Risk Factors Comparison 2024-02-29 to 2023-03-16 Form: 10-K

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Investing in shares of our common stock involves a high degree of risk. You should carefully consider the following risks and uncertainties, together with all of the other information contained in this Annual Report, including our financial statements and related notes included elsewhere in this Annual Report, before making an investment decision. The risks described below are not the only ones we face ~~. Moreover, we may have already experienced the circumstances described in one or more of the risk factors described below~~ . Many of the following risks and uncertainties are, and will continue to be, exacerbated by any worsening of the global geo- political, business, and economic environment. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could materially and adversely affect our business, financial condition, reputation, or results of operations. In such a case, the trading price of shares of our common stock could decline, and you may lose all or part of your investment. Risks Related to Our Business and Industry Our ex vivo and in vivo cell engineering platforms are based on novel technologies that are unproven and may not result in approvable or marketable products. This uncertainty exposes us to unforeseen risks, makes it difficult for us to predict the time and cost that will be required for the development and potential regulatory approval of our product candidates, and increases the risk that we may ultimately not be successful in our efforts to use and expand our technology platforms to build a pipeline of product candidates. A key element of our strategy is to identify and develop a broad pipeline of product candidates using our ex vivo and in vivo cell engineering platforms and advance those product candidates through clinical development for the treatment of various different diseases. ~~We have not commenced clinical trials for any product candidates developed with these platforms.~~ The scientific research that forms the basis of our efforts to develop product candidates with our platforms is still ongoing. We are not aware of any ~~United States Food and Drug Administration (~~ FDA ~~)~~ - approved therapeutics that are cell products derived from pluripotent stem cells (PSCs) or that utilize our fusogen technology. Further, the scientific evidence that supports the feasibility of developing therapeutic treatments based on our platforms is ~~both~~ preliminary ~~and~~ **,** limited ~~. As a result~~ , ~~we~~ **and remains ongoing. We** are **therefore** exposed to a number of unforeseen risks, and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates. Preclinical and clinical testing of product candidates is inherently unpredictable and may lead to unexpected results, in particular when such product candidates are based on novel technologies. For example, we have not tested our cell engineering platforms on all pluripotent and differentiated cell types or in all microenvironments, and results from one cell type or microenvironment may not translate into other cell types or microenvironments. In addition, our current gene editing approaches rely on novel gene editing reagents that may have unanticipated or undesirable effects or prove to be less effective than we expect. Also, we **are in** ~~have not tested any of~~ the **early stages of testing** product candidates **developed** ~~that we are developing~~ using our cell engineering platforms in humans ~~. Further~~ , **and most of** our current data are limited to animal models and preclinical cell lines and assays, which may not accurately predict the safety and efficacy of our product candidates in humans **. Additionally, we and third parties may have limited preclinical and clinical data, and a more limited understanding generally, with respect to certain indications, including autoimmune diseases, and we cannot predict the extent to which the safety and efficacy of a product candidate may vary across indications** . We may encounter significant challenges creating appropriate models and assays for evaluating the safety and purity of our product candidates and may not be able to provide sufficient data or other evidence, to the satisfaction of regulatory authorities, that certain unexpected results observed in preclinical and clinical testing of our product candidates are not indicative of the potential safety issues of such product candidates. In addition, we may use manufacturing reagents and materials across various programs and initiatives. Certain reagents and materials may be novel and have unknown or unanticipated effects, including with respect to a product candidate' s safety, efficacy, or manufacturability. Any unanticipated or adverse effects related or attributed to such reagents or materials could affect all the programs and initiatives in which they are used, and result in delays and harm our ability to timely and successfully progress our product candidates through preclinical and clinical development. **We may develop program plans and timelines for certain product candidates based on our experience with such product candidates in different indications or with other product candidates that incorporate or were developed with the same technologies based on our expectation that such product candidates will perform and act similarly. However, our product candidates may reveal unexpected, important differences, including with respect to safety or efficacy, when developed in different indications or as compared to such other product candidates, including differences that may require changes to the manufacturing process or clinical development plan that require additional time and resources beyond what we initially anticipated. Any such occurrence could require us to adjust or alter our development plans, which could delay, harm, or prevent our ability to develop and commercialize such product candidates.