may play a role in initiating or maintaining** disease treatment, potential patients and their doctors may be inclined to use conventional therapies, such as corticosteroids or systemic immunosuppressive medications, rather than enroll patients in our clinical trial. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our ongoing and planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates. Our DesCAARTesTM trial, our MusCAARTesTM trial **, our RESETTM trials in SLE, myositis, SSc, and gMG,** and any additional expected ~~Phase 1~~ clinical trials for each of our product candidates will **enroll** ~~be pilot dose escalation studies with~~ a limited number of patients. The activity and toxicity data from these clinical trials of our

product candidates may differ from future results of **subsequent** ~~Phase 2 and / or Phase 3~~ clinical trials that enroll a larger number of patients. Since the number of patients that we plan to dose in our DesCAARTesTM trial ~~and ,~~ our MusCAARTesTM trial **, and our RESETTM trials in SLE, myositis, SSc and gMG** is small, and the number of patients in clinical trials for any future product candidates may be small, the results from such clinical trials, once completed, may be less reliable than results achieved in larger clinical trials, which may hinder our efforts to obtain regulatory approval for our product candidates. In both our DesCAARTesTM trial and our MusCAARTesTM trial, we plan to evaluate the toxicity profile of our product candidates and establish the recommended dose for the next clinical trial. The preliminary results of clinical trials with smaller sample sizes, such as our DesCAARTesTM trial ~~and ,~~ our MusCAARTesTM trial **and our RESETTM trials** , as well as any clinical trials for future product candidates, can be disproportionately influenced by various biases associated with the conduct of small clinical trials, such as the potential failure of the smaller sample size to accurately depict the features of the broader patient population, which limits the ability to generalize the results across a broader community, thus making the clinical trial results less reliable than clinical trials with a larger number of patients. As a result, there may be less certainty that such product candidates would achieve a statistically significant effect in any future clinical trials. If we conduct any future clinical trials of DSG3- CAART ~~or ,~~ MuSK- CAART **, or CABA- 201** , we may not achieve a statistically significant result or the same level of statistical significance, if any, that we might have anticipated based on the results observed in our DesCAARTesTM trial ~~and ,~~ our MusCAARTesTM trial **, and RESETTM trials** , respectively. Risks Related to Sales, Marketing and Competition The market opportunities for our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small. Our projections of both the number of people who have ~~the B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** we are targeting, as well as the subset of people with these diseases in a position to receive second or later lines of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** . The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for our product candidates may be limited or may not be amenable to treatment with our product candidates ~~. For instance, we expect DSG3- CAART to initially target a small patient population that suffers from mPV. Furthermore, patients for whom a preconditioning regimen is contraindicated, or is not acceptable to the patient, may not be eligible for treatment with the product candidate, further reducing the potential target population. Even if we obtain significant market share for our product candidates, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional indications~~ . We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively. The biopharmaceutical and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong focus on intellectual property. We face competition from many different players, including large and specialty pharmaceutical and biotechnology companies, academic research organizations and governmental agencies. Any therapeutic candidates we successfully develop and commercialize will compete with the existing standard of care as well as novel therapies that may gain regulatory approval in the future. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. We believe we are the first and only company developing CAAR T drug candidates, and one of **several** ~~only a few~~ developing CAR T drug candidates, for the treatment ~~of B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** . However, despite the significant differences in discovery, development and target populations between oncology and autoimmune targets, we recognize that companies with an investment and expertise in CAR T cell development for oncology indications could attempt to leverage their expertise into **autoimmune diseases where** B ~~cell~~ **cells** ~~- mediated autoimmune~~ **may play a role in initiating or maintaining** disease affected populations. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. Specifically, while rituximab is the first drug for the treatment of PV, the target indication for DSG3- CAART to have received regulatory approval in the United States in over 60 years, we are aware that multiple biopharmaceutical companies have therapies in clinical development. We are also aware of other biopharmaceutical companies developing therapies for muscle- specific kinase myasthenia gravis, or MuSK MG, **SLE** ~~and PLA2R- associated membranous nephropathy~~ , ~~or PLA2R MN~~ **myositis, SSc and gMG** . While we do not expect these product candidates to be directly competitive to our product candidates, even if we obtain regulatory approval of our product candidates, the availability and price of these other products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. Even if we obtain regulatory approval of our product candidates, the products may not gain the market acceptance among physicians, patients, hospitals, treatment centers and others in the medical community necessary for commercial success. The use of engineered T cells as a potential treatment for B cell- mediated autoimmune diseases is a recent development and may not become broadly accepted by

physicians, patients, hospitals, treatment centers and others in the medical community. We expect physicians to be particularly influential and we may not be able to convince them to use our product candidates for many reasons. Additional factors will influence whether our product candidates are accepted in the market, including: • the clinical indications for which our product candidates are licensed; • physicians, hospitals, treatment centers and patients considering our product candidates as a safe and effective treatment; • the potential and perceived advantages of our product candidates over alternative treatments; • the prevalence and severity of any side effects; • product labeling or product insert requirements of the FDA or other regulatory authorities; • limitations or warnings contained in the labeling approved by the FDA; • the timing of market introduction of our product candidates as well as competitive products; • the cost of treatment in relation to alternative treatments; • the availability of coverage and adequate reimbursement and pricing by third- party payors and government authorities; • the willingness of patients to pay out- of- pocket in the absence of coverage and adequate reimbursement by third- party payors and government authorities; • relative convenience and ease of administration, including as compared to alternative treatments and competitive therapies; and • the effectiveness of our sales and marketing efforts. The product candidates we plan to develop and commercialize are premised on offering a potential cure for ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** , which may result in a high degree of uncertainty related to pricing and long- term demand for our product. Our target patient populations are relatively small. Because of this pricing and demand for our product candidates, if licensed, may not be adequate to support an extended period of commercial viability, which could adversely affect our continued ability to successfully produce and market our product or any follow- on products. In addition, if our product candidates are licensed but fail to achieve market acceptance among physicians, patients, hospitals, treatment centers or others in the medical community, we will not be able to generate significant revenue. Even if our products achieve market acceptance, we may not be able to maintain that market acceptance over time if new products or technologies are introduced that are more favorably received than our products, are more cost effective or render our products obsolete. Risks Related to Business Development We may not be successful in our efforts to identify additional product candidates. Due to our limited resources and access to capital, we must prioritize development of certain product candidates, which may prove to be wrong and may adversely affect our business. Although we intend to explore other therapeutic opportunities, in addition to the product candidates that we are currently developing, we may fail to identify viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed. Research programs to pursue the development of our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs may initially show promise in identifying potential indications and / or product candidates, yet fail to yield results for clinical development for a number of reasons, including: • the research methodology used may not be successful in identifying potential indications and / or product candidates; • potential product candidates may be identified but may not be able to be expressed on T cells in a manner that enables product activity; • potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective drugs; or • it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio. Because we have limited financial and human resources, we intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forego or delay pursuit of opportunities with other 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. Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful. If we fail to develop additional product candidates, our commercial opportunity will be limited. One of our core strategies is to pursue clinical development of additional product candidates beyond CABA- 201, DSG3- CAART ~~,~~ **and** MuSK ~~- CAART, DSG3 / 1- CAART, and PLA2R -~~ CAART. Developing, obtaining regulatory approval and commercializing additional product candidates will require substantial additional funding and is prone to the risks of failure inherent in medical product development. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Even if we receive FDA approval to market additional product candidates for the treatment of ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** , we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity will be limited. Moreover, a failure in obtaining regulatory approval of additional product candidates may have a negative effect on the approval process of any other, or result in losing approval of any approved, product candidate. We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific, and medical personnel, including our Chief Executive Officer and President, our Scientific Advisory Board members, our President, Science and Technology, our Chief Medical Officer, and our Chief Financial Officer. The loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or

at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided stock options that vest over time. The value to employees of stock options that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employment agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain " key person " insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior managers as well as junior, mid- level and senior scientific and medical personnel. We expect to grow the size of our organization, and we may experience difficulties in managing this growth. As of December 31, ~~2022~~ **2023** , we had ~~58~~ **101** full- time employees and two part- time employees. As our development and commercialization plans and strategies develop, and as we continue to broaden our operational capabilities, we expect to expand our employee base and continue to add managerial, operational, sales, research and development, marketing, financial and other personnel. For example, we are still dependent on Penn and certain Penn- affiliated entities to continue providing certain research and development as well as manufacturing services under that certain research services agreement. Current and future growth imposes significant added responsibilities on members of management, including: • identifying, recruiting, integrating, retaining and motivating additional employees in an increasingly competitive, inflationary market; • managing our internal development efforts effectively, including the clinical and FDA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize our product candidates will depend, in part, on our ability to effectively manage our 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 certain research and development as well as general and administrative support, pursuant to agreements which expire after a certain period of time. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, or if we are not able to raise sufficient funds in the future to support our hiring efforts beyond our research and development personnel, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals. Business disruptions **, including due to natural disasters, global conflicts or political unrest,** could seriously **impact our operations, research and trials and** harm our future revenue and financial condition ~~and increase our costs and expenses~~ . Our operations, Penn **' s operations, WuXi** ' s operations and those of any CMOs, CROs and other contractors and consultants that we may engage could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics and other natural or man- made disasters or business interruptions, for which we are predominantly self- insured **. Further, global conflicts or political unrest, such as the ongoing military conflict between Russia and Ukraine and the Israel- Hamas war, may disrupt our global clinical trials and increase the likelihood of supply interruptions** . The occurrence of any of these business disruptions could seriously harm our **research, clinical trials,** operations and financial condition and increase our costs and expenses ~~. We currently rely on Penn to produce and process DSG3- CAART and anticipate that in the future we will rely on a third- party CMO for the same~~ . Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption **. There are also current geopolitical tensions with China. Recently, the Biden administration has signed multiple executive orders regarding China. One particular executive order titled Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy signed on September 12, 2022 will likely impact the pharmaceutical industry to encourage U. S. domestic manufacturing of pharmaceutical products. Moreover, there have been Congressional legislative proposals, such as the recent bill titled the BIOSECURE Act, which would, among other things, prohibit U. S. federal funding in connection with biotechnology equipment or services produced or provided by Chinese biotechnology service providers and loans and grants to, and federal contracts with any entity that uses biotechnology equipment or services from one of these entities in performance of the government contract. Any additional executive action, legislative action or potential sanctions with China could materially impact one of our current manufacturing partners, WuXi, and our agreement with them. For example, in February 2024, the chair and ranking member of the House Select Committee on the Chinese Communist Party, Representatives Mike Gallagher and Raja Krishnamoorthi, respectively, along with Senators Gary Peters and Bill Haggerty sent a letter to the Biden administration requesting that both WuXi AppTec Co., Ltd., WuXi' s parent company, and the affiliated WuXi Biologics be added to the Department of Defense' s Chinese Military Companies List (1260H list), the Department of Commerce' s Bureau of Industry and Security Entity List, and the Department of Treasury' s Non- SDN Chinese Military- Industrial Complex Companies List. While the Biden administration has yet to take action on this letter, adding either or both previously mentioned WuXi entities on any or**

all of the aforementioned lists could materially impact the WuXi Agreement. Additionally, on February 28, 2024, President Biden signed Executive Order 14117 (" Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government- Related Data by Countries of Concern") which implements a new framework to protect the privacy of personal data shared between the U. S. and Europe, which may, in effect, impact privacy laws with" countries of concern" such as China or Russia . In addition, due to our adoption of a more flexible work model following the COVID-19 pandemic, our increased prevalence of personnel working from home may negatively impact productivity, or disrupt, delay, or otherwise adversely impact our business operations. Further, this could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators, ethics committees, manufacturing sites, research or clinical trial sites and other important agencies and contractors. Risks Related to Our Financial Condition and Capital Requirements Risks Related to Past Financial Condition We have incurred net losses in every period since our inception and anticipate that we will incur substantial net losses over the next several years, and may never achieve or maintain profitability. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We initially licensed rights to the patents underlying our product candidates in August 2018 and initiated our DesCAARTesTM trial in June 2020. We have no products licensed for commercial sale, and we will continue to incur significant research and development and other expenses related to our ongoing operations. Our net losses may fluctuate significantly from quarter to quarter and year to year. We have to date financed our operations primarily through private placements of our preferred stock, the sale of common stock in our initial **and secondary** public ~~offering~~ **offerings** and sales of our common stock from time to time in " at- the- market " offerings. As a result, we are not profitable and have incurred net losses in each period since our inception. For the years ended December 31, **2023 and** 2022 ~~and 2021~~ , we recorded net losses of $ **67. 7 million and $** 53. 0 million ~~and $ 46. 3 million~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~165~~ **233** . ~~6~~ **2** million. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if, and as, we: • continue our research and development efforts and submit additional INDs for our product candidates; • conduct preclinical studies and clinical trials for our current and future product candidates; • further develop our product candidate platform; • continue to discover and develop additional product candidates; • maintain, expand and protect our intellectual property portfolio; • hire additional clinical, scientific manufacturing and commercial personnel; • establish a commercial manufacturing source and secure supply chain capacity sufficient to provide commercial quantities of any product candidates for which we may obtain regulatory approval, whether through a CMO or through a manufacturing facility that we establish; • acquire or in- license other product candidates and technologies, including advanced manufacturing and translational capabilities that we will need for the further development and possible commercialization of our product candidates; • seek marketing approvals for any product candidates that successfully complete clinical trials; • establish a sales, marketing and distribution infrastructure to support the sales and marketing of any product candidates for which we may obtain marketing approvals; and • add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts, as well as to support our operations as a public company. To become and remain profitable, we must succeed in developing, and eventually commercializing, a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities and have not yet demonstrated our ability to successfully develop any product candidate, obtain regulatory 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. We may never be able to develop, manufacture or commercialize a marketable product. Even if we are able to succeed in these activities, we may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Our expenses will increase if, among other things: • there are any delays in completing our clinical trials or the development of any of our product candidates; • we are required by the FDA or other regulatory authorities to perform trials or studies in addition to, or different than, those expected; or • there are any third- party challenges to our intellectual property or we need to defend against any intellectual property- related claim. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek regulatory approval for and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. We have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability, and we may face significant challenges and expense as we test our product candidates and build our capabilities. We were incorporated in 2017 and initially acquired rights to license certain patent rights from Penn in August 2018, and acquired rights to license certain patent rights from Nanjing IASO Biotherapeutics Co., Ltd., or IASO, in October 2022. **All of our product candidates are still in the preclinical development or clinical stage.** We **have not yet demonstrated our ability to successfully complete any clinical trials, including** ~~are~~ **large** ~~early in~~ **- scale,**