** In addition, product candidates developed with our hypoimmune and fusogen technologies have potential safety risks, including those related to genotoxicity associated with the delivery of genome-modifying payloads. For example, DNA sequences that randomly integrate into a cell' s DNA may increase **the** risk for or cause certain cancers. Additionally, gene editing approaches may edit the genome at sites other than the intended DNA target or cause DNA rearrangements, each of which may have oncogenic or other adverse effects. PSC- derived cell products may have potential safety risks related to genomic and epigenomic variations that have ~~been observed~~ **occurred or may occur** during **the manufacturing process** ~~passage (i. e., amplification) and differentiation of pluripotent cell lines~~ . We cannot always predict the types and potential impact of these genomic changes, including whether certain changes are or may eventually be harmful. Accordingly, it may be difficult for us to conduct the level of testing and **assay** development ~~of assays~~ necessary to ensure that our PSC- derived cell product candidates have an acceptable safety profile when used in humans. These risks related to genetic variation are also relevant to our product candidates created from donor- derived cells. Additionally, our stem cell- based product candidates have potential safety risks that may result from cells that are undifferentiated or have not been completely differentiated to the desired phenotype and lead to oncogenic transformations or other adverse effects. As a result, it is possible that safety events or concerns could negatively affect the development of our product candidates, as described elsewhere in these Risk Factors. Given the novelty of our technologies, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates. However, due to a lack of experience with similar therapeutics or delivery methods, the regulatory pathway with the FDA and comparable foreign regulatory authorities may be more complex, time- consuming, and unpredictable relative to more well- known therapeutics. ~~Moreover~~ **For example**, even if we obtain human data to support continued evaluation and approval of our product candidates, the FDA or comparable foreign regulatory authorities may lack experience in evaluating the safety and efficacy of therapeutics similar to our product candidates or may scrutinize such data more closely than data generated from more established types of biological products. ~~For example~~ **In addition**, given that there are no approved PSC- or donor- derived cell therapy products on the market, the FDA and comparable foreign regulatory authorities have not established consistent standards by which to evaluate the safety of such products, and any such standards that they do establish may subsequently change. Moreover, the FDA remains focused on potential safety issues associated with gene and cell therapy products, and as the number of new gene and cell therapy product candidates submitted for FDA review has increased in recent years, the number of clinical holds imposed by the FDA has also increased. For example, the FDA has placed clinical holds on certain product candidates pending further evaluation of genomic abnormalities detected in as few as a single patient following administration of such product candidates. We cannot be certain that the FDA or comparable foreign regulatory authorities will determine that the potential safety risks associated with our product candidates outweigh the potential therapeutic benefits **in each indication for which we develop our products**, and that they will allow us to commence clinical trials of such product candidates in a timely manner, or at all, or to continue such clinical trials once they have commenced. If we become subject to a clinical hold with respect to any of our product candidates due to a potential safety issue, we cannot guarantee that we will be able to provide the applicable regulatory authority with sufficient data or other evidence regarding the safety profile of such product candidate such that we will be able to commence or resume clinical development of such product candidates in a timely manner or at all. ~~This~~ **Any such event** could delay clinical development of such product candidate **, including in other indications,** or our other product candidates, increase our expected development costs, increase the length of the regulatory review process, and delay or prevent commercialization of our product candidates. In addition, the evaluation process for our product candidates will take time and resources and may require independent third- party analyses, and our product candidates may ultimately not be accepted or approved by the FDA or comparable foreign regulatory authorities. As such, even if **we** are successful in building our pipeline of product candidates **from our ex vivo and in vivo cell engineering platforms**, we cannot be certain that **such efforts** ~~our ex vivo and in vivo cell engineering platforms~~ will lead to the development of approvable or marketable products, either alone or in combination with other therapies **. In response to reports of T cell malignancies in patients that