pivotal clinical trials, obtain marketing approvals, manufacture clinical and commercial scale therapeutics, ~~our~~ **or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful commercialization. Our ability to generate product revenue or profits, which we do not expect will occur for many years, if ever, will depend heavily on the successful** development ~~efforts, have a limited operating history~~ and **eventual commercialization of our product candidates** ~~are subject to the risks inherent to any newly- formed organization~~ , **which** ~~including, among others, risks that we~~ may ~~not~~ **never occur. We may never** be able to **develop or commercialize a marketable product** ~~hire sufficient qualified personnel and establish operating controls and procedures~~ . Our limited operating history, particularly in light of the rapidly evolving cell therapy field, may make it difficult to evaluate our **current business** ~~technology and industry~~ and predict our future performance. Our **relatively** short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by ~~early~~ **clinical** - stage companies in rapidly evolving fields. If we do not address these risks successfully, our business will suffer. Similarly, we expect that our financial condition and operating results will **continue to** fluctuate ~~significantly~~ from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. As a result, our shareholders should not rely upon the results of any quarterly or annual period as an indicator of future operating performance. We currently do not have in- house resources sufficient to enable the development of our product candidates, including our CAR T and CAAR T cell platforms. We are reliant on several manufacturing and support services from Penn through ~~a~~ **two** Master Translational Research **Service Agreements, or the CAART** Services Agreement **and CARTA** ~~, or the~~ Services Agreement, **respectively,** ~~as well as certain research~~ and **collectively, the** ~~development and general and administrative services~~ **Services** ~~through three sponsored research agreements~~ **Agreements** . We also rely on Penn for ~~access to key technologies for~~ current manufacturing of DSG3- CAART **and CABA- 201** . Our ability to rely on services from Penn is limited to a specified period of time, to specific capabilities, and is subject to Penn' s right to terminate these services with or without cause. We are reliant on **WuXi** manufacturing services ~~from WuXi~~ **for MuSK- CAART and for the planned global clinical development of CABA- 201 in multiple indications** through a Development, Manufacturing and Testing Services Agreement, or the WuXi Agreement. Our ability to rely on services from WuXi is limited to a specified period of time, to specific capabilities, and is subject to WuXi' s right to terminate these services with or without cause. If we are unable to establish necessary relationships with third party partners and **/ or** build our own capabilities, our operating and financial results could differ materially from our expectations, and our business could suffer. As we build our own capabilities, and enter into agreements with third parties, we expect to encounter risks and uncertainties frequently experienced by growing companies in new and rapidly evolving fields, including the risks and uncertainties described herein. All of our programs require additional preclinical research and development, clinical development, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, capacity and expertise, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenue from product sales. Other programs of ours require additional discovery research and then preclinical and clinical development. In addition, our product candidates must be licensed for marketing by the FDA before we may commercialize any product ~~. In addition, as an early- stage company, we have encountered and may continue to encounter unforeseen expenses, difficulties, complications, delays and other known and unknown circumstances. As we advance our product candidates, we will need to transition from a company with a research focus to a company capable of supporting clinical development and if successful, commercial activities. We may not be successful in such a transition~~ . We have not generated any revenue from our product candidates and our ability to generate revenue from product sales and become profitable depends significantly on our success in a number of areas. To become and remain profitable, we or any potential future collaborator must develop and eventually commercialize products with significant market potential at an adequate profit margin after cost of goods sold and other expenses. All of our product candidates are in the early stages of development and we will require additional preclinical studies, clinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We initiated our DesCAARTesTM trial of DSG3- CAART, ~~our most advanced product candidate,~~ targeting pathogenic B cells in patients with mucosal pemphigus vulgaris, or mPV, in June 2020. Our IND for MuSK- CAART, targeting pathogenic B cells in a subset of patients with myasthenia gravis, or MG, became effective in January 2022. Our **INDs for** ~~other product candidates, which include~~ CABA- 201, **which are designed to treat** ~~targeting undisclosed autoimmune disease (s), DSG3 / 1- CAART, targeting pathogenic B cells in~~ patients with **active LN** ~~mucocutaneous pemphigus vulgaris,~~ or ~~mcPV~~ **active SLE without renal involvement** , ~~and PLA2R- CAART, targeting pathogenic B cells in~~ patients with ~~PLA2R~~ **myositis, patients with SSc, and patients with gMG became effective in March 2023, May 2023, September 2023 and November 2023, respectively. Our ability to generate revenue depends on a number of factors, including, but not limited to: • timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third** - ~~associated membranous nephropathy,~~ **party academic and commercial contractors; •** ~~or~~ **our ability** ~~PLA2R- associated MN, have yet~~ to complete IND- enabling studies ~~. We have not yet administered any of our product candidates other than DSG3- CAART in humans and, as such, we face significant translational risk as our product candidates advance to the clinical stage. Our ability to generate revenue depends on a number of factors, including, but not limited to: • timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third- party academic and commercial contractors; • our ability to complete IND- enabling studies~~ and successfully submit INDs or comparable applications; • whether we are required by the FDA to conduct additional clinical trials or other studies beyond those planned to support the licensure and commercialization of our product candidates or any future product candidates; • our ability to demonstrate to the satisfaction of the FDA the safety, potency, purity and acceptable risk to benefit profile of our product candidates or any future product candidates; • the prevalence, duration and severity of potential side effects or other

safety issues experienced with our product candidates or future product candidates, if any; • the cost of manufacturing and processing our product candidates being greater than we anticipate; • the timely receipt of necessary marketing approvals from the FDA; • the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or future product candidates to treat ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** ; • our ability and the ability of third parties with whom we contract to manufacture adequate clinical and commercial supplies of our product candidates or any future product candidates, remain in good standing with regulatory authorities and develop, validate and maintain commercially viable manufacturing processes that are compliant with FDA' s current Good Manufacturing Practices, or cGMP; • our ability to successfully develop a commercial and competitive strategy and thereafter commercialize our product candidates or any future product candidates in the United States, if licensed for marketing, reimbursement, sale and distribution, whether alone or in collaboration with others; • patient demand for our product candidates and any future product candidates, if licensed; and • our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates. Many of the factors listed above are beyond our control and could cause us to experience significant delays or prevent us from obtaining regulatory approvals or commercialize our product candidates. Even if we are able to commercialize our product candidates, we may not achieve profitability soon after generating product sales, if ever. If we are unable to generate sufficient revenue through the sale of our product candidates or any future product candidates, we may be unable to continue operations without continued funding. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Additionally, even if we succeed in commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to research, develop and market additional product candidates. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause you to lose all or part of your investment. Risks Related to Future Financial Condition We will require substantial additional financing to develop and commercialize our product candidates and implement our operating plans. If we fail to obtain additional financing or cannot obtain financing at the levels we require due to we may be delayed in our plans or unable to complete the development and commercialization of our product candidates. Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the preclinical and clinical development of our product candidates, including our DesCAARTesTM trial, our MusCAARTesTM trial, **our RESETTM trials,** and our research and development, preclinical studies and clinical trials for ~~CABA- 201, PLA2R- CAART and DSG3 / 1- CAART and~~ any future product candidates, to seek regulatory approvals for our product candidates, to enable commercial production of our products, if licensed, and to initiate and complete registration trials for multiple products. **As of December 31, 2023, we had $ 241. 2 million of cash, cash equivalents and short- term investments. Since our initial public offering, we have generated cash from public offerings of our common stock and pre- funded warrants to purchase our common stock resulting in aggregate net proceeds of approximately $ 272. 1 million.** While we currently expect our existing cash ~~and~~ **,** cash equivalents and **short- term** investments to be sufficient to fund our operations ~~through~~ **into** the ~~announcement~~ **first half** of **2026** ~~six month combination cohort data from the DesCAARTesTM and MusCAARTesTM clinical trials~~ , **which includes** ~~as well as~~ initial clinical data **on efficacy endpoints and tolerability** from the **initial** CABA- 201 **treated patients in the RESETTM** clinical ~~trial~~ **trials** ~~, assuming the clearance of our CABA- 201 IND by the FDA~~ , we expect to require significant additional financing to complete these **clinical** ~~Phase 1~~ trials ~~,~~ and any future clinical trials of these and our other product candidates. Further, if ~~licensed~~ **marketing approval is received** , we will require significant additional amounts of cash to launch and commercialize our product candidates ~~. As of December 31, 2022, we had $ 106. 5 million of cash and cash equivalents and investments. On October 29, 2019, we completed an initial public offering of our common stock by issuing 7, 275, 501 shares of our common stock (including 475, 501 shares of our common stock pursuant to the underwriters' option to purchase additional shares that we issued in November 2019), at $ 11. 00 per share, for gross proceeds of $ 80. 0 million, or net proceeds of $ 71. 0 million. In 2021, we raised $ 49. 7 million, or net proceeds of $ 48. 3 million, in " at- the- market " offerings, pursuant to a Sales Agreement with Cowen and Company, LLC which provides for the offering, issuance and sale of up to an aggregate amount of $ 75. 0 million of our common stock. In December 2022, we issued 126, 815 shares of our common stock at a price of $ 5. 52 per share and to certain investors in lieu of common stock, pre- funded warrants to purchase 6, 213, 776 shares of common stock at a price of $ 5. 51999 per pre- funded warrant. The purchase price per share of each pre- funded warrant represents the per share offering price for the common stock, minus the $ 0. 00001 per share exercise price of such pre- funded warrant. Aggregate net proceeds were $ 32. 6 million after deducting underwriting discounts and commissions and offering expenses. Based on our current operating plan, we believe that our existing cash and cash equivalents and investments will be sufficient to fund our operations into the first quarter of 2025~~ . However, we have based this estimate on assumptions that may prove to be wrong. Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may require substantial additional capital for the further development and commercialization of our product candidates, including funding our internal manufacturing capabilities, and may need to raise additional funds sooner if we choose to expand more rapidly than we presently anticipate. Because the length of time and activities associated with development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any approved marketing and commercialization activities. Our future funding requirements, both near- and long- term, will depend on many factors, including, but not limited to: • the initiation, progress, timing, costs and results of preclinical studies and clinical trials for our product candidates; • the clinical development plans we establish for these product candidates; • the number and characteristics of product candidates that we may develop or in- license; • the terms of any collaboration agreements we may choose to conclude; • the outcome, timing and cost of meeting regulatory requirements established by the FDA; • the cost of filing,

prosecuting, defending and enforcing our patent claims and other intellectual property rights; • the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us or our product candidates; • the effect of competing technological and market developments; • the costs of establishing and maintaining a supply chain for the development and manufacture of our product candidates; • the cost and timing of establishing, expanding and scaling manufacturing capabilities; • the cost of maintaining the amount patient data for which we would be responsible following commercialization of one or more of our product candidates; and • the cost of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own. We cannot be certain that additional funding will be available on acceptable terms, or at all. As widely reported, global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, inflation, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Until we are able to generate sufficient revenue to finance our cash requirements, we will need to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our research and development initiatives and clinical development plans. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock. Pursuant to our equity incentive plans, our management is authorized to grant stock options to our employees, directors and consultants. Additionally, the number of shares of our common stock reserved for issuance under the 2019 Stock Option and Incentive Plan **, or the 2019 Plan,** automatically increased on January 1, 2023 and will automatically increase each January 1 thereafter through and including January 1, 2029, by 4 % of the total number of shares of our capital stock outstanding on December 31 of the preceding calendar year, or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall **. In addition, on April 7, 2023, our board of directors adopted, and at our 2023 annual meeting our stockholders approved, an amendment to the 2019 Plan, or the Plan Amendment, to increase the aggregate number of shares authorized for issuance under the 2019 Plan by 3, 000, 000 shares, subject to adjustment. Our compensation committee determined the size of the increase to the reserved pool under the Plan Amendment based on projected equity awards to anticipated new hires, projected annual equity awards to existing employees and an assessment of the magnitude of increase that our institutional investors and the firms that advise them would likely find acceptable. We anticipate that the increased share reserve under our 2019 Plan, as amended by the Plan Amendment, will be sufficient to provide equity incentives to attract, retain, and motivate employees for a period of two years following the effective date of the Plan Amendment** . Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline. Risks Related to Our Intellectual Property We rely heavily on certain in- licensed patent and other intellectual property rights in connection with our development of our product candidates and, if we fail to comply with our obligations under our existing and any future intellectual property licenses with third parties, we could lose license rights that are important to our business. Our ability to develop and commercialize our product candidates is heavily dependent on in- licenses to patent rights and other intellectual property granted to us by third parties. For example, we depend heavily on our License Agreement with Penn and CHOP, which was entered into in 2018, amended and restated in July 2019, and further amended in May 2020 and October 2021, pursuant to which we obtained (a) a non- exclusive, non- sublicensable, worldwide research license to intellectual property controlled by Penn and CHOP to make, have made and use products in two subfields of use, (b) effective as of October 2018, an exclusive, worldwide, royalty- bearing license, with the right to sublicense, under certain of such intellectual property to make, use, sell, offer for sale and import products in the same two subfields of use, and (c) effective as of October 2018, a non- exclusive, worldwide, royalty- bearing license, with limited rights to sublicense, under certain of Penn' s know- how, which know- how satisfies certain criteria and is listed on a mutually agreed to schedule, to make, have made, use, sell, offer for sale, import and have imported products in the same two subfields of use. We also depend on our Exclusive License Agreement with IASO, which was entered into in October 2022, pursuant to which we obtained a worldwide, exclusive license under certain intellectual property to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of an autoimmune or alloimmune indication in humans, or the IASO Agreement. We may enter into additional license agreements in the future. Our license agreements with Penn, CHOP and IASO impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with our obligations under these licenses, our licensors, including Penn, CHOP and IASO may have the right to terminate these license agreements, in which event we might not be able to market our product

candidates. Termination of any of our license agreements or reduction or elimination of our licensed rights may also result in our having to negotiate new or reinstated licenses with less favorable terms. We may need to obtain additional licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we may be required to expend significant time and resources to develop or license replacement technology. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business significantly. We cannot provide any assurances that third- party patents do not exist which might be enforced against our current product candidates or future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and / or other forms of compensation to third parties. Furthermore, in many cases, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in- license from third parties. For example, pursuant to our IASO Agreement, IASO controls such activities for the patent rights licensed to us under such agreement. Pursuant to our License Agreement with Penn and CHOP, Penn controls such activities for the patent rights licensed to us under such agreement. Therefore, although we provide input to IASO, Penn and CHOP on these activities, we cannot be certain that these patents will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our current or future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected. Disputes may arise between us and our current and future licensors regarding intellectual property subject to a license agreement, including those related to: • the scope of rights granted under the License Agreement or IASO Agreement and other interpretation- related issues; • whether we have breached the License Agreement or IASO Agreement and whether any such breach is subject to a cure period; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • our right to sublicense patent and other rights to third parties under collaborative development relationships; • our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and • the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners. Furthermore, disputes may arise between us and our current or future licensors regarding the ownership of intellectual property developed by us, such that we may be required to assign or otherwise transfer such intellectual property to such licensor. In the event that the assigned or transferred intellectual property is covered by an existing license agreement with such licensor we may be required to make additional royalty or milestone payments, or both, to such licensor. If the assigned or transferred intellectual property is not covered by an existing license agreement, then we may be required to enter into an additional license agreement to advance our research or allow commercialization of our product candidates, which may not be available on commercially reasonable terms or at all. If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If our efforts to protect the proprietary nature of the intellectual property related to our current and any future product candidates are not adequate, we may not be able to compete effectively in our market. Our success depends in large part on our ability to obtain and maintain intellectual property protection in the United States and other countries with respect to our product candidates. If we do not adequately protect or enforce our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we have in- licensed patent rights in the United States and abroad relating to the product candidates that are important to our business. The patent application and approval process is expensive, complex and time- consuming. Our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain. No consistent policy regarding the breadth of claims allowed in biotechnology and pharmaceutical patents has emerged to date in the United States or in many foreign jurisdictions. In addition, the determination of patent rights with respect to biological and pharmaceutical products commonly involves complex legal and factual questions, which has in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that our licensors were the first to make the inventions claimed in the patents or pending patent applications we in- license, or that our licensors were the first to file for patent protection of such inventions. Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, the patents or pending patent applications we in- license may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U. S. Patent and Trademark Office, or USPTO, or become involved in post- grant review procedures, derivation proceedings, reexaminations, or inter partes review in the United States, or oppositions and other comparable proceedings in foreign jurisdictions, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. In addition, given the amount of time required for the development, testing and regulatory review of