previously received chimeric antigen receptor (CAR) T cell immunotherapies, the FDA announced in November 2023 that it is investigating the risk of secondary cancers and the need for regulatory action for such therapies as a class and has advised of new patient monitoring and reporting requirements with respect to such therapies. In January 2024, the FDA imposed a class- wide boxed warning requirement regarding the occurrence of T cell malignancies for all approved CAR T therapies. The FDA has noted that it currently believes that the overall benefits of these therapies continue to outweigh their potential risks for their approved uses. However, all currently approved CAR T cell immunotherapies are approved only in oncology indications, and there can be no assurance that the FDA or comparable foreign regulatory authorities will reach the same risk- benefit determination in other indications, such as autoimmune diseases. We have received and may in the future receive FDA correspondence requesting updates to certain of our CAR T cell clinical trials to address these developments. Additionally, we and our product candidates may be subject to further regulatory actions or requirements of the FDA or comparable foreign regulatory authorities relating to these therapies, such as requiring a black box warning or other labeling disclosures for any approved products. The occurrence of any of the foregoing could increase the cost and complexity of development and commercialization of, and limit the commercial opportunity for, such product candidates, any of which could have a material adverse effect on our business**. If we are unable to successfully identify, develop, and commercialize any product candidates, or experience significant delays in doing so, our business, financial condition, and results of operations will be materially adversely affected. Our ability to generate revenue from sales of any of our product candidates, which we do not expect to occur for at least the next several years, if ever, will depend heavily on the timely and successful identification, development, regulatory approval, and eventual commercialization of any such product candidates, which may never occur. To date, we have not generated revenue from sales of any products, and we may never be able to develop, obtain regulatory approval for, or commercialize a marketable product. ~~All of our current product candidates are in preclinical development, and, before~~ **Before** we generate any revenue from product sales **of any of our current or potential future product candidates**, **we** will **need to** ~~require that we~~ manage preclinical, clinical, and manufacturing activities, **including** ~~undertake~~ **undertaking** significant clinical development, obtain regulatory approval in multiple jurisdictions, establish manufacturing supply, including commercial manufacturing supply, and build a commercial organization, which will require ~~a~~ substantial investment and significant marketing efforts. We may never receive regulatory approval for any of our product candidates, which would prevent us from marketing, promoting, or selling any of our product candidates and generating revenue. The successful development of our product candidates will depend on or be affected by numerous factors, including the following: • our successful and timely completion of preclinical studies and clinical trials for which the FDA and any comparable foreign regulatory authorities agree with the design, endpoints, and implementation; • the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials; • the timely receipt of regulatory approvals or authorizations to conduct ~~future~~ clinical trials; • our ability to timely and successfully initiate, enroll patients in, and complete clinical trials; • our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate meets the FDA' s or such comparable foreign regulatory authority' s legal standards with respect to safety, purity, and potency, or efficacy, which may include, among other things, demonstrating that the benefits of the product candidate outweigh its known risks for the intended patient population, and that such product candidate can be manufactured in accordance with applicable legal requirements; • the timely receipt of marketing approvals for our product candidates from applicable regulatory authorities, including the impact of any changes to the FDA' s Accelerated Approval Program; • our ability to address any potential interruptions or delays resulting from external factors, including those related to the current global geo- political, business, and economic environment ~~, including due to the ongoing COVID- 19 pandemic~~ ; • the extent of any clinical or regulatory setbacks experienced by other companies developing similar products or within adjacent fields, including **autologous and** allogeneic cell- based therapies and the fields of gene editing and gene therapy, which could negatively impact the perceptions of the value and risk of our **product candidates and** technologies; • the extent of any ~~required~~ post- marketing approval commitments we may be required to make to applicable regulatory authorities, including the conduct of any post- marketing approval clinical studies, and our ability to comply with any such commitments; and • our ability to establish, scale up, and scale out, either alone or with ~~third- party contract development manufacturing organizations (~~ CDMOs ~~)~~ , manufacturing capabilities for clinical supply of our product candidates for our clinical trials and, if any of our product candidates are