new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of the patents we in- license or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law is more restrictive than U. S. patent law in connection with the patentability of methods of treatment of the human body and Chinese bankruptcy law may not provide a licensee the same protections as U. S. bankruptcy law. This could impact our in- license under the IASO Agreement with IASO, a China- based company, if IASO declared bankruptcy, and could have a material adverse effect on the development of CABA- 201. A European Unified Patent Court ~~(~~ **, or the** UPC **,** ~~) is scheduled to come~~ **came** into force during 2023. The UPC **is** ~~will be~~ a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of ~~any of~~ our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of our European patents. ~~We~~ **Although we have decided, and** may **continue to** decide **,** to opt out **certain of** our European patents and patent applications from the UPC ~~. If~~ **, if** certain formalities and requirements are not met, **then** ~~however,~~ our European patents and patent applications could be challenged for non- compliance and brought under the jurisdiction of the UPC. ~~We~~ **Thus, we** cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction ~~of the UPC, if we decide to opt out~~ of the UPC. We cannot predict whether the patent applications we in- license currently being pursued will issue as patents, whether the claims of any patent that has or may issue will provide us with a competitive advantage or prevent competitors from designing around the claims to develop competing technologies in a non- infringing manner, or whether we or our licensors will be able to successfully pursue patent applications in the future relating to our current product candidates or future products and product candidates. Moreover, the patent application and approval process is expensive and time- consuming. We or our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Furthermore, we, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to seek additional patent protection. It is possible that defects of form in the preparation or filing of patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If there are material defects in the form, preparation, prosecution or enforcement of the patents or patent applications we in- license, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. Even if the patent applications we in- license issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patent rights by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our product candidates. Alternatively, our competitors may seek to market generic versions of any approved products by submitting abbreviated BLAs to the FDA during which process they may claim that patents licensed by us are invalid, unenforceable or not infringed. In these circumstances, we may need to defend or assert our intellectual property rights, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find the patents we in- license invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, even if we have in- licensed valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. In the future, we likely will need to expand our patent portfolio to pursue patent coverage for new product candidates that we wish to develop. The patent prosecution process is competitive, and other companies, some which may have greater resources than we do in this area, may also be pursuing intellectual property rights that we may consider necessary or attractive in order to develop and commercialize future product candidates. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than those in the United States. ~~The deadline to pursue protection in foreign jurisdictions for some of the patent families licensed under the License Agreement with Penn has not yet expired. Prior to applicable deadlines, we and Penn will need to decide where to pursue protection, and we will not have the opportunity to pursue protection unless we do so in applicable jurisdictions prior to the deadlines.~~ Although our License Agreement and IASO Agreement grant us worldwide rights, there can be no assurance that we will obtain or maintain patent rights in or outside the United States under any future license agreements. 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 United States even in jurisdictions where we and our licensors pursue patent protection. Consequently, we and our licensors may not be able to prevent third parties from practicing our inventions in all countries outside the United States, even in jurisdictions where we and our licensors pursue patent protection, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we and our licensors have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our licensors have patent protection, but

enforcement is not as strong as that in the United States. These products may compete with our product candidates and the patents we in- license 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 certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement of the patents we in- license or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights, even if obtained, in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put the patents we in- license at risk of being invalidated or interpreted narrowly and the patent applications we in- license at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We or our licensors may be subject to claims challenging the inventorship or ownership of the patents and other intellectual property that we own or license. We or our licensors may be subject to claims that former employees, collaborators or other third parties have an ownership interest in the patents and intellectual property that we in- license or that we may own or in- license in the future. While it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own or such assignments may not be self- executing or may be breached. Our licensors may face similar obstacles. We or our licensors could be subject to ownership disputes arising, for example, from conflicting obligations of employees, consultants or others who are involved in developing our product candidates ~~. For example, our scientific co- founders, Drs. Payne and Milone, are members of our scientific advisory board and are also employed by and subject to Penn' s intellectual property policy~~ . Litigation may be necessary to defend against any claims challenging inventorship or ownership. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, results of operations and financial condition. Some intellectual property which we have in- licensed was discovered through government funded programs and thus is subject to federal regulations such as " march- in " rights, certain reporting requirements, and a preference for U. S. industry. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. Certain of the intellectual property rights we have licensed, including rights licensed to us by Penn relating to our DSG3- CAART and DSG3 / 1- CAART product candidates, was generated through the use of U. S. government funding and may therefore be subject to certain federal laws and regulations. As a result, the U. S. government has certain rights to intellectual property embodied in our DSG3- CAART and DSG3 / 1- CAART product candidates and may have rights in future product candidates pursuant to the Bayh- Dole Act of 1980. These U. S. government rights in certain inventions developed under a government- funded program include a non- exclusive, non- transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U. S. government has the right to require us to grant exclusive, partially exclusive, or non- exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations, also referred to as " march- in rights ". The U. S. government also has the right to take title to these inventions if we, or the applicable licensor, such as Penn, fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, the U. S. government requires that products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U. S. manufacturers may limit our ability to contract with non- U. S. product manufacturers for product candidates covered by such intellectual property. We may become involved in lawsuits to protect or enforce our patent rights or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe, misappropriate or otherwise violate patents, trademarks, copyrights or other intellectual property that we own or in- license. To counter infringement, misappropriation or other unauthorized use, we may be required to file claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived violators could provoke these parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property, in addition to counterclaims asserting that the patents we in- license are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent we in- license is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. In the U. S., grounds for a validity challenge in a court proceeding could be an alleged failure to meet one or more statutory requirements for patentability, including, for example, lack of novelty, obviousness, lack of written description or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Additionally, third parties are able to challenge the validity of issued patents through administrative proceedings in the patent offices of certain countries, including the USPTO and the European Patent Office. Even if the validity of a patent is upheld during a court proceeding, there is a risk that the court will construe the patent' s claims

narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that the patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving the patents we in- license could limit our ability to assert the patent we in- license against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Even if we establish infringement, misappropriation or another violation of our intellectual property rights, the court may decide not to grant an injunction against the offender and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. Changes in either the patent laws or the interpretation of the patent laws in the United States or other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. On September 16, 2011, the Leahy- Smith America Invents Act, or the Leahy- Smith Act, was signed into law. When implemented, the Leahy- Smith Act included several significant changes to U. S. patent law that impacted how patent rights could be prosecuted, enforced and defended. In particular, the Leahy- Smith Act also included provisions that switched the United States from a " first- to- invent " system to a " first- to- file " system, allowed third- party submission of prior art to the USPTO during patent prosecution and set forth additional procedures to attack the validity of a patent by the USPTO administered post grant proceedings. Under a first- to- file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO developed new regulations and procedures governing the administration of the Leahy- Smith Act, and many of the substantive changes to patent law associated with the Leahy- Smith Act, and in particular, the first to file provisions, became effective on March 16, 2013. It remains unclear what impact, if any, the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of the patent applications we in- license and the enforcement or defense of the issued patents we in- license, all of which could have a material adverse effect on our business. The patent positions of companies engaged in the development and commercialization of biologics are particularly uncertain. For example, the Supreme Court of the United States issued its decision in Association for Molecular Pathology v. Myriad Genetics, Inc., or Myriad, a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2. Myriad held that an isolated segment of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent- eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent- eligible. Thereafter, the USPTO issued a guidance memorandum instructing USPTO examiners on the ramifications of the Prometheus and Myriad rulings and apply the Myriad ruling to natural products and principles including all naturally occurring nucleic acids. Certain claims of our in- licensed patent applications contain, and any future patents we may obtain may contain, claims that relate to specific recombinant DNA sequences that are naturally occurring at least in part and, therefore, could be the subject of future challenges made by third parties. We cannot assure you that our efforts to seek patent protection for one or more of our product candidates will not be negatively impacted by this Supreme Court decision, rulings in other cases or changes in guidance or procedures issued by the USPTO. We cannot fully predict what impact the Supreme Court' s decisions in Myriad may have on the ability of life science companies to obtain or enforce patents relating to their products in the future. These decisions, the guidance issued by the USPTO and rulings in other cases or changes in USPTO guidance or procedures could have a material adverse effect on our existing patent rights and our ability to protect and enforce our intellectual property in the future. If we are unable to protect the confidentiality of trade secrets, our business and competitive position would be harmed. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect certain proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidate discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect and some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors, and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. Competitors and other third parties could infringe, misappropriate or otherwise violate our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to

prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets. Patent term may be inadequate to protect our competitive position on our product candidates for an adequate amount of time. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication (or any additional indications approved during the period of extension). However, a patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of the product' s approval by the FDA, only one patent applicable to an approved drug is eligible for the extension, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. In the future, if and when our product candidates receive FDA approval, we plan to apply for patent term extensions on patents covering those product candidates in any jurisdiction where these are available. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to the patents we in- license, or may grant more limited extensions than we request. Moreover, we may not receive 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. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case. We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Certain of our employees, consultants or advisors are currently, or were previously, employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Our licensors may face similar risks, which could have an adverse impact on intellectual property that is licensed to us. We may become subject to claims that we are infringing certain third- party patents or other third- party intellectual property rights, any of which may prevent or delay our development and commercialization efforts and have a material adverse effect on our business. Our commercial success depends in part on avoiding infringing, misappropriating and otherwise violating the patents and other intellectual property and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, and administrative proceedings such as interferences, inter partes review and post grant review proceedings before the USPTO and opposition proceedings before foreign patent offices. Numerous U. S. and foreign issued patents and pending patent applications, which are owned or controlled by third parties, including our competitors, exist in the fields in which we are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Third parties may assert that we or our licensors are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to materials, methods of manufacture or methods for treatment relating to our product candidates and, because patent applications can take many years to issue, there may be currently pending third party patent applications which may later result in issued patents, in each case that our product candidates, their manufacture or use may infringe or be alleged to infringe. We may fail to identify potentially relevant patents or patent applications, incorrectly conclude that a patent is invalid or does not cover our activities, or incorrectly conclude that a patent application is unlikely to issue in a form of relevance to our activities. Parties making patent infringement claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, including demonstrating non- infringement, invalidity or unenforceability of the respective patent rights in question, regardless of their merit, is time- consuming, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. For example, in order to successfully challenge the validity of any U. S. patent in federal court, we would need to overcome a presumption of validity. This is a high burden requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, and we can provide no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. We may not have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our shares. In the event that a holder of any such patents seeks to enforce its patent rights against us with respect to one or more of our product candidates, and our defenses against the infringement of such patent rights are unsuccessful, we may be precluded from commercializing our product candidates, even if approved, without first obtaining a license to some or all of these patents, which may not be available on commercially reasonable terms or at all. Moreover, we may be required to pay significant fees and royalties to secure a license to the applicable patents. Such a license may only be non- exclusive, in which case our ability to stop others from using or commercializing technology and products similar or

identical to ours may be limited. Furthermore, we could be liable for damages to the holder of these patents, which may be significant and could include treble damages if we are found to have willfully infringed such patents. In the event that a challenge to these patents were to be unsuccessful or we were to become subject to litigation or unable to obtain a license on commercially reasonable terms with respect to these patents, it could harm our business, financial condition, results of operations and prospects. We are aware of third- party issued U. S. patents relating to the lentiviral vectors which may be used in the manufacture or use of our product candidates. If these patent rights were enforced against us, we believe that we have defenses against any such action, including that these patents would not be infringed by our product candidates and / or that these patents are not valid. However, if these patents were enforced against us and defenses to such enforcement were unsuccessful, unless we obtain a license to these patents, which may not be available on commercially reasonable terms, or at all, we could be liable for damages and precluded from commercializing any product candidates that were ultimately held to infringe these patents, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even in the absence of a finding of infringement, we may need or may choose 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, or at all. In that event, we would be unable to further develop and commercialize our product candidates. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Any of the foregoing could materially adversely affect our business, results of operations and financial condition. Intellectual property rights do not necessarily address all potential threats. 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 make products that are similar to our product candidates or utilize similar cell therapy technology but that are not covered by the claims of our current or future patent portfolio; • we, or our current or future licensors or collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent application that we license now or that we may license or own in the future; • we, or our current or future licensors or collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our licensed intellectual property rights; • it is possible that our current or future licensed patent applications will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • our competitors or other third parties 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; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; • we may choose not to file a patent application in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent application covering such intellectual property; and • third- party patents may issue with claims covering our activities; we may have infringement liability exposure arising from such patents. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects. Risks Related to Our Reliance on Third Parties We are reliant on a research services agreement..... Penn during the transition period. We currently, and will likely continue to, rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates. We depend and will continue to depend upon third parties, including independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners, to conduct our preclinical studies and clinical trials under agreements with us. Specifically, we depend on clinical trial sites to enroll patients and conduct the DesCAARTesTM trial ~~and ,~~ MusCAARTesTM trial **and RESETTM trials** in a timely and appropriate manner. If our clinical trial sites do not conduct the trials on the timeline we expect or otherwise fail to support the trials, our clinical trial results could be significantly delayed, thereby adversely impacting our leadership position in the ~~CAAR T industry~~ **autoimmune cell therapy space** and our ability to progress additional ~~product candidates. Further, although we intend to transition our manufacturing needs to a CMO and eventually secure our own clinical manufacturing facility, we must currently rely on Penn to manufacture supplies and process our~~ product candidates. As we open additional clinical trial sites, we expect to have to negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We will rely heavily on these third parties, including Penn and WuXi, to conduct our manufacturing, and as a result, will have limited control over pace at which these activities are carried out. Nevertheless, we are responsible for ensuring that each of our trials is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with FDA' s GCPs which are regulations and guidelines enforced by the FDA for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our marketing applications. We cannot provide assurance that, upon inspection, such regulatory authorities will not determine that some or all of our clinical trials do not fully comply with the GCP requirements. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled and warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will require a large number of test patients. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. As widely reported, global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in

consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. In the event that one or more of our current or future service providers, manufacturers and other partners do not successfully carry out their contractual duties, meet expected deadlines, or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, due to the economic downturn **, the enactment of legislative proposals** or for any other reasons, then we may not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our medicines. Our failure or the failure of these third parties to comply with applicable regulatory requirements or our stated protocols could also subject us to enforcement action. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws **. We currently rely on certain foreign or foreign- owned third- party vendors, including WuXi, to manufacture certain clinical materials or to provide services in connection with certain clinical trials. Such foreign and foreign- owned vendors may be subject to U. S. legislation or investigations, including the proposed BIOSECURE Act, sanctions, trade restrictions and other foreign regulatory requirements, which could increase the cost or reduce the supply of material available to us, delay the procurement or supply of such material, delay or impact clinical trials, have an adverse effect on our ability to secure significant commitments from governments to purchase our potential therapies and could adversely affect our financial condition and business prospects** . Any third parties conducting our clinical trials will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical 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 studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. If any of our relationships with trial sites, or any CRO that we may use in the future, terminates, we may not be able to enter into arrangements with alternative trial sites or CROs or do so on commercially reasonable terms. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is often a natural transition period when a new third party commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. ~~For example, in October 2021, one of our CROs that provides data management, biostatistics and pharmacovigilance data services for the DesCAARTesTM trial, provided us a 60- day notice of termination for convenience, and as a result in December 2021 we transitioned to a new provider of data management, biostatistics and pharmacovigilance data services.~~ 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. We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our medicines, producing additional losses and depriving us of potential product revenue. We intend to rely on third parties to manufacture our clinical product supplies, and we may have to rely on third parties to produce and process our product candidates, if licensed. Although we may eventually secure our own clinical manufacturing facility for any late phase clinical development that we undertake, we currently rely on third parties, including Penn ~~, to supply raw materials and other important components~~ and WuXi **,** ~~for certain key technologies that are used~~ to manufacture our product candidates **,** and **we** intend in the future **to continue** to rely on CMOs. In the case of any manufacturing performed for us by third parties, the services performed for us risk being delayed because of the competing priorities that such parties have for utilization of their manufacturing resources and any capacity issues that thereby arise. We do not yet have sufficient information to reliably estimate the cost of the manufacturing and processing of our product candidates in clinical quantity or commercial quantity, and the actual cost to manufacture and process our product candidates could ultimately materially and adversely affect the commercial viability of our product candidates. As a result, we may never be able to develop a commercially viable product. In addition, our anticipated reliance on a limited number of third- party manufacturers exposes us to the following risks: • We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA may have questions regarding any replacement contractor. This may require new testing and regulatory interactions. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA questions, if any. • Our third- party manufacturers might be unable to timely formulate and manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any. • Contract manufacturers may not be able to execute our manufacturing procedures appropriately. • Any contract manufacturers that we engage may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store and distribute our product candidates. • Manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMP and other government regulations. We do not have control over third- party manufacturers' compliance with these regulations and standards. • We may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates. • Our third- party manufacturers could breach or terminate their agreement with us. Furthermore, all of our contract manufacturers are engaged with other companies to supply and / or manufacture materials or products for such companies, which exposes our manufacturers to regulatory risks related to

the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may affect the regulatory clearance of our contract manufacturers' facilities generally. If the FDA does not approve these facilities for the manufacture of our product candidates or if any agency withdraws its approval in the future, we may need to find alternative manufacturing facilities, which would negatively impact our ability to develop, obtain regulatory approval for or market our product candidates, if licensed. Our contract manufacturers would also be subject to the same risks we face in developing our own manufacturing capabilities, as described above. Each of these risks could delay our clinical trials, the approval, if any of our product candidates by the FDA or the commercialization of our product candidates or result in higher costs or deprive us of potential product revenue. In addition, we will rely on third parties to perform release tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm. For more information, see " Risk Factors — Risks Related to Manufacturing and Supply ". We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements. We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency and purity. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture. For instance, our License Agreement with Penn and CHOP requires significant research and development commitments that may not result in the development and commercialization of our product candidates, including DSG3- CAART and our other product candidates. We cannot be certain that, following a strategic transaction or license, we will achieve the results, revenue or specific net income that justifies such transaction. We may not realize the benefits of acquired assets or other strategic transactions, including any transactions whereby we acquire or license manufacturing and other advanced technologies. In August 2018, we entered into a License Agreement with Penn and CHOP which was amended and restated in July 2019, and further amended in May 2020 and October 2021, or the License Agreement, pursuant to which we were granted licenses to certain patent rights for the research and development of products, as well as an exclusive license under those same patent rights to make, use, sell and import such products, in the autoimmune disease and alloimmune response subfields, in each case, for the treatment of humans. In January 2021 and as amended in August 2022, we entered into an agreement with WuXi to serve as ~~our~~ **an additional** cell processing manufacturing partner for our MusCAARTesTM trial, and have since completed enabling **engineering and patient production runs. In August 2023, we entered into an agreement with WuXi to serve as a manufacturing partner for the global clinical development of CABA- 201 in multiple indications, including potential late-stage clinical trials and commercial readiness activities for CABA- 201, and have completed** engineering runs. In October 2022, we entered into the IASO Agreement, pursuant to which we were granted worldwide license under certain intellectual property to develop, manufacture, commercialize and otherwise exploit T cell products directed to CD19 for the purpose of diagnosis, prevention or treatment of an autoimmune or alloimmune indication in humans. We actively evaluate various strategic transactions on an ongoing basis. We may acquire other businesses, products or technologies as well as pursue joint ventures or investments in complementary businesses. The success of our strategic transactions, including the License Agreement, and any future strategic transactions depends on the risks and uncertainties involved including: • unanticipated liabilities related to acquired companies or joint ventures; • difficulties integrating acquired personnel, technologies and operations into our existing business; • retention of key employees; • diversion of management time and focus from operating our business to management of strategic alliances or joint ventures or acquisition integration challenges; • increases in our expenses and reductions in our cash available for operations and other uses; • disruption in our relationships with collaborators or suppliers as a result of such a transaction; and • possible write- offs or impairment charges relating to acquired businesses or joint ventures. If any of these risks or uncertainties occur, we may not realize the anticipated benefit of any acquisition or strategic transaction. Additionally, foreign acquisitions and joint ventures are subject to additional risks, including those related to integration of operations across different cultures and languages, currency risks, potentially adverse tax consequences of overseas operations and the particular economic, political, legal and regulatory risks associated with specific countries. For example, IASO is based in China and we may not receive the same protections under Chinese law, including with respect to applicable bankruptcy, insolvency, liquidation, arrangement, moratorium or similar laws relating to or affecting our rights. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We ~~currently rely upon~~ **are reliant on** Penn and **WuXi** ~~commercial CMOs~~ for our **current** manufacturing ~~needs~~ **activities and Penn and / or WuXi' s failure to perform or termination would disrupt normal business operations** , and we intend to continue to rely on other third parties for our future manufacturing needs prior to establishing our own manufacturing facility. We are ~~currently~~ reliant ~~upon~~ **on** Penn ~~for our cell product manufacturing for DSG3- CAART~~ and WuXi for **are reliant** ~~action,legislative action or potential sanctions with China could materially impact one~~ **on a research services agreement with Penn for a significant portion** of our **nonclinical research and development activities and** current manufacturing **activities** ~~partners,WuXi,and our agreement with~~

them . For example, **If Penn and its affiliated entities were to fail to perform their obligations** in **accordance** February 2024,the chair and ranking member of the House Select Committee on the Chinese Communist Party,Representatives Mike Gallagher and Raja Krishnamoorthi,respectively,along with Senators Gary Peters **the terms of the Services Agreement or terminate the Services Agreement with little notice,we may have difficulty continuing our normal business operations** and Bill Haggerty sent **our business prospects,financial condition and results of operations could be harmed.In addition,the termination of our relationship with Penn and the Services Agreement and any delay in appointing or finding** a letter **suitable replacement provider,if one exists,could make it difficult for us** to the Biden administration requesting **operate our business for** that **period** both WuXi AppTec Co . **Moreover** , **we will** Ltd.,WuXi' s parent company,and the affiliated WuXi Biologies be **reliant** added to the Department of Defense' s Chinese Military Companies List (1260H list),the Department of Commerce' s Bureau of Industry and Security Entity List,and the Department of Treasury' s Non - **on Penn** - SDN Chinese Military- Industrial Complex Companies List.While the Biden administration has yet to **assist us with** take action on this letter,adding either or both previously mentioned WuXi entities on any **necessary technology transfer.Any delays** or all of **inadequacies in such technology transfer,or disputes regarding** the aforementioned lists **scope of such technology transfer,** could materially impact the WuXi Agreement **delay our operations,including our clinical trials,require us to expend additional resources and otherwise have an adverse effect on our business** .Additionally, **over time we will need** on February 28,2024,President Biden signed Executive Order 14117 (" Preventing Access to **transition from receiving** Americans' Bulk Sensitive Personal Data and United States Government- Related Data by Countries of Concern ") which implements a new framework to protect the **services that Penn currently provides to performing** privacy of personal data shared between the U.S.and Europe,which may,in effect,impact privacy laws with " countries of concern " such **services internally** as China or Russia .The CAART Services Agreement is scheduled to expire on the later of October 19,2021 or completion of all research and development projects,and unless the CAART Services Agreement is amended,Penn will not be obligated to provide any further services under the CAART Services Agreement after that time.We currently anticipate that research and development projects under the CAART Services Agreement will continue through at least 2024 **2023** .In addition,Penn has the right to terminate the CAART Services Agreement in whole at any time with 90 days' notice and to terminate any research and development project being performed under the CAART Services Agreement if the Penn service provider appointed to lead such project is unavailable and Penn is unavailable to find a replacement within 60 days for such service provider.Penn also has the right to terminate certain manufacturing services being performed under the CAART Services Agreement with 180 days' written notice.From time to time,we may enter into further addenda to the CAART Services Agreement that provide Penn with the right to terminate such addenda with limited notice periods.If we do not have adequate personnel and capabilities at the time that we assume responsibilities for such services,we may not be successful in effectively or efficiently transitioning these services from Penn,which could disrupt our business and have a material adverse effect on our financial condition and results of operations. **Further,we will incur costs relating to establishing our own financial,administrative,information technology and other support functions as well as running and maintaining such functions on a going- forward basis.In addition,the process of establishing such functions may distract our management from focusing on business and strategic opportunities and could result in disruptions to our business.** Even if we are able to successfully transition these services,they may be more expensive or less efficient than the services we are receiving from Penn during the transition period. **We** The CARTA Services Agreement MuSK- CAART **and CABA- 201** . To support **In August 2023, we entered into new work orders under** the scale up **WuXi Agreement for WuXi to serve as one** of **our cell processing** manufacture **manufacturing partners for the planned global clinical development of CABA- 201 in multiple indications, including potential late- stage clinical trials** and to support commercially -- **commercial** compliant production **readiness activities for CABA- 201. Under the August 2023 work orders** , we **WuXi** will need **convert our non- dedicated suite to a dedicated suite for GMP manufacturing for our CABA- 201 and MuSK- CAART programs, or the Dedicated Suite, for an initial term of 18 months with** to **two** maintain (in **18 month extensions at our sole option on six months notice prior to** the ease **end** of **the term. We may terminate for convenience with six months prior written notice, however, we may not terminate the Dedicated Suite without terminating both the MuSK- CAART and CABA- 201 GMP run work orders. In lieu of the existing 18 month termination right for convenience under the** WuXi) or develop new relationships **Agreement, WuXi may not terminate prior to February 2028. If WuXi were to fail to perform their obligations in accordance** with **the terms of the WuXi Agreement or terminate the WuXi Agreement, our clinical trials and** commercially -- **commercial readiness** compliant and scalable suppliers, increase the scale of production, and demonstrate comparability of the material produced at these facilities to the material that was previously produced, if a facility change was made. Transferring manufacturing processes and know- how is complex and involves review and incorporation of both documented and undocumented processes that may have evolved over time. In addition, transferring production to different facilities may require utilization of new or different processes to meet the specific requirements of a given facility. We would expect additional comparability work will also need to be **adversely** conducted to support the transfer of certain manufacturing processes and process improvements. We cannot be certain that all relevant know- how and data has been adequately incorporated into the manufacturing process until the completion of studies (and the related evaluations) intended to demonstrate the comparability of material previously produced with that generated by any CMO that we engage for our manufacturing needs. If we are not able to successfully transfer and produce comparable product candidates, our ability to further develop and manufacture our product candidates may be negatively impacted **which** . We may plan to eventually establish our own manufacturing facility. While the addition of our own manufacturing facility would **could in turn materially and adversely affect** provide us with future flexibility within our manufacturing network, we still may need to identify additional CMOs for continued production of supply for some or **our business** all of our product candidates. Given the nature of our manufacturing processes , **results** the number of **operations** CMOs who possess the requisite skill and **prospects** capability to manufacture our

~~CAR T and CAAR T cell immunotherapy product candidates is limited~~ . Further, we may not be able to achieve clinical manufacturing and cell processing through our CMOs or on our own on a timely basis. While our current manufacturing process is similar to the ~~validated~~ **well- established** process developed at Penn for CD19 CAR **-** T, or CART19, which was later commercialized, we have limited experience as an organization in managing the CAR **-** T or CAAR T engineering process at commercial scale. Finally, because clinical manufacturing and cell processing is highly complex and patient donor material is inherently variable, we cannot **yet** be sure that ~~the~~ **our** manufacturing ~~processes~~ -- **process** ~~employed by Penn, any CMO that we engage in the future, or by us at a manufacturing facility that we establish~~ , will consistently result in **product** ~~T cells~~ that **meets specifications for release** ~~will be safe and effective~~ . Success in manufacturing in smaller early phase clinical trials may not predict the frequency of success at larger late phase clinical trials, or success at the commercial phase production **until process qualification and validation is completed and submitted for BLA filing** . Our product candidates are uniquely manufactured. If we ~~, Penn~~ or any of our third- party manufacturers encounter difficulties in manufacturing our product candidates, our ability to provide supply of our product candidates for clinical trials or, if licensed, for commercial sale, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure. The manufacturing process used to produce our product candidates is complex and novel, and it has not yet been validated for commercial production. **The** ~~Among the complex processes used in the manufacture of our product candidates is the manufacture of the lentiviral delivery vector used to deliver the applicable CAR or CAAR gene into the T cells. For example, the~~ manufacture of our product candidates includes harvesting white blood cells from each patient, stimulating certain T cells from the white blood cells and thereby causing them to activate and proliferate, combining patient T cells with ~~our~~ lentiviral delivery vector through a process known as transduction, expanding the transduced T cells to obtain the desired dose **, formulating and freezing the cell product** , and ultimately infusing the modified T cells back into the patient' s body. **Because** ~~Notably, the manufacture of both DSG3 / 1- CAART may be more challenging or require new gene delivery technology due to~~ the ~~need to deliver large transgenes~~ **bespoke nature of this product** for **patients** ~~these programs, and vector delivery systems have size limitations. Because of these complexities~~ , the cost to manufacture our product candidates is higher than traditional small molecule chemical compounds and monoclonal antibodies ~~, and the manufacturing process is less reliable and is more difficult to reproduce~~ . Furthermore, our manufacturing process development and scale- up is at an early stage **, and evaluation of cost at large scale has not yet been finalized** . The actual cost to manufacture and process our product candidates could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. Our manufacturing process may be susceptible to technical and logistics delays or failures due to the fact that each patient is an independent manufacturing lot, and also due to unique supply chain requirements. These include the collection of white blood cells from patients' blood, variability in the quality of white blood cells collected from patients' blood, cryopreservation of the white blood cells collected, packaging and shipment of frozen white blood cells to the manufacturing site in order to enable multi- site studies, procurement of lentiviral vectors that meet potency and purity requirements and shipment to the product candidate manufacturing site, shipment of the final product to clinical centers, manufacturing issues associated with interruptions in the manufacturing process, scheduling constraints for cell manufacturing slots, process contamination, equipment or reagent failure or supply shortage (s) / interruption (s), improper installation or operation of equipment, vendor or operator error, and inconsistency in cell growth. Even minor deviations from normal manufacturing processes could result in reduced production yields, lot failures, product defects, product recalls, product liability claims and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, production at such manufacturing facilities may be interrupted for an extended period of time to investigate and remedy the contamination. Further, as product candidates are developed through preclinical studies to late- stage clinical trials toward approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes may result in the need to enroll additional patients or to conduct additional clinical studies to evaluate the impact of changes on product safety and efficacy. Penn has informed us that it will be unable provide clinical supply for any late- phase **or non- U. S.** clinical trials of our product candidates that we may conduct. Therefore, we will need ~~to enter into~~ **maintain and / or add** new agreements with **additional** CMOs to produce clinical supply of our product candidates for late- phase clinical trials **and at the necessary scale** . We cannot guarantee that we will be able to enter into such agreements on commercially acceptable terms ~~, if at all. We will need to transfer the technology to manufacture our product candidates to these CMOs, and these CMOs may decide or be required to adopt different manufacturing protocols or processes, which may require us to amend any ongoing or proposed clinical trial protocols or perform additional preclinical studies to demonstrate the comparability of any such new manufacturing protocols or processes. We cannot provide any assurance that Penn will provide adequate support to efficiently and effectively transfer the technology or that disputes will not arise between us and Penn regarding the necessary scope of technology transfer, that the technology transfer will be successful, or that any CMO will be successful in producing our product candidates in sufficient quantities or of acceptable quality~~ , if at all. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of ongoing and planned clinical trials or other future clinical trials. Although we continue to optimize our manufacturing process for our product candidates, doing so is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, lot consistency and timely availability of reagents and / or raw materials. ~~We ultimately may not be successful in transferring our production system from our contract manufacturer to any manufacturing facilities we may establish ourselves, or our contract manufacturer may not have the necessary capabilities to complete the implementation and development process.~~ If we are unable to adequately ~~validate or~~ scale- up the manufacturing process for our product candidates with **WuXi** ~~our current manufacturer~~ , we ~~will~~ **may** need to transfer to another manufacturer and ~~complete the manufacturing validation process~~ **/ or our**