approved, commercial supply (including licensure) of such product candidates. If we experience issues ~~with~~ or delays with respect to any one or more of these factors, we could experience significant delays or be unable to successfully develop and commercialize our product candidates, which would materially adversely affect our business, financial condition, and results of operations. We may not realize the benefits of technologies that we have acquired or in- licensed ~~,~~ or will acquire or in- license in the future. A key component of our strategy is to acquire and in- license technologies to support our mission of using engineered cells as medicines. Our ex vivo and in vivo cell engineering technologies represent an aggregation of years of innovation and technology from multiple academic institutions and companies, including hypoimmune technology that we licensed from the President and Fellows of Harvard College (Harvard) and The Regents of the University of California (UCSF), our ex vivo cell engineering program focused on certain brain disorders that we acquired from Oscine Corp., our fusogen technology that we acquired from Cobalt Biomedicine, Inc. (Cobalt), ~~,~~ and gene editing technology that we licensed from Beam Therapeutics Inc., among others. We continue to actively evaluate various acquisition and licensing opportunities on an ongoing basis. The level of success of these acquisition and in- licensing arrangements, including any that we may enter ~~to~~ **into** in the future, will depend on the risks and uncertainties involved, including: • unanticipated liabilities related to acquired companies; • difficulty integrating acquired personnel, technologies, and operations into our existing business; • difficulty retaining key employees, including of any acquired businesses; • diversion of management time and focus from operating our business to management of acquisition and integration efforts; • increases in our expenses and reductions in our cash available for operations and other uses; • higher than expected acquisition or integration costs; • disruption in our relationships with collaborators, key suppliers, manufacturers, or customers as a result of an acquisition; • incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs; • possible write- offs of assets, goodwill or impairment charges, or increased amortization expenses relating to acquired businesses; • difficulty in and cost of combining the operations and personnel of any acquired business with our own; and • challenges integrating acquired businesses into our business, including our existing operations and culture. For example, in ~~November~~ **October** ~~2022~~ **2023** , we underwent a **strategic repositioning pursuant to which we updated our** portfolio ~~prioritization and corporate restructuring designed~~ to **increase** ~~optimize development of our programs at or~~ **our focus on** ~~nearing clinical development, to continue investments in our core research platforms and innovation, and to maintain a strong balance sheet. As part of the restructuring, we halted further investment in~~ our ex vivo cell ~~engineering program~~ **therapy product candidates and reduce our near- term investment in our fusogen platform. As part of this reduction, we shifted our** ~~focused~~ -- **focus** on ~~replacing damaged heart cells (the Cardiac Program), which~~ **fusogen to research activities. We expect to encounter increased costs and difficulties if and when** we ~~had been~~ **expand preclinical** ~~developing~~ **development** ~~since we acquired Cytocardia~~ **and initiate clinical development for product candidates derived from our fusogen platform** , **including those related to scaling up and driving forward clinical development and manufacturing activities** ~~Inc., a privately- held early stage biotechnology company, in November 2019~~ . As a result, **there is increased risk that the benefits** we ~~will~~ **expected from the fusogen platform at the time of the Cobalt acquisition may be more expensive and difficult to obtain or may** not **occur** ~~realize the full extent of the benefits from this program that we anticipated~~ at **all** ~~the time of the acquisition~~ . In addition, foreign acquisitions 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, and regulatory risks associated with specific countries. The occurrence of any of these risks or uncertainties may preclude us from realizing the anticipated benefit of any acquisition, and our financial condition may be harmed. Additionally, we may not be successful in our efforts to acquire or obtain rights to certain technologies or products that are necessary for the success of our product candidates **or technologies** on acceptable terms or at all, including because we may be unable to successfully or timely negotiate the terms of an agreement with the third- party owner of such technology or products or ~~because~~ such third party may have determined to deprioritize such technology or products **. Such transactions, as well as other strategic relationships we may enter into, may also be impacted by policies of or actions by certain regulatory authorities, such as the Federal Trade Commission (FTC), that have jurisdiction over various aspects of such transactions and relationships** . If we are not able to acquire or obtain rights to certain technologies or products on which certain of our product candidates **or technologies** may depend, it may be necessary for us to delay, reduce, or curtail the development of such product candidates **or technologies, or incur additional costs in order