own facility , which can be lengthy. If we are able to adequately ~~validate~~ **establish** and scale- up the manufacturing process for our product candidates with ~~a contract~~ **an alternative** manufacturer, we will still need to negotiate with such ~~contract~~ manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us. **This** ~~As a result, we~~ may **impact our** ~~ultimately be unable to reduce the~~ cost of goods ~~for our product candidates to levels that will allow for an~~ **and thus** ~~attractive return on investment if and when those product candidates are commercialized~~ ---- **commercial viability and / or competitiveness** . In addition, many of the components which are required to support our cell manufacturing process, such as equipment, media, growth factors and disposables, are highly specialized and it is possible that the supply chain for these materials may be interrupted. If we are unable to promptly remedy such interruption, then there may be delays to our clinical development efforts. The manufacturing process for any products that we may develop is subject to the FDA approval process, and we will need to contract with manufacturers who can meet all applicable FDA requirements on an ongoing basis. The manufacturing process for any products that we may develop is subject to the FDA approval process, and we will need to contract with manufacturers **,** who can meet all applicable FDA requirements on an ongoing basis. If we or our CMOs are unable to reliably produce products to specifications acceptable to the FDA, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product in accordance with requirements from the FDA, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, suspension of production or recalls of the product candidates or marketed biologics, operating restriction and criminal prosecutions, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our products, if licensed, on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements, and an inability to do so could have a material adverse effect on our business, financial condition, and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change, and we could need to replace, modify, design, or build and install equipment, all of which would require additional capital expenditures. Specifically, because our product candidates may have a higher cost of goods than conventional therapies, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. The manufacture of viral vectors is complex and variable, and there are a limited number of manufacturers able to supply us with viral vectors. Our DSG3- CAART ~~and~~ **,** MuSK- CAART **and CABA-201** product candidates utilize a lentiviral delivery vector and some or all of our other product candidates may require a lentiviral delivery vector, a key drug substance that delivers the CAR or CAAR to the target T cells. We do not have the capability to manufacture lentiviral vector and plan to obtain the vector we require from third parties. The manufacturing process for lentiviral vector is variable and still evolving. It is not uncommon for manufacturing runs to fail, whether due to contamination, supplier error, or equipment failure, or to be delayed. To the extent our product candidates use a lentiviral delivery vector, a lack of vector supply will cause us to be unable to manufacture our CAR T or CAAR T cells as well as a delay in patient enrollment, which may have a negative impact on our ability to successfully develop our product candidates. Further, there are a limited number of manufacturers capable of producing lentiviral vectors. It can be challenging to secure a relationship with any of these manufacturers, and the manufacturing and release process can take a significant amount of time **. We have secured a supply of lentiviral vector from CAROT sufficient for a portion of the patients we plan to enroll in our MusCAARTesTM trial and our RESETTM clinical trials in SLE, myositis, SSc and gMG** . We have secured a supply of lentiviral vector from CHOP sufficient for a portion of the patients we plan to enroll in our DesCAARTesTM trial. We have also reserved additional vector manufacturing capacity at Penn and CHOP and in December 2021 **and in May 2023** , we secured a license and supply agreement with Oxford ~~Biomedica~~ to establish a process and supply lentiviral vector for the clinical and commercial development of our DSG3- CAART **and CABA- 201** ~~candidate~~ **candidates** . There is no assurance that we will be able **to continue** to secure adequate and timely supply of lentiviral vector. Moreover, we cannot be certain that our CAR T or CAAR T cell product candidates produced with lentiviral vector from different manufacturers will be comparable or that results of clinical trials will be consistent if conducted with lentiviral vector from different manufacturers. Vector production also requires the production of high- quality DNA plasmids, for which there is also a limited number of suppliers. Although we have established relationships with multiple suppliers for lentiviral vector and plasmids, we do not yet have our own clinical- scale manufacturing facility established, and are therefore highly dependent on the ability of these suppliers to manufacture necessary materials and to deliver these materials to us on a timely and reliable basis. If we are to operate our own manufacturing facility, significant resources will be required and we may fail to successfully operate our facility, which could adversely affect our clinical trials and the commercial viability of our product candidates. If we establish our own manufacturing facility, our operations will be subject to review and oversight by the FDA and the FDA could object to our use of our manufacturing facility. We must first receive approval from the FDA prior to licensure to manufacture our product candidates, which we may never obtain. Even if licensed, we would be subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations. Our license to manufacture product candidates will be subject to continued regulatory review. Our cost of goods development is at an early stage. The actual cost to manufacture and process our product candidates **at a manufacturing facility of our own** could be greater than we expect and could materially and adversely affect the commercial viability of our product candidates. The manufacture of biopharmaceutical products is complex and requires significant expertise, and can be impacted by resource constraints, labor disputes and workforce limitations. The manufacture of biopharmaceutical products is complex and requires significant expertise, including

the development of advanced manufacturing techniques and process controls. Manufacturers of cell therapy products often encounter difficulties in production, particularly in scaling out and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our supply of product candidates or in the manufacturing facilities upon which we currently or will rely, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability or other issues relating to the manufacture of our product candidates, whether by Penn, ~~by a~~ **WuXi, or other** third- party ~~CMO~~ **CMOs** , or at any manufacturing facility that we may establish, will not occur in the future. Penn, **WuXi or other** third- party CMOs that we engage, or we may fail to manage the logistics of storing and shipping our product candidates. Storage failures and shipment delays and problems caused by us, our vendors or other factors not in our control, such as weather, could result in loss of usable product or prevent or delay the delivery of product candidates to patients. Penn, **WuXi, or other** third- party CMOs that we engage, or we may also experience manufacturing difficulties due to resource constraints, labor disputes or workforce limitations arising from the expanding need for manufacturing in the cell therapy field and the limited number of training programs for technical staff. If we were to encounter any of these difficulties, our ability to provide our product candidates to patients would be jeopardized. We are dependent upon the availability of specialty raw materials and the production capabilities of small manufacturers to source the components of our product candidates. Our product candidates require many specialty raw materials, some of which are manufactured by small companies with limited resources and experience to support a commercial product, and the suppliers may not be able to deliver raw materials to our specifications. In addition, those suppliers generally do not have the capacity to support commercial products manufactured under cGMP by biopharmaceutical firms. The suppliers may be ill- equipped to support our needs, especially in non- routine circumstances like an FDA inspection or medical crisis, such as widespread contamination. We also do not have contracts with many of these suppliers, and we may not be able to contract with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key raw materials to support clinical or commercial manufacturing. In addition, some raw materials are currently available from a single supplier, or a small number of suppliers. We cannot be sure that these suppliers will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these materials for our intended purpose. In addition, the lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in meeting demand in the event we must switch to a new supplier. The time and effort to qualify a new supplier could result in additional costs, diversion of resources or reduced manufacturing yields, any of which would negatively impact our operating results. Further, we may be unable to enter into agreements with a new supplier on commercially reasonable terms, which could have a material adverse impact on our business. We are also unable to predict how changing global economic conditions or global health concerns ~~such as the ongoing COVID- 19 pandemic~~ will affect our third- party suppliers and manufacturers. Any negative impact of such matters on our third- party suppliers and manufacturers may also have an adverse impact on our results of operations or financial condition. We may encounter difficulties in production, particularly with respect to process development or scaling up of our manufacturing capabilities. If we encounter such difficulties, our ability to provide supply of our CAR T or CAAR T cells for clinical trials or for commercial purposes could be delayed or stopped. Establishing clinical and commercial manufacturing and supply is a difficult and uncertain task, and there are risks associated with scaling to the level required for advanced clinical trials or commercialization, including, among others, increased costs, potential problems with process scale- out, process reproducibility, stability issues, lot consistency, and timely availability of reagents or raw materials. For example, we may find it difficult to establish a manufacturing process that is consistent. If this occurs, we may need to complete more than one manufacturing run for each treated patient, which would impact the availability of adequate coverage and reimbursement from third- party payors. Competitors that have developed CAR T cell therapies have had difficulty reliably producing engineered T cell therapies in the commercial setting. If we experience similar challenges manufacturing product candidates to approved specifications, this may limit our product candidates' utilization and our ability to receive payment for these product candidates once licensed. Alternatively, these challenges may require changes to our manufacturing processes, which could require us to perform additional clinical studies, incurring significant expense. We may ultimately be unable to reduce the expenses associated with our product candidates to levels that will allow us to achieve a profitable return on investment. If we or our third- party suppliers use hazardous, non- hazardous, biological or other materials in a manner that causes injury or violates applicable law, we may be liable for damages. Our research and development activities involve the controlled use of potentially hazardous substances, including chemical and biological materials. We and our suppliers are subject to federal, state and local laws and regulations in the United States governing the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that we and our suppliers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we and our suppliers cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations. Changes in product candidate manufacturing or formulation may result in additional costs or delay, which could adversely affect our business, results of operations and financial condition. As product candidates are developed through preclinical studies to later- stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods or formulation, are altered along the

way in an effort to optimize processes and results. Any of these changes could cause our product candidates to perform differently and affect the results of ongoing and planned clinical trials or other future clinical trials conducted with the altered materials or with materials made with the altered methods. Such changes may also require additional testing, or notification to, or approval by the FDA or other regulatory authorities. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and / or jeopardize our ability to commence product sales and generate revenue. Risks Related to Government Regulation The FDA regulatory approval process is lengthy and time- consuming, and we may experience significant delays in the clinical development and regulatory approval of our product candidates. The research, testing, manufacturing, labeling, approval, selling, import, export, marketing and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. We are not permitted to market any biological drug product in the United States until we receive approval of a Biologics License Application, or BLA, from the FDA. We have not previously submitted a BLA to the FDA, or similar licensure filings to comparable foreign authorities. A BLA must include extensive preclinical and clinical data and supporting information to establish the product candidate' s safety, potency and purity for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing and controls for the product, including with respect to chain of identity and chain of custody of the product. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. For example, to our knowledge, the FDA has not previously reviewed regulatory applications for **marketing authorization** ~~the commercial development~~ of CAR T cells for treatment of autoimmune disease or CAAR T cells for treatment of pemphigus, and there is no cell therapy currently approved by the FDA for the treatment of mPV ~~or~~ **,** MuSK myasthenia gravis **, SLE, myositis, SSc or gMG** . Because of this, we have little guidance as to which endpoints will be accepted, how many clinical trials we may expect to conduct, and whether open- label clinical trials will be deemed acceptable, among other things. We may also request regulatory approval of future CAR T or CAAR T cell- based product candidates by target, regardless of disease type or origin, which the FDA may have difficulty accepting if our clinical trials only involved diseases of certain origins. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety, potency and purity data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials, as the FDA often adheres to the Advisory Committee' s recommendations. Further, given the rapidly evolving landscape of cell therapy, we could encounter a significant change in the regulatory environment for our product candidates once we have already begun one or more lengthy and expensive clinical trials for our product candidates. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. We may also experience delays in completing ongoing and planned clinical trials for a variety of reasons, including delays related to: • obtaining regulatory authorization to begin a trial, if applicable; • the availability of financial resources to commence and complete the planned trials; • reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • obtaining approval at each clinical trial site by an independent IRB; • recruiting suitable patients to participate in a trial; • having patients complete a trial, including having patients enrolled in clinical trials dropping out of the trial before the product candidate is manufactured and returned to the site, or return for post- treatment follow- up; • clinical trial sites deviating from trial protocol or dropping out of a trial; • addressing any patient safety concerns that arise during a trial; • adding new clinical trial sites; or • manufacturing sufficient quantities of qualified materials under cGMPs and applying them on a patient by patient basis for use in clinical trials. We could also encounter delays if physicians encounter unresolved ethical issues associated with enrolling patients in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles. If we experience delays in the completion of, any future clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may ultimately lead to the denial of regulatory approval of our product candidates. We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to a licensed biologic. Under the BPCIA, an application for a biosimilar product cannot be licensed by the FDA until 12 years after the reference product was licensed under a BLA. The law is complex and is still being interpreted and implemented by the FDA. We believe that any of the product candidates we develop that is licensed in the United States as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. The regulatory landscape that will govern our product candidates is uncertain; regulations relating to more established cell therapies and other therapies for ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** are still developing, and changes in regulatory requirements could result in delays or

discontinuation of development of our product candidates or unexpected costs in obtaining regulatory approval. Because we are developing novel CAR T and CAAR T cell product candidates that are unique biological entities, the regulatory requirements that we will be subject to are not entirely clear. Even with respect to more established products that fit into the categories of gene therapies or cell therapies, the regulatory landscape is still developing. For example, regulatory requirements governing gene therapy products and cell therapy products have changed frequently and may continue to change in the future. Moreover, there is substantial, and sometimes uncoordinated, overlap in those responsible for regulation of existing gene therapy products and cell therapy products. For example, in the United States, the FDA established the Office of Tissues and Advanced Therapies, or OTAT, in 2016, within its Center for Biologics Evaluation and Research, or CBER, to consolidate the review of gene therapy and related products, and the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER on its review. In September 2022, the FDA announced retitling of OTAT to the Office of Therapeutic Products, or OTP, and elevation of OTP to a " Super Office " to meet its growing cell and gene therapy workload. In addition, under guidelines issued by the National Institutes of Health, or NIH, gene therapy clinical trials are also subject to review and oversight by an institutional biosafety committee, or IBC, a local institutional committee that reviews and oversees research utilizing recombinant or synthetic nucleic acid molecules at that institution. Before a clinical trial can begin at any institution, that institution' s institutional review board, or IRB, and its IBC assesses the safety of the research and identifies any potential risk to public health or the environment. While the NIH guidelines are not mandatory unless the research in question is being conducted at or sponsored by institutions receiving NIH funding of recombinant or synthetic nucleic acid molecule research, many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Although the FDA decides whether individual gene therapy protocols may proceed, review process and determinations of other reviewing bodies can impede or delay the initiation of a clinical study, even if the FDA has reviewed the study and approved its initiation. Conversely, the FDA can place an IND application on clinical hold even if such other entities have provided a favorable review. Furthermore, each clinical trial must be reviewed and approved by an independent IRB at or servicing each institution at which a clinical trial will be conducted. In addition, adverse developments in clinical trials of gene therapy products conducted by others **or in the post- approval context** may cause the FDA or other regulatory bodies to change the requirements for approval of any of our product candidates **. For example, after the FDA' s November 2023 announcement of its investigation into reports of T cell malignancies for BCMA- and CD19- directed CAR T cell immunotherapies, the FDA informed us that, based on those reports, patients receiving CABA- 201 in our clinical trials will require life- long monitoring for new malignancies** . Complex regulatory environments exist in other jurisdictions in which we might consider seeking regulatory approvals for our product candidates, further complicating the regulatory landscape. For example, in the European Union, a special committee called the Committee for Advanced Therapies was established within the EMA in accordance with Regulation (EC) No 1394 / 2007 on advanced-therapy medicinal products, or ATMPs, to assess the quality, safety and efficacy of ATMPs, and to follow scientific developments in the field. ATMPs include gene therapy products as well as somatic cell therapy products and tissue engineered products. These various regulatory review committees and advisory groups and new or revised guidelines that they promulgate from time to time may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post- approval limitations or restrictions. Because the regulatory landscape for our CAR T and CAAR T cell product candidates is new, we may face even more cumbersome and complex regulations than those emerging for gene therapy products and cell therapy products. Furthermore, even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn because of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market could decrease our ability to generate sufficient product revenue to maintain our business. If we are not able to obtain, or if there are delays in obtaining, required regulatory approvals for our product candidates, we will not be able to commercialize, or will be delayed in commercializing, our product candidates, and our ability to generate revenue will be materially impaired. Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States. Before we can commercialize any of our product candidates, we must obtain marketing approval. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction and it is possible that none of our product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. We, as a company, have no experience in filing and supporting the applications necessary to gain regulatory approvals and expect to rely on third- party CROs and / or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the drug candidate' s safety, potency and purity. Securing regulatory approval also requires the submission of information about the drug manufacturing process to, and inspection of manufacturing facilities by, the relevant regulatory authority. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use. The process of obtaining regulatory approvals is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted IND, BLA or equivalent application types, may cause delays in the approval or rejection of an application. The FDA has substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other

studies. Our product candidates could be delayed in receiving, or fail to receive, regulatory approval for many reasons, including the following: • the FDA may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA that a drug candidate is safe, potent and pure for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations; • the results of clinical trials may not meet the level of statistical significance required by the FDA for approval; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an BLA or other submission or to obtain regulatory approval in the United States or elsewhere; • the FDA may fail to approve the manufacturing processes, test procedures and specifications, or facilities that we may establish or of third- party manufacturers with which we may contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of drugs in development, only a small percentage successfully complete the FDA approval process and are commercialized. The lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval. As a result, our ability to develop product candidates and obtain regulatory approval may be significantly impacted. For example, the general approach for FDA approval of a new biologic or drug is for sponsors to seek licensure or approval based on dispositive data from well- controlled, Phase 3 clinical trials of the relevant product candidate in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. We believe that we may be able to utilize the FDA' s Regenerative Medicine Advanced Therapy designation for our product candidates given the limited alternatives for treatments for certain rare diseases and ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** , but the FDA may not agree with our plans. Moreover, approval of genetic or biomarker diagnostic tests may be necessary to advance some of our product candidates to clinical trials or potential commercialization. In the future, regulatory agencies may require the development and approval of such tests. Accordingly, the regulatory approval pathway for such product candidates may be uncertain, complex, expensive and lengthy, and approval may not be obtained. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, if licensed, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates **. On November 28, 2023, the FDA issued a statement that it is investigating serious risk of T- cell malignancy following BCMA- directed or CD19- directed autologous CAR T cell immunotherapies. While the FDA noted that it currently believes that the overall benefits of the approved products continue to outweigh their potential risks for their approved uses, the FDA stated that it is investigating the identified risk of T- cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action. However, because all currently approved CAR T- cell immunotherapies are in oncology indications, there can be no assurance that FDA will reach the same risk- benefit analysis in other indications, such as autoimmune. Given that the autoimmune diseases we are seeking to treat with CABA- 201, a CD19- directed CAR T immunotherapy, are different indications from the approved oncology indications, the FDA and other regulatory authorities may apply a different benefit- risk assessment threshold such that even if our product candidate demonstrated a similar safety profile as current CAR T therapies, the FDA could ultimately determine that the harmful side effects outweigh the benefits and require us to cease clinical trials or deny approval of our product candidates. The FDA' s investigation may impact the FDA' s review of product candidates that we are developing, or that we may seek to develop in the future, which may, among other things, result in additional regulatory scrutiny of our product candidates, delay the timing for receiving any regulatory approvals or impose additional post- approval requirements on any of our product candidates that receive regulatory approval** . If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired. Even though we may apply for orphan drug designation for our product candidates, we may not be able to obtain orphan drug marketing exclusivity. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population of 200, 000 or more in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. In order to obtain orphan drug designation, the request must be made before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages, and user- fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product that has orphan drug designation subsequently receives the first FDA approval of that particular product for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a BLA, to market the same biologic (meaning, a product with the same principal molecular structural features) for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a

result, even if one of our product candidates receives orphan exclusivity, the FDA can still approve other biologics that do not have the same principal molecular structural features for use in treating the same indication or disease or the same biologic for a different indication or disease during the exclusivity period. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product or if a subsequent applicant demonstrates clinical superiority over our product. We have obtained from the FDA orphan drug designation for DSG3- CAART for the treatment of pemphigus vulgaris ~~and~~ **,** for MuSK- CAART for the treatment of MuSK MG **and for CABA- 201 for the treatment of idiopathic inflammatory myopathies (IIM, or myositis) and systemic sclerosis** . We may seek orphan drug designation for certain other of our product candidates, but may be unable to obtain orphan drug designation for some or all of our product candidates in specific orphan indications in which we believe there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition, or if a subsequent applicant demonstrates clinical superiority over our products, if licensed. Although we may seek orphan drug designation for other product candidates, we may never receive such designations. In addition, the FDA may further reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted **. The FDA has granted rare pediatric disease designation to CABA- 201 for the treatment of juvenile dermatomyositis. However, a marketing application for CABA- 201 or any other product candidate, if approved, may not meet the eligibility criteria for a priority review voucher. The FDA has granted rare pediatric disease designation to CABA- 201 for the treatment of juvenile dermatomyositis. Designation of a drug as a drug for a rare pediatric disease does not guarantee that an NDA or BLA for such drug will meet the eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Under the FDCA, we will need to request a rare pediatric disease priority review voucher in our original BLA for CABA- 201. The FDA may determine that a BLA for CABA- 201, if approved, does not meet the eligibility criteria for a priority review voucher, including for the following reasons: • juvenile dermatomyositis no longer meets the definition of a rare pediatric disease; • the BLA contains an active ingredient that has been previously approved by the FDA; • the BLA does not rely on clinical data derived from studies examining a pediatric population and dosages of the drug intended for that population (that is, if the BLA does not contain sufficient clinical data to allow for adequate labeling for use by the full range of affected pediatric patients); or • the BLA is approved for a different adult indication than the rare pediatric disease for which CABA- 201 is designated. The authority for the FDA to award rare pediatric disease priority review vouchers for drugs and biologics that receive rare pediatric disease designation on or prior to September 30, 2024 is currently limited to those candidates that receive rare pediatric disease designation on or prior to September 30, 2024, and the FDA may only award rare pediatric disease priority review vouchers through September 30, 2026. However, it is possible the FDA' s authority to award rare pediatric disease priority review vouchers will be further extended by Congress. Absent any such extension, if a BLA for CABA- 201 is not approved prior to September 30, 2026 for any reason, regardless of whether it meets the criteria for a rare pediatric disease priority review voucher, it will not be eligible for a priority review voucher** . A fast track designation by the FDA, even if granted, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our current product candidate and any future product candidates will receive marketing approval. If a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation for a particular indication. Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious or life-threatening conditions and address an unmet medical need. We have received fast track designation for DSG3- CAART for improving healing of mucosal blisters in patients with mPV **,** ~~. We have also received fast track designation~~ for MuSK- CAART for improving activities of daily living and muscle strength in patients with MuSK antibody- positive myasthenia gravis **and for CABA- 201, designed to deplete CD19- positive B cells and improve disease activity in patients with SLE, LN and the myositis subtype of dermatomyositis and for the treatment of patients with systemic sclerosis to improve associated organ dysfunction** . We may also apply for fast track designation for certain of our other product candidates, but there is no assurance that the FDA will grant this status to any of our other current or future product candidates. Marketing applications filed by sponsors of products in fast track development may qualify for priority review under the policies and procedures offered by the FDA, but the fast track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant fast track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even though we have received fast track designation for **certain** ~~DSG3- CAART for improving healing~~ of **our product candidates** ~~mucosal blisters in patients with mPV and for MuSK- CAART for improving activities of daily living and muscle strength in patients with MuSK antibody-positive myasthenia gravis~~ , we may not experience a faster development process, regulatory review or approval **for these product candidates as** compared to conventional FDA procedures, and receiving a fast track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any fast track designation at any time. Although we may pursue expedited regulatory approval pathways for a product candidate, it may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to a faster development or regulatory review or approval process. Although we believe there may be an opportunity to accelerate the development of certain of our product candidates through one or more of the FDA' s expedited programs, such as fast track,

breakthrough therapy, Regenerative Medicine Advanced Therapy, accelerated approval or priority review, we cannot be assured that any of our product candidates will qualify for such programs. For example, we may seek a Regenerative Medicine Advanced Therapy, or RMAT, designation for some of our product candidates. An RMAT is defined as cell therapies, therapeutic tissue engineering products, human cell and tissue products, and combination products using any such therapies or products. Gene therapies, including genetically modified cells that lead to a durable modification of cells or tissues may meet the definition of a Regenerative Medicine Therapy. The RMAT program is intended to facilitate efficient development and expedite review of RMATs, which are intended to treat, modify, reverse, or cure a serious or life- threatening disease or condition. A new drug application or a BLA for an RMAT may be eligible for priority review or accelerated approval through (1) surrogate or intermediate endpoints reasonably likely to predict long- term clinical benefit or (2) reliance upon data obtained from a meaningful number of sites. Benefits of such designation also include early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. A Regenerative Medicine Therapy that is granted accelerated approval and is subject to post- approval requirements may fulfill such requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence, such as electronic health records; the collection of larger confirmatory data sets; or post- approval monitoring of all patients treated with such therapy prior to its approval. Although RMAT designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. If we apply for RMAT designation or any other expedited program for our product candidates, the FDA may determine that our proposed target indication or other aspects of our clinical development plans do not qualify for such expedited program. Even if we are successful in obtaining a RMAT designation or access to any other expedited program, we may not experience faster development timelines or achieve faster review or approval compared to conventional FDA procedures. Access to an expedited program may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, qualification for any expedited review procedure does not ensure that we will ultimately obtain regulatory approval for such product candidate. Disruptions at the FDA, the SEC and other government agencies ~~caused by funding shortages~~ **, including from government shutdowns,** or ~~global health concerns~~ **other disruptions to these agencies' operations,** could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs or biologics to be reviewed ~~and / or approved by necessary government agencies~~ , which would adversely affect our business. For example, over the ~~last~~ **past decade** ~~several years, including most recently from December 22, 2018 to January 25, 2019~~ , the U. S. government has shut down several times **,** and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical ~~FDA, SEC and other government~~ employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. **Further** ~~Since March 2020 when foreign and domestic inspections were largely placed on hold~~ , ~~the FDA has been working~~ **future government shutdowns could impact our ability** to **access the public markets** ~~resume pre- pandemic levels of inspection activities, including routine surveillance, bioresearch monitoring and pre- approval inspections. Should FDA determine that an~~ **and obtain** ~~inspection is~~ necessary ~~for approval and~~ **capital in order to properly capitalize** ~~an~~ **and continue** ~~inspection cannot be completed during the review cycle due~~ to **fund** ~~restrictions on travel, and the FDA does not determine a remote interactive evaluation to be adequate, FDA has stated that it generally intends to issue, depending on the circumstances, a complete response letter or~~ **our operations** ~~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 the COVID- 19 pandemic and may experience delays in their regulatory activities~~ . Risks Related to Ongoing Regulatory Obligations Even if we receive regulatory approval of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates. Any regulatory approvals that we receive for our product candidates will require surveillance to monitor the safety, potency and purity of the product candidate. We believe it is likely that the FDA will require a Risk Evaluation and Mitigation Strategy, or REMS, in order to approve our product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA approves our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we conduct post- approval. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMP and adherence to commitments made in any BLA, other marketing application and previous responses to inspectional observations. Additionally, manufacturers and manufacturers' facilities are required to comply with extensive FDA, and comparable foreign regulatory authority requirements, including ensuring that

quality control and manufacturing procedures conform to cGMP regulations and applicable product tracking and tracing requirements. 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. In addition, the FDA could require us to conduct another study to obtain additional safety or biomarker information. Additionally, under the Food and Drug Omnibus Reform Act of 2022, or FDORA, sponsors of approved drugs and biologics must provide six months' notice to the FDA of any changes in marketing status, such as the withdrawal of a drug, and failure to do so could result in the FDA placing the product on a list of discontinued products, which would revoke the product' s ability to be marketed. Further, we will be required to comply with FDA promotion and advertising rules, which include, among others, standards for direct- to- consumer advertising, restrictions on promoting products for uses or in patient populations that are not described in the product' s approved uses (known as " off- label use "), limitations on industry- sponsored scientific and educational activities and requirements for promotional activities involving the internet and social media. Later discovery of previously unknown problems with our product candidates through follow- up programs with our clinical trial patients, including adverse events of unanticipated severity or frequency, or with our third- party suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, imposition of post- market studies or clinical studies 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 product candidates, withdrawal of the product from the market or voluntary or mandatory product recalls; • fines, warning letters or holds on clinical trials; • refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals; • product seizure or detention, or refusal to permit the import or export of our product candidates; and • injunctions or the imposition of civil or criminal penalties. The FDA' s 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 or executive action. If these executive actions impose restrictions on FDA' s ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and 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, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. Breach of certain environmental, health and safety laws and regulations could also in certain circumstances constitute a breach of our License Agreement with Penn. 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 production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. 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 or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to comply with the laws of the FDA, provide true, complete and accurate information to the FDA, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws, or report financial information or data accurately or to disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. Risks Related to Healthcare Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our product candidates, if licensed, profitably. Successful commercialization of our product candidates, if licensed, will depend in part on the extent to which reimbursement for those

drug products will be available from government health administration authorities, private health insurers, and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which drug products they will pay for and establish reimbursement levels. The availability and extent of reimbursement by governmental and private payors is essential for most patients to be able to afford a drug product. Sales of drug products depend substantially, both domestically and abroad, on the extent to which the costs of drugs products are paid for by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payors. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval. Any product candidate for which we seek regulatory approval and reimbursement will need to meet or surpass our target product profile, or TPP, to be deemed a viable alternative to currently approved therapies. In addition, because our product candidates represent new approaches to the treatment of ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** , we cannot accurately estimate the potential revenue from our product candidates. For more information, see " Business – Government Regulation – Pricing and Reimbursement, United States. " ~~Third- party payors decide which drugs and treatments they will cover and the amount of reimbursement. Reimbursement by a third- party payor may depend upon a number of factors, including, but not limited to, the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • cost- effective; and • neither experimental nor investigational.~~ Obtaining coverage and reimbursement of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide the payor with supporting scientific, clinical and cost- effectiveness data for the use of our products, if licensed. In the United States, the principal decisions about reimbursement for new drug products are typically made by the Centers for Medicare and Medicaid Services, or CMS, an agency within the U. S. Department of Health and Human Services, or HHS. CMS decides whether and to what extent a new drug product will be covered and reimbursed under Medicare, and private payors tend to follow CMS to a substantial degree. However, no uniform policy of coverage and reimbursement for drug products exists among third- party payors and coverage and reimbursement levels for drug products can differ significantly from payor to payor. Further, one payor' s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third- party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Even if we obtain coverage for a given product, if the resulting reimbursement rates are insufficient, hospitals may not approve our product for use in their facility or third- party payors may require co- payments that patients find unacceptably high. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our product candidates. Separate reimbursement for the product itself may or may not be available. Instead, the hospital or administering physician may be reimbursed only for providing the treatment or procedure in which our product is used. Further, from time to time, CMS revises the reimbursement systems used to reimburse health care providers, including the Medicare Physician Fee Schedule and Outpatient Prospective Payment System, which may result in reduced Medicare payments. In some cases, private third- party payors rely on all or portions of Medicare payment systems to determine payment rates. Changes to government healthcare programs that reduce payments under these programs may negatively impact payments from private third- party payors, and reduce the willingness of physicians to use our product candidates. The marketability of any product candidates for which we receive regulatory approval for commercial sale may suffer if government and other third- party payors fail to provide coverage and adequate reimbursement. We expect downward pressure on pharmaceutical pricing to continue. Further, coverage policies and third- party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Healthcare legislative measures aimed at reducing healthcare costs may have a material adverse effect on our business and results of operations. In the United States, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay regulatory approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we, or any collaborators, may receive for any approved products. For more information, see " Business – Government Regulation – Current and Future Legislation. " ~~In August 2022, the IRA was signed into law. The IRA includes several provisions that will impact our business to varying degrees, including provisions that create a $ 2, 000 out- of- pocket cap for Medicare Part D beneficiaries, impose new manufacturer financial liability on all drugs in Medicare Part D, allow the U. S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologies without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The effect of IRA on our business and the healthcare industry in general is not yet known.~~ We cannot predict the initiatives that may be adopted in the future. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: • the demand for our product candidates, if we obtain regulatory approval; • our ability to set a price that we believe is fair for our products, if licensed; • our ability to generate revenue and achieve or maintain profitability; • the level of taxes that we are required to pay; and • the availability of capital. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability **. We expect that the healthcare reform measures that have been adopted and 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 and could seriously harm our future revenues. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private 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 products . Our relationships with customers, healthcare providers, physicians, and third- party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we could face substantial penalties. These laws may impact, among other things, our clinical research program, as well as our proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services is subject to extensive laws and regulations designed to prevent fraud, kickbacks, self- dealing and other abusive practices, including, without limitation, the federal Anti- Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute pharmaceutical products. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive and other business arrangements. We may also be subject to federal, state and foreign laws governing the privacy and security of individual identifiable health information and other personally identifiable information. For more information, see " Business – Government ~~Regulations~~ **Regulation** – Other Healthcare Laws and Compliance Requirements. " The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from the business. The failure to comply with any of these laws or regulatory requirements subjects entities to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restructuring of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management' s attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, or our arrangements with physicians, some of whom receive stock options as compensation, could be subject to challenge under one or more of such laws. If we or our employees, independent contractors, consultants, commercial partners and vendors violate these laws, we may be subject to investigations, enforcement actions and / or significant penalties. We have adopted a code of business conduct and ethics, but it is not always possible to identify and deter employee misconduct or business noncompliance, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and / or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Risks Related to Data and Privacy Data collection is governed by restrictive regulations governing the use, processing, and cross- border transfer of personal information. We are subject to stringent privacy and data protection requirements and these requirements may become more complex as we grow our business and begin to operate in other jurisdictions. For example, the collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area ~~(" , or the~~ EEA ~~")~~, including personal health data, is subject to the EU General Data Protection Regulation ~~(" , or the~~ EU GDPR ~~, ")~~ and similarly, processing of personal data regarding individuals in the UK is subject to the UK General Data Protection Regulation and the UK Data Protection Act 2018 ~~(" , or the~~ UK GDPR ~~",~~ and together with the EU GDPR ~~" , or the~~ GDPR ~~")~~. The GDPR is wide- ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to **having a legal basis for** processing ~~health and~~ **personal data, stricter requirements relating to** ~~other~~ **the processing of** sensitive data **(such as health data)** , **where required by the GDPR** 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, **requiring data protection impact assessments for high risk processing** 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 EEA / UK, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of