to continue development without such rights** . We may fail to enter into new strategic relationships or may not realize the benefits of any strategic relationships that we have entered into, either of which could materially adversely affect our business, financial condition, commercialization prospects, and results of operations. Our product development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. In addition, our ex vivo and in vivo cell engineering platforms are attractive technologies for potential collaborations due to their breadth of application. Therefore, for certain of our product candidates, including product candidates that we may develop in the future, we may decide to form or seek strategic alliances, collaborations, or similar arrangements with pharmaceutical or biotechnology companies that we believe will complement or augment our development and potential commercialization efforts with respect to such product candidates, including in territories outside the United States or for certain indications. We may also pursue joint ventures or investments in complementary businesses that align with our strategy. To the extent we enter into strategic relationships involving companies located outside the United States, we are subject to similar risks to those described elsewhere in these Risk Factors with respect to foreign acquisitions. We face significant competition in seeking appropriate collaborators. Collaborations are complex and time- consuming to negotiate and document. We may not be successful in our efforts to establish a collaboration or other alternative arrangements for our product candidates on acceptable terms or at all, including because our product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view our product candidates as having the requisite potential to demonstrate success in clinical trials and ultimately obtain regulatory approval. Additionally, there have been a significant number of recent business combinations among large pharmaceutical companies that have reduced the number of potential future collaborators and changed the strategies of the resulting combined companies. In addition, under the terms of certain license agreements applicable to our product candidates, we may be restricted from entering into collaboration or similar agreements relating to those product candidates on certain terms or at all. If and when we collaborate with a third party for development and commercialization of a product candidate, we expect that we may have to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration, and the proposed collaborator' s evaluation of our technologies, product candidates, and market opportunities. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and could determine that such other collaboration is more attractive than a collaboration with us for our product candidate. Similar risks exist with respect to any joint ventures we may pursue, as well as risks and uncertainties related to the costs, time, and other resources required to manage and gain the benefit of any such joint venture, and any potential liabilities we may incur in connection with a joint venture. In instances where we enter into collaborations, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects, and financial condition: • collaborators may have significant discretion in determining the efforts and resources that they will apply to a collaboration and may not commit sufficient efforts, funding, and other resources to the development or marketing programs for collaboration product candidates or may misapply those efforts, funding, or resources; • collaborators may experience financial difficulties, including those that could negatively impact their ability to perform their obligations pursuant to the collaboration agreement, such as funding and development obligations; • collaborators may not pursue development and commercialization of collaboration product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results or changes in their strategic focus; • collaborators may decide or may be required by regulatory authorities to delay clinical trials, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing; • we may be required to relinquish important rights to our product candidates, such as marketing, distribution, and intellectual property rights; • we may be required to agree to exclusivity, non- competition, or other terms that restrict our ability to research, develop, or commercialize certain existing or potential future product candidates, including our ability to develop our product candidates in certain indications or geographic regions or combine our product candidates with certain third- party products; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property rights or proprietary information or expose us to potential liability; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • collaborators may acquire outside of the collaboration or develop, independently or in collaboration with third parties, including our competitors, products that compete directly or indirectly with our product candidates and may decide to advance such product candidates instead of ours; • collaborators may own or co- own intellectual property rights covering the product candidates that result from our collaboration, and in such cases, we may not have the exclusive right to commercialize such product candidates; • we and our collaborators may disagree regarding the development plan for a **collaboration** product candidate ~~with respect to which we are collaborating~~ , including, for example, with respect to target