up to € 20 million (~~(~~£ 17. 5 million under UK GDPR) 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. In addition, the GDPR includes restrictions on cross- border data transfers of personal data to countries outside the EEA / UK that are not considered by the European Commission and UK government as providing " adequate " protection to personal data ~~(" ,~~ **or** third countries ~~")~~, including the United States. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is 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. To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards (for example, the European Commission approved Standard Contractual Clauses ~~(" ,~~ **or** SCCs ~~")~~) must be implemented in compliance with European and UK data protection laws. In addition, transfers made pursuant to the SCCs (and other similar appropriate transfer safeguards) need to be assessed on a case- by- case basis taking into account the legal regime applicable in the destination country, in particular regarding applicable surveillance laws and relevant rights of individuals with respect to the transferred personal data, to ensure an " essentially equivalent " level of protection to that guaranteed in the EEA in the jurisdiction where the data importer is based ~~(" ,~~ **or the** Transfer Impact Assessment ~~")~~. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU / EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU / EEA ~~. The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive~~ . The UK is not subject to the EC' s new standard contractual clauses but has published its own transfer mechanism, the International Data Transfer Agreement and International Data Transfer Addendum ~~(" ,~~ **or the** IDTA ~~")~~, which enable transfers from the UK, and has also implemented a similar Transfer Impact Assessment requirement. **Further, the EU and United States have adopted its adequacy decision for the EU- U. S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the EU and the United States is comparable to that offered in the EU. This provides a further avenue to ensuring transfers to the United States are carried out in line with GDPR. There has been an extension to the Framework to cover UK transfers to the United States. The Framework could be challenged like its predecessor frameworks.** We will be required to implement these ~~new~~ safeguards and carry out Transfer Impact Assessments when conducting restricted data transfers under the GDPR and doing so will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA or UK personal data is stored and transferred, and which service providers we can utilize for the processing of EEA / UK personal data. Although the UK is regarded as a third country under the EU GDPR, the European Commission has issued a decision recognizing the UK as providing adequate protection under the EU GDPR ~~(" ,~~ **or the** Adequacy Decision **,** ~~")~~ and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing. The UK Government has also now introduced a Data Protection and Digital Information Bill ~~(" ,~~ **or the** UK Bill **,** ~~")~~ into the UK legislative process. The aim of the UK Bill is to reform the UK' s data protection regime ~~following Brexit~~ . If passed, the final version of the UK Bill may have the effect of further altering the similarities between the UK and EEA data protection regime ~~and threaten the UK Adequacy Decision from the EU Commission~~ . This may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties **.** In the United States, there has been a flurry of activity at the state level. In California, the California Consumer Privacy Act, or CCPA, **went into** ~~was enacted in June 2018, became effective~~ --- **effect** on January 1, 2020, and became subject to enforcement by the California Attorney General' s office on July 1, 2020. The CCPA broadly defines personal information, and creates ~~new~~ **comprehensive** individual privacy rights and protections for California consumers (as defined in the law), places increased privacy and security obligations on entities handling personal data of consumers or households, and provides for civil penalties for violations and a private right of action for data breaches. The CCPA requires covered companies to provide certain disclosures to consumers about ~~its~~ **their** data collection, use and sharing practices, and to provide affected California residents with ways to opt- out of certain sales or transfers of personal information **. Additionally, a California ballot initiative, the California Privacy Rights Act, or CPRA, was passed in November 2020 and as of January 1, 2023 has imposed additional obligations on companies covered by the legislation. The CPRA significantly modified the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also created a new state agency that is vested with authority to implement and enforce the CCPA and the CPRA** . While there is an exception for protected health information that is subject to HIPAA and clinical trial regulations, the ~~CCPA may impact our business activities if we become a " Business " regulated by the scope of the CCPA. Additionally, a California ballot initiative, the California Privacy Rights Act, or CPRA, was passed in November 2020 and became effective on January 1, 2023. The CPRA imposes additional obligations on companies covered by the legislation and significantly modifies the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA. The~~ effects of the CCPA, as amended by the CPRA are potentially significant and may require us to modify our data collection or processing practices and policies and to incur substantial costs and expenses in an effort to comply and ~~increase~~ **decrease** our potential exposure to regulatory enforcement and / or litigation. ~~Certain~~ **Similar laws have been passed in numerous** other ~~state~~ **states and other states have proposed similar new privacy** laws **. Such proposed** ~~impose similar privacy obligations and we also anticipate that more states will increasingly enact~~ legislation ~~similar to~~ **, if enacted, may add additional complexity, variation in requirements, restrictions**

and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the ~~CCPA~~ **availability of previously useful data and could result in increased compliance costs and / or changes in business practices and policies** . The **existence** ~~CCPA has prompted a number~~ of ~~proposals for new federal and state- level privacy legislation and in some states efforts to pass~~ comprehensive privacy laws ~~have been successful~~ **in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information** . For example, **Washington state recently passed a health privacy** ~~on March 2, 2021, Virginia enacted the Consumer Data Protection Act, or CDPA, which became effective on January 1, 2023. The CDPA regulates how businesses collect and share personal information. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the~~ law that will ~~change~~ **regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition,** ~~the~~ **other** ~~operational practices~~ **states have proposed and / or passed legislation that regulates the privacy and / or security** of ~~controllers~~ **certain specific types of information** . **For example, a small number of states have passed laws that regulate biometric data specifically.** ~~The~~ **These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there is discussion in the U. S. Congress of a** new **comprehensive federal** ~~law will impact how controllers collect and process personal sensitive~~ data ~~, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Also, on July 8, 2021, Colorado' s governor signed the Colorado Privacy Act, or CPA, into law. The CPA is rather similar to Virginia' s CPDA but also contains additional requirements. Moreover, on March 24, 2022, Utah' s governor signed the Utah Consumer Privacy Act, or UCPA. The UCPA, which is largely based on Virginia' s CDPA, will take effect on December 31, 2023. Also, in May 2022, Connecticut Governor Lamont signed the Connecticut Data Privacy Act (CTDPA) into laws. The CTDPA draws heavily upon their predecessors in Virginia and Colorado. With the CTDPA, Connecticut became the fifth state to enact a comprehensive~~ privacy law **to which we** ~~. New privacy and data security laws have been proposed in more than half of the states in the U. S. and in the U. S. Congress. With bills proposed in many~~ **may likely become subject, if enacted. All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. Further, various** other jurisdictions ~~, it remains quite possible that other states will follow suit. The effects of the CCPA, and other similar state or federal laws, are potentially significant and may require us to modify our data processing practices and policies and to incur substantial costs and potential liability in an effort to comply with such legislation. The existence of comprehensive privacy laws in different states in the country, if enacted, will add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data, and has resulted in and will result in increased compliance costs and / or changes in business practices and policies. Further, various jurisdictions~~ around the world continue to propose new **and / or amended** laws that regulate the privacy and / or security of certain types of personal data. Complying with these laws, if enacted, would require significant resources and leave us vulnerable to possible fines and penalties if we are unable to comply. The regulatory framework governing the collection, processing, storage, use and sharing of certain information is rapidly evolving and is likely to continue to be subject to uncertainty and varying interpretations. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our existing data management practices or the features of our services and platform capabilities. Compliance with the above and any other applicable privacy and data security laws and regulations is a rigorous and time- intensive process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules **, modify our data processing practices and policies, utilize management' s time and / or divert resources from other initiatives and projects** . Any failure or perceived failure by us, or any third parties with which we do business, to comply with our posted privacy policies, evolving laws, rules and regulations, industry standards, or contractual obligations to which we or such third parties are or may become subject, may result in actions or other claims against us by governmental entities or private actors, the expenditure of substantial costs, time and other resources or the incurrence of significant fines, penalties or other liabilities. In addition, any such action, particularly to the extent we were found to be guilty of violations or otherwise liable for damages, would damage our reputation and adversely affect our business, financial condition and results of operations. If our security measures **or those of our contractors, consultants or other service providers** are breached or unauthorized access to **confidential and / or proprietary information or other sensitive information, including** individually identifiable health information or other personally identifiable information **,** is otherwise obtained, our reputation may be harmed, and we may incur significant liabilities. Unauthorized access to, or security **compromises or** breaches of, our systems and databases could result in unauthorized access to data and information and loss, compromise **, misuse,** or corruption of such data and information. The systems of ~~Penn,~~ any CMOs that we may engage **now or** in the future, and present and future CROs, contractors ~~and~~ **,** consultants **and other service providers** also could experience breaches **or compromises** of security leading to the exposure of confidential and sensitive information. Cyber incidents have been increasing in sophistication and frequency and can include third parties gaining access to employee or customer data using stolen or inferred credentials, **wrongful conduct by employees, vendors, or other third parties, hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud or cyber- attacks,** computer malware, viruses, spamming, phishing attacks **and social engineering, business email compromise** , ransomware, card skimming code, and other deliberate attacks and attempts to gain unauthorized access **to or disrupt or compromise our information technology systems** . Because the techniques used by computer programmers who may attempt to penetrate and

sabotage our **information technology systems and infrastructure,** network security or our website change frequently and may not be recognized until launched against a target, we may be unable to anticipate these techniques **or to adequately prevent or address them** . It is also possible that unauthorized access to **our confidential and / or proprietary information or other sensitive information, including** customer ~~data~~ **or employee information,** may be obtained through inadequate use of security controls by customers, suppliers or other vendors. We rely on such third parties to implement effective security measures and identify and correct for any failures, deficiencies **, compromises** or breaches. In the event of a security **compromise or** breach, our company could suffer loss of business, severe reputational damage adversely affecting investor confidence, regulatory **inquiries,** investigations and orders, litigation, indemnity obligations, damages for contract breach, penalties **and fines** for violation of applicable laws or regulations, significant costs for remediation and other liabilities. For example, the loss of preclinical study or clinical trial data from completed or future preclinical studies or clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security **compromise or** breach were to result in a loss **or misappropriation** of, or damage to, our data **, systems,** or applications, or inappropriate disclosure of confidential or proprietary **information or other sensitive** information, we could incur liability and the further development and commercialization of our product candidates could be delayed. We have incurred and expect to incur significant expenses to prevent security **compromises or** breaches, including costs related to deploying additional personnel and protection technologies, training employees, and engaging third- party solution providers and consultants. Although we expend significant resources to create security protections that **are designed to** shield our **confidential and / or proprietary information or other sensitive information, including** customer data **,** against potential theft and security **compromises or** breaches, such measures cannot provide absolute security. Moreover, as we outsource more of our information systems to vendors and rely more on cloud- based information systems, the related security risks will increase, and we will need to expend additional resources to protect our technology and information systems. We have in the past experienced security incidents, and we may in the future experience other data security incidents **, compromises** or breaches affecting personally identifiable information or other confidential business information. We remain at risk for future **compromises or** breaches, including, without limitation, **compromises or** breaches that may occur as a result of third- party action, or employee, vendor or contractor error or malfeasance and other causes. If, in the future, we experience a data breach or security incident, we would be likely to experience harm to our reputation, financial performance, and customer and vendor relationships, and the possibility of litigation or regulatory investigations or actions by state and federal governmental authorities and non- U. S. authorities **, including fines, penalties, and other legal and financial exposure and liabilities** . Additionally, actual, potential or anticipated attacks **or compromises** may cause us to incur increasing costs, including costs to deploy additional personnel and protection technologies, train employees, **conduct security incident investigation or remediation** and engage third- party experts and consultants. Although we maintain cyber liability insurance, we cannot be certain that our coverage will be adequate for liabilities actually incurred or that insurance will continue to be available to us on economically reasonable terms, or at all. Interruptions in the availability of server systems or communications with internet or cloud- based services, or failure to maintain the security, confidentiality, accessibility or integrity of data stored on such systems, could harm our business. We rely upon a variety of internet service providers, third- party web hosting facilities and cloud computing platform providers to support our business. Failure to maintain the security, confidentiality, accessibility or integrity of data stored on **or processed by** such systems could result in interruptions in our operations, damage our reputation in the market, increase our service costs, cause us to incur substantial costs, subject us to liability for damages and / or fines, and divert our resources from other tasks, any one of which could materially adversely affect our business, financial condition, results of operations and prospects. If our security measures or those of our third- party data center hosting facilities, cloud computing platform providers, or third- party service partners, are breached, and unauthorized access is obtained to **or there is misuse of** our data or our information technology systems, we may incur significant legal and financial exposure and liabilities. We also do not have control over the operations of the facilities of our cloud service providers and our third- party web hosting providers, and they also may be vulnerable to damage **, security compromise** or interruption from natural disasters, cybersecurity attacks, terrorist attacks, power outages and similar events or acts of misconduct. In addition, any changes in these providers' service levels may adversely affect our ability to meet our requirements and operate our business. Risks Related to Ownership of Our Common Stock Risks Related to Ownership Generally Our principal stockholders and management own a significant percentage of our stock and ~~will~~ **could** be able to exert significant control over matters subject to stockholder approval. As of December 31, ~~2022~~ **2023** , our executive officers, directors, and 5 % stockholders beneficially owned, in the aggregate, approximately ~~71~~ **39** % of our outstanding voting common stock, or ~~73~~ **38** % of our common stock, assuming all shares of non- voting common stock are converted into voting common stock in accordance with the terms of our Third Amended and Restated Certificate of Incorporation, or the amended and restated certificate of incorporation. Accordingly, these stockholders ~~will~~ **could** have the ability to influence us through this ownership position and significantly affect the outcome of all matters requiring stockholder approval. For example, these stockholders may be able to significantly affect the outcome of elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed. As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. The Sarbanes- Oxley Act requires that we evaluate and determine the effectiveness of our internal control over financial reporting and, beginning with our second annual report following our initial public offering, provide a management report on internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm.

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time- consuming effort that needs to be re- evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. We have begun the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes- Oxley Act. We have begun recruiting additional finance and accounting personnel with certain skill sets that we need as a public company. Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers. The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions. The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non- voting common stock are not entitled to any votes. Nonetheless, each share of our non- voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the limitations provided for in our amended and restated certificate of incorporation. Entities affiliated with or managed by Baker Brothers Life Sciences, L. P. hold an aggregate of 1, ~~860~~ **444** , ~~759~~ **295** shares of our non- voting common stock pursuant to our amended and restated certificate of incorporation. At any time, upon written notice, a portion of these shares of non- voting common stock could be converted into up to an aggregate of ~~6~~ **3** % of our shares of common stock. Upon 61 days' prior written notice, any or all of the non- voting common stock could be converted into shares of common stock. Consequently, if holders of our non- voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non- voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10 % of our common stock and non- voting common stock, but 10 % or less of our common stock, and are not otherwise a company insider, may not be required to report changes in their ownership due to transactions in our non- voting common stock pursuant to Section 16 (a) of the Exchange Act, and may not be subject to the short- swing profit provisions of Section 16 (b) of the Exchange Act. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. On ~~November 10~~ **March 16** , ~~2020~~ **2023** , we filed a registration statement on Form S- 3 (File No. 333- ~~250006~~ **270599**) with the SEC, which was declared effective on ~~November 18~~ **April 26** , ~~2020~~ **2023** , or the **2023** Shelf Registration Statement, in relation to the registration of common stock, preferred stock, debt securities, warrants and / or units of any combination thereof for the purposes of selling, from time to time, our common stock, debt securities or other equity securities in one or more offerings. We also simultaneously entered into a Sales Agreement, or the **2023** Sales Agreement, with Cowen and Company, LLC, or the Sales Agent, to provide for the offering, issuance and sale of up to an aggregate amount of $ ~~75~~ **100** . 0 million of our common stock from time to time in " at- the- market " **,** offerings under the **2023** Shelf Registration Statement and subject to the limitations thereof. We **paid** ~~will pay~~ to the Sales Agent cash commissions of **up to** 3. 0 percent of the aggregate gross proceeds of sales of common stock under the **2023** Sales Agreement ~~. During the year ended December 31, 2021, we sold 4, 792, 562 shares pursuant to the ATM Program at an average price of $ 10. 38 per share for net proceeds of $ 48. 3 million, after deducting commissions of $ 1. 4 million~~ . Sales of common stock, debt securities or other equity securities by us may represent a significant percentage of our common stock currently outstanding. If we sell, or the market perceives that we intend to sell, substantial amounts of our common stock under the **2023** Shelf Registration Statement or otherwise, the market price of our common stock could decline significantly. In **2023, we sold 4, 760, 899 shares of common stock pursuant to the 2023 Sales Agreement, for net proceeds of $ 91. 7 million, after deducting commissions of $ 2. 4 million. From** December **31,** ~~2022~~ **2023 to March 21, 2024, we sold 258, 070 additional shares, completing the 2023 Sales Agreement for net proceeds of $ 5. 7 million, after deducting commissions of $ 0. 1 million. In May 2023** , we issued ~~126~~ **8** , ~~815~~ **337, 500** shares of common stock at a price of $ ~~5~~ **12** . ~~52~~ **00** per share **in connection with** ~~and~~ **an underwritten public** ~~, to certain investors in lieu of common stock, pre- funded warrants to purchase 6, 213, 776 shares of common stock at a price of $ 5. 51999 per pre- funded warrant. The purchase price per share of each pre- funded warrant represents the per share~~ offering ~~price for the common stock, minus the $ 0. 00001 per share exercise price of such pre- funded warrant~~ . Aggregate net proceeds were $ ~~32~~ **93** . ~~6~~ **8** million after deducting underwriting discounts and commissions and offering expenses. ~~In connection with this offering, our executive officers and directors entered into lock- up agreements, whereby they agreed to, among other things, subject to certain exceptions, not to offer, sell, assign, transfer, pledge, contract to sell, lend or otherwise dispose of or announce the intention to otherwise dispose of, any shares of common stock or securities convertible into or exercisable or exchangeable for common stock for a period of 90 days. At the expiration of such lock- up period, sales of a substantial number of shares of our common stock in the public market could occur, which could~~