indications, inclusion or exclusion criteria for a clinical trial, or the decision to seek approval as front- line therapy versus second-, third-, or fourth- line therapy; • disputes may arise with our collaborators that could result in the delay or termination of the research, development, or commercialization of the applicable product candidates or costly litigation or arbitration that diverts management attention and resources; • business combinations or significant changes in a collaborator' s business strategy may adversely affect our or the collaborator' s willingness to complete our or such collaborator' s obligations under the collaboration; • collaborations may be terminated, which may require us to obtain additional capital to pursue further development or commercialization of the applicable product candidates; or • we may not achieve the revenue, specific net income, or other anticipated benefits that justify our having entered into, or otherwise led us to enter into, the collaboration. If our strategic collaborations do not result in the successful development and commercialization of product candidates, or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. Moreover, our initial estimates of the potential revenue we are eligible to receive under our strategic collaborations may include potential payments related to therapeutic programs for which our collaborators may discontinue development. If we are unable to enter into strategic collaborations, or if any of the other events described in this Risk Factor occur after we enter into a collaboration, we may have to curtail the development of a particular product candidate, reduce or delay the development program for such product candidate or one or more of our other product candidates, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue. Our ability to develop our cell engineering platforms and product candidates and our future growth depend on retaining our key personnel and recruiting additional qualified personnel. Our success depends upon the continued contributions of our key management, scientific, and technical personnel, many of whom have been instrumental for us and have substantial experience with our cell engineering platforms and their underlying technologies and related product candidates. Given the specialized nature of our ex vivo and in vivo cell engineering **technologies** and the fact that we are operating in novel and emerging fields, there is an inherent scarcity of personnel with the requisite experience to fill the roles across our organization. As we continue developing our product candidates and building our pipeline, we will require personnel with medical, scientific, or technical qualifications **and expertise** specific to each program. The loss of key management and senior scientists **or other personnel** could delay our research and development activities. In addition, the loss of key executives could disrupt our operations and our ability to conduct our business. Despite our efforts to retain valuable employees, all of our employees are at- will employees, and members of our management, scientific, and development teams may terminate their employment with us at any time, with or without notice. Moreover, regulations or legislation impacting our workforce, such as the proposed rule published by the ~~Federal Trade Commission (~~ FTC ~~)~~ that would, if issued, generally prohibit employers from imposing non- compete obligations on their employees and require employers to rescind existing non- compete obligations, may lead to increased uncertainty in hiring and competition for talent, and harm our ability to protect our company, including our intellectual property, after termination of employment. If our retention efforts are unsuccessful now or in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business. Further, certain of our key employees, including Drs. Terry Fry and Steve Goldman, retain partial employment at academic institutions. We may in the future have other employees that have similar employment arrangements. These arrangements expose us to the risk that these individuals may return to their academic positions full- time ~~or~~ **,** devote less of their **time or** attention to us than is optimal, ~~and~~ **or** potentially expose us to claims of intellectual property ownership or co-ownership by ~~the~~ **their** respective academic institutions. The competition for qualified personnel in the biotechnology and pharmaceutical industries is intense, and our future success depends upon our ability to attract, retain, and motivate highly skilled employees, including executives, scientists, engineers, clinical operations and manufacturing personnel, and sales professionals. We expect that we may continue to face competition for personnel from other companies, universities, public and private research institutions, and other organizations. We have from time to time experienced, and we expect to continue to experience, difficulty in hiring and retaining qualified employees on acceptable terms, or at all. Many of the companies with which we compete for experienced personnel may have greater resources than we do and may be able to provide prospective job candidates or our existing employees with more attractive roles, salaries, or benefits than we can provide. If we hire employees from competitors or other companies, their former employers may attempt to assert that these employees or we have breached legal obligations, including non- solicitation or non- compete obligations, which may result in a diversion of our time and resources