~~reduce the market price of our common stock~~ We have also filed registration statements on Form S- 8 to register shares issued or reserved for issuance under our equity compensation plans and will file additional registration statements on Form S- 8 to register additional shares pursuant to the " evergreen " provisions under **our equity compensation plans, the Plan Amendment and any subsequent amendments to** our equity compensation plans. Shares registered under these registration statements on Form S- 8 can be freely sold in the public market upon issuance and once vested, subject to volume limitations applicable to affiliates and the lock- up agreements described above. If any of these additional shares are sold, or if it is perceived that they will be sold, in the public market, the market price of our common stock could decline. In addition, certain of our employees, executive officers, and directors may enter into Rule 10b5- 1 trading plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5- 1 trading plan, a broker executes trades pursuant to parameters established by the employee, director, or officer when entering into the plan, without further direction from the employee, officer, or director. A Rule 10b5- 1 trading plan may be amended or terminated in some circumstances. Our employees, executive officers, and directors also may buy or sell additional shares outside of a Rule 10b5- 1 trading plan when they are not in possession of material, nonpublic information. Risks Related to our Charter and Bylaws Anti- takeover provisions under our charter documents and Delaware law could delay or prevent a change of control which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management. Our amended and restated certificate of incorporation and amended and restated bylaws, as amended, or the amended and restated bylaws, contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include: • a board of directors divided into three classes serving staggered three- year terms, such that not all members of the board will be elected at one time; • a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders; • a requirement that special meetings of stockholders be called only by the chairman of the board of directors, the chief executive officer, or by a majority of the total number of authorized directors; • advance notice requirements for stockholder proposals and nominations for election to our board of directors; • a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of not less than 75 % of the votes that all our stockholders would be entitled to cast in an annual election of directors; • a requirement of approval of not less than 75 % of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our amended and restated certificate of incorporation; and • the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15 % or more of our outstanding voting stock. These anti- takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by the then- current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline. Our amended and restated bylaws designate certain courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, or other employees to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law or our amended and restated certificate of incorporation or amended and restated bylaws (including the interpretation, application or validity thereof); or (iv) any action asserting a claim governed by the internal affairs doctrine (the Delaware Forum Provision). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act of 1933, as amended (the Securities Act) or the Securities Exchange Act of 1934. Our amended and restated bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America are the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or the rules and regulations promulgated thereunder ~~(~~**, or** the Federal Forum Provision ~~)~~. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing Delaware Forum Provision and Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U. S. federal securities laws and the rules and regulations thereunder. The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. While the Delaware Supreme Court and other states have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on us and / or our stockholders who assert that the provision is invalid or unenforceable. The

Court of Chancery of the State of Delaware or the federal district courts of the United States of America may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders. Risks Related to Tax Changes in tax laws could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. Prospective investors in our common stock should consult with their legal and tax advisors with respect to potential changes in tax laws and the tax consequences of investing in or holding our common stock. Our ability to utilize our net operating losses and certain other tax attributes to offset future taxable income may be subject to certain limitations. As of December 31, ~~2022~~ **2023**, we had U. S. federal, state and local net operating loss carryforwards of $ ~~99~~ **121**. ~~2~~ **6** million, $ ~~101~~ **131**. ~~4~~ **9** million and $ ~~82~~ **83**. ~~2~~ **0** million, respectively. $ 0. 3 million of the federal amounts expire in 2037. The state net operating losses begin to expire in 2037 and the local net operating losses ~~begin~~ **began** to expire in ~~2023~~ **2024**. Approximately $ ~~98~~ **121**. ~~9~~ **3** million of the federal net operating losses can be carried forward indefinitely. Certain net operating loss carryforwards could expire unused and be unavailable to offset future taxable income. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, and corresponding provisions of state law, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change net operating loss carryforwards or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5 % of a corporation' s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Our existing NOLs or credits may be subject to limitations arising from previous ownership changes, and if we undergo an ownership change, our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code. In addition, future changes in our stock ownership, many of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Our NOLs or credits may also be impaired under state law. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U. S. federal and state taxable income. As described above under " — Risks Related to Our Financial Condition and Capital Requirements ", we have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U. S. federal or state taxable income necessary to utilize our NOLs or credits. Under current law, U. S. federal net operating loss carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration. However, any such net operating loss carryforwards may only offset 80 % of our annual taxable income in taxable years beginning after December 31, 2020. General Risk Factors Adverse developments affecting the financial services industry could adversely affect our current and projected business operations and our financial condition and results of operations. Adverse developments that affect financial institutions, **such as** ~~transactional counterparties or other third parties, or concerns or rumors about any~~ events ~~of these kinds~~ **involving liquidity that are rumored** or **actual** ~~other similar risks~~, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank ~~(" SVB ")~~ was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ~~(" FDIC ")~~ as receiver ~~. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. The Department of the Treasury, the Federal Reserve and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts. We had a minimal amount of exposure to the SVB closure and did not experience any adverse impact to our liquidity or to our current and projected business operations, financial condition or results of operations. However, uncertainty remains over liquidity concerns in the broader financial services industry, and there may be additional impacts to our business and our industry that we cannot predict at this time. Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U. S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $ 25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U. S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion~~. Although we assess our banking relationships as we believe necessary or appropriate, our access to ~~cash~~ **funding sources and other credit arrangements** in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that ~~affect~~ us, the financial institutions with which we have ~~banking relationships~~ **credit agreements or arrangements directly, or the financial services industry or economy in general**. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. **Public health crises** ~~These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships~~, **such** ~~but could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material~~

and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and / or delays in accessing or actual loss of funds subject to cash management arrangements. In addition, widespread investor concerns regarding the U. S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and / or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and / or projected business operations and financial condition and results of operations. In addition, a vendor on which we are reliant could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in material adverse impacts on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any critical vendor bankruptcy or insolvency, or any breach or default by a critical vendor, or the loss of any significant vendor relationships, may have a material adverse impact on our business. The ongoing COVID- 19 pandemic and the future **, epidemic or** outbreak of other highly infectious or contagious diseases **,** could seriously harm our research, development and potential future commercialization efforts, increase our costs and expenses and have a material adverse effect on our business, financial condition and results of operations. Public health crises **,** such as **a** ~~pandemics~~ **pandemic, epidemic** or ~~similar outbreaks~~ **outbreak of other highly infectious or contagious diseases,** could adversely impact our business, the business operations of third parties on whom we rely and our ongoing or planned research and development activities ~~. Although many activities have returned to normal, new variants of COVID- 19 have been identified and spread, which have led to various responses, including government- imposed quarantines, travel restrictions and other public health safety measures in response to the emergence of new variants. The extent to which COVID- 19 will continue to impact our operations or those of our third party partners will depend on future developments, which are uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information that may emerge concerning the severity of COVID- 19, the impact of new strains of the virus, the effectiveness, availability and utilization of vaccines and treatments and the actions to contain COVID- 19 or treat its impact, among others~~ . Additionally, timely enrollment in our ongoing and planned clinical trials is dependent upon clinical trial sites which may be adversely affected by global health **concerns** ~~matters, such as COVID- 19~~ . **Public health crises** ~~The ongoing COVID- 19 pandemic~~ could result in increased adverse events and deaths in our clinical trials ~~due to COVID- 19 related infections, and implementing a lymphodepleting and / or immunomodulatory preconditioning regimen may result in the likelihood that patients are more immunosuppressed and therefore at a greater risk of developing more severe symptoms from a COVID- 19 infection~~ . Some factors from **public health crises** ~~the ongoing COVID- 19 pandemic~~ that ~~have delayed and~~ could ~~further~~ delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include: • the potential diversion of healthcare resources away from the conduct of clinical trials to focus on ~~pandemic concerns~~ **public health crises** , including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials and the need for drugs, such as tocilizumab, and other supplies that clinical trial sites must have on hand to conduct our clinical trials to be used to ~~treat COVID- 19~~ **address such public health crises** ; • limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government- imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face- to- face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials; • interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials; • interruptions in operations at our third- party manufacturers, which could result in delays or disruptions in the supply of our current product candidates and any future product candidates; and • business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, product manufacturing and supply, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors. ~~These and other factors arising from the ongoing COVID- 19 pandemic could worsen.~~ Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of ~~operation~~ **operations** and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates. The price of our stock may be volatile, and you could lose all or part of your investment. The trading price of our common stock has been, and is likely to be in the future, highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this " Risk Factors " section, these factors include: • the commencement, enrollment or results of our planned preclinical studies or clinical trials of our product candidates or any preclinical studies or future clinical trials we may conduct, or changes in the development status of our product candidates; • our decision to initiate a preclinical study or clinical trial, not to initiate a preclinical study or clinical trial or to terminate an existing preclinical study or clinical trial; • adverse results or delays in preclinical studies or clinical trials of our

product candidates; • any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including, without limitation, the FDA' s issuance of a " refusal to file " letter or a request for additional information; • our failure to commercialize our product candidates; • adverse regulatory decisions, including failure to receive regulatory approval of our product candidates; • changes in laws or regulations applicable to our product candidates, including, but not limited to, clinical trial requirements for approvals; • adverse developments concerning our manufacturers or suppliers; • our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices; • our inability to establish collaborations, if needed; • additions or departures of key scientific or management personnel; • unanticipated serious safety concerns related to the use of our product candidates; • introduction of new products or services offered by us or our competitors; • announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; • our ability to effectively manage our growth; • the size and growth of our initial target markets; • our ability to successfully treat additional types of ~~B cell- mediated~~ autoimmune diseases **where B cells may play a role in initiating or maintaining disease** ; • actual or anticipated variations in annual or quarterly operating results; • our cash position; • our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; • publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts; • changes in the market valuations of similar companies; • overall performance of the equity markets; • sales of our common stock by us or our stockholders in the future; • trading volume of our common stock; • changes in accounting practices; • ineffectiveness of our internal controls; • disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies; • significant lawsuits, including patent or stockholder litigation; • general political and economic conditions, including inflation; • global health concerns ~~, such as the ongoing COVID- 19 pandemic~~ ; and • other events or factors, many of which are beyond our control. In addition, the stock market in general, and The Nasdaq Global Select Market and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations in recent years 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 common stock, regardless of our actual operating performance. Securities class action litigation has often been instituted against companies, particularly in the biopharmaceutical and life sciences industries, following periods of volatility in the market price of a company' s securities. We have been subject to such a securities class action lawsuit filed in February 2022 and voluntarily dismissed by the plaintiff in October 2022, against certain of our officers and certain of our current and former directors, and may become subject to additional securities class action lawsuits in the future ~~. See " Part II, Item 1. Legal Proceedings " for more information~~ . This type of litigation could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results or financial condition. Our business is affected by macroeconomic conditions, including rising inflation, interest rates and supply chain constraints. Various macroeconomic factors could adversely affect our business and the results of our operations and financial condition, including changes in inflation, interest rates and overall economic conditions and uncertainties such as those resulting from the current and future conditions in the global financial markets. Recent supply chain constraints have led to higher inflation, which if sustained could have a negative impact on our product development and operations. If inflation or other factors were to significantly increase our business costs, our ability to develop our current pipeline and new therapeutic products may be negatively affected. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the operation of our business and our ability to raise capital on favorable terms, or at all, in order to fund our operations. Similarly, these macroeconomic factors could affect the ability of our third- party suppliers and manufacturers to manufacture clinical trial materials for our product candidates. We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to the appreciation of their stock. We are an emerging growth company and a " smaller reporting company, " and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common stock less attractive to investors. We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002, as amended, or the Sarbanes- Oxley Act, reduced disclosure obligations regarding executive compensation in 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 emerging growth company for up to five years following the date of completion of our initial public offering, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering, (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 million as of the prior June 30th, and (2) the date on which we have issued more than $ 1 billion in non- convertible debt during the prior three- year period. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, we are not subject to the same new or revised accounting standards as other public companies that are not emerging growth companies and our financial

statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates. **Assuming we do not surpass one of the other thresholds, our status as an emerging growth company will end on December 31, 2024, which will be the last day of the fiscal year ending after the fifth anniversary of our initial public offering. As such, we will be subject to the disclosure requirements applicable to other public companies that were not applicable to us as an emerging growth company. These requirements include: • compliance with the auditor attestation requirements of Section 404 of Sarbanes- Oxley Act; • compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor' s report on the financial statements. • full disclosure obligations regarding executive compensation; and • compliance with the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. When our independent registered public accounting firm is required to undertake an assessment of our internal control over financial reporting, the cost of our compliance with Section 404 of Sarbanes- Oxley Act will correspondingly increase. Moreover, if we are not able to comply with the requirements of Section 404 of the Sarbanes- Oxley Act applicable to us in a timely manner, or if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities. Additionally, we expect that our loss of emerging growth company and smaller reporting company status will require additional attention from management and will result in increased costs to us, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others.** We are also a " smaller reporting company, " as defined in Rule 12b- 2 under the Securities Exchange Act of 1934, as amended. We would cease to be a smaller reporting company if we have a public float in excess of $ 250 million, or have annual revenues in excess of $ 100 million and a public float in excess of $ 700 million, determined on an annual basis. Consequently, even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company " which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates or grant licenses on terms unfavorable to us. We could be subject to significant legal proceedings which may adversely affect our results of operations or financial condition. We are subject to the risk of litigation, derivative claims, securities class actions, regulatory and governmental investigations and other proceedings, including proceedings arising from investor dissatisfaction with us or our performance or claims brought by employees, government agencies or supplies. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and pharmaceutical companies have experienced significant stock price volatility in recent years. In addition, if any individuals acting on our behalf fails to satisfy his or her relevant legal or contractual duties, we could have liability to third parties, including the government or investors. If any claims were brought against us and resulted in a finding of substantial legal liability, the finding could materially adversely affect our business, financial condition or results of operations or cause significant reputational harm to us, which could seriously adversely impact our business. Allegations of improper conduct by private litigants or regulators, regardless of veracity, also may harm our reputation and adversely impact our ability to grow our business. Even if the allegations against us in future legal matters are unfounded or we ultimately are not held liable, the costs to defend ourselves may be significant and the litigation may subject us to substantial settlements, fines, penalties or judgments against us and may consume management' s bandwidth and attention, some or all of which may negatively impact our financial condition and results of operations. Litigation also may generate negative publicity, regardless of whether the allegations are valid, or we ultimately are liable, which could damage our reputation, and adversely impact our sales and our relationship with our employees, customers, and partners. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. In the event that one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.