and, potentially, damages. In addition, job candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline or are otherwise viewed unfavorably compared to those of companies with which we compete for talent, or if we or our prospects are otherwise viewed unfavorably, this could negatively impact our ability to recruit, motivate, and retain highly skilled employees. ~~If~~ **As part of our November 2022 and October 2023 restructurings,** we ~~fail~~ **reduced our then- current headcount by approximately 15 % and 29 %, respectively. Reductions in our workforce may result in reduced employee morale and negative publicity, which may damage our reputation and make it more difficult for us** to **retain and motivate our current personnel as well as** attract new personnel **. These workforce reductions have also caused us to lose institutional knowledge, capabilities, and subject matter expertise and could negatively affect** ~~or~~ **our** ~~fail~~ **efforts** to ~~retain~~ **obtain** and ~~motivate~~ **maintain our intellectual property rights in the event we are unable to identify inventions made** ~~our~~ - **or** ~~current personnel,~~ **identify or recreate the necessary scientific records or data. Any of the foregoing could significantly harm** our business and future growth prospects ~~could be harmed~~ . Though many of our personnel have significant experience with respect to manufacturing biopharmaceutical products, we, as a company, do not have experience in developing or maintaining a manufacturing facility. We cannot guarantee that we will be able to maintain a compliant facility and manufacture our product candidates as intended, given the complexity of manufacturing novel therapeutics. If we fail to successfully operate our facility and manufacture a sufficient and compliant supply of our product candidates, our clinical trials and the commercial viability of our product candidates could be adversely affected. The manufacture of biopharmaceutical products is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of gene and cell therapy products often encounter difficulties in production, particularly in scaling up, scaling out, validating initial production, ensuring the absence of contamination, and ensuring process robustness after initial production. These include difficulties with production costs and yields, quality control, including stability of the product, quality assurance testing, operator error, and shortages of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. As a result of the complexities involved in biopharmaceutical manufacturing, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds and the manufacturing process is less reliable and ~~is~~ more difficult to reproduce, and this is particularly true with respect to our product candidates. The application of new regulatory guidelines or parameters, such as those related to control strategy testing, may also adversely affect our ability to manufacture our product candidates in a compliant and cost- effective manner or at all. We continue to invest in building world class capabilities in key areas of manufacturing sciences and operations, including development of our ~~ex vivo and in vivo~~ cell engineering platforms, product characterization, and process analytics. Our investments also include scaled research solutions, scaled infrastructure, and novel technologies to improve efficiency, characterization, and scalability of manufacturing, including establishing our internal manufacturing capabilities. However, we have limited experience in managing the manufacturing processes necessary for making cell and gene therapies. We cannot be sure that the manufacturing processes that we use, or the technologies that we incorporate into these processes, will result in viable or scalable yields of ex vivo and in vivo cell engineering product candidates that will have acceptable safety, purity, and potency, or efficacy **,** profiles and meet market demand. A key part of our strategy is operating our own manufacturing capabilities, including our own manufacturing facilities. In ~~July~~ **June** ~~2021~~ **2022** , we entered into a long- term lease to establish and ~~operate~~ **develop** our own current good manufacturing practices (cGMP) manufacturing facility in ~~Fremont, California (the Fremont facility). In June 2022, we decided to move the site of our planned manufacturing facility from Fremont, California and entered into a long- term lease to establish and develop our cGMP manufacturing facility in~~ Bothell, Washington (the Bothell facility) ~~. We expect to enter into a sublease or terminate the lease for the Fremont facility in 2023. However, we cannot guarantee that we will be able to do so on terms that are acceptable to us, and we may be required to incur additional costs beyond what we currently anticipate. We expect that it will take at least several years before we are able to begin manufacturing our product candidates at the Bothell facility, if we are able to do so at all~~. In addition, in January 2022, we entered into an agreement with the University of Rochester, pursuant to which we have obtained access to manufacturing capabilities within University of Rochester Medical Center’ s (URMC) cell- based manufacturing facility (the URMC site) to support manufacturing of product candidates across our portfolio for early- stage clinical trials. Designing and building out the Bothell facility and the URMC site are time- consuming and require significant resources, including a reallocation of certain of our existing financial, human, and other resources, including the time and attention of our senior management. In addition, given the volatility in the costs of building materials, **as well as the impact of rising rates of inflation in recent years and which may occur in the future,** building out our manufacturing capabilities may be more expensive than we expect. We do not have experience as a company in developing internal manufacturing capabilities, and we may experience unexpected costs or delays or be unsuccessful in developing our internal manufacturing capabilities in time to support registration- enabling clinical trials of our product candidates or at all. In order to build out the Bothell facility and the URMC site, we will need **to continue** to engage third- party service providers and obtain equipment and third- party technology necessary to manufacture our product candidates. However, we may not be able to negotiate agreements with third parties or access necessary technologies on commercially reasonable terms or at all. Moreover, there is no guarantee that the ~~industrial~~ space that we are leasing to develop the Bothell facility will not change ownership over the term of the lease or be subject to additional zoning or other restrictions, and that, in such an event, we will be able to continue to build or operate the facility without restriction or further delay or cost. In addition, operating the Bothell facility and the URMC site will require us to continue to hire and retain experienced scientific, quality control, quality assurance, and manufacturing personnel. As described elsewhere in these Risk Factors, this may be difficult given the intense competition for qualified personnel in the biotechnology and pharmaceutical industries. In addition, though we plan to design and build out our manufacturing capacities at the URMC site, we do not control URMC’ s cell- based manufacturing facility, nor do we have control over how URMC manages and operates this facility. If URMC does not maintain its cell- based manufacturing facility in accordance with our requirements, we may not be able to manufacture our product candidates in a timely manner or at all, which may delay our ability to commence clinical trials for, obtain regulatory approval for, and commercialize our product candidates. **We currently rely** ~~Until we are able to begin manufacturing our product candidates internally~~ , **and expect** we will **continue to** rely **,** on CDMOs to manufacture our product candidates for preclinical studies and clinical trials. Moreover, ~~given our decision to move the site of our planned manufacturing facility from the Fremont facility to the Bothell facility,~~ it may take us longer to establish and operationalize our Bothell facility than we originally anticipated, which may delay our ability to begin manufacturing certain of our product candidates internally and extend the period of time during which we must **solely** rely on CDMOs for the manufacture of such product candidates. For example, we may rely on our CDMOs for the potential registration and commercial launch of our first product candidate under our current clinical development timelines, and if there are any delays in our ability to establish and operationalize the Bothell facility, we may be required to rely **more heavily** on our CDMOs for the potential registrations and commercial launches of additional product candidates as well. Once we have completed the build- out of the Bothell facility and the URMC site, we may be required to transition manufacturing processes and know- how ~~of~~ **for** certain of our product candidates from our CDMOs to the Bothell facility and **the** URMC site. To date, we and our CDMOs have limited experience in the technology transfer of manufacturing processes. 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 the Bothell facility and the URMC site may require utilization of new or different processes to meet our facility requirements. Additional studies may also need to be conducted to support the transfer of certain manufacturing processes and process improvements. We will not know with certainty whether all relevant know- how and data ~~has~~ **have** been adequately incorporated into the manufacturing process being conducted at our facilities until the completion of studies and evaluations intended to demonstrate the comparability of material previously produced by our CDMOs with that generated by our facilities **. Similar risks and considerations apply to the initial technology transfer from us to our CDMOs for manufacturing of pre- clinical and clinical supply, as well as between CDMOs in the event we are required to switch to a new CDMO** . Operating the Bothell facility and the URMC site will require us to comply with complex regulations. Moreover, the Bothell facility, and any future commercial manufacturing facilities we may operate, will require FDA or comparable foreign regulatory authority approval, which we may not obtain in time to support registration- enabling clinical trials for our product candidates, if at all. Even if approved, we would be subject to ongoing periodic unannounced inspections by the FDA, the Drug Enforcement Administration, corresponding state agencies, and comparable foreign regulatory authorities to ensure strict compliance with cGMP, current good tissue practices (cGTPs), and other government regulations. We may be unable to manufacture our product candidates if we fail to meet regulatory requirements and may be unable to scale up or scale out our manufacturing to meet market demand. Any failure or delay in the development of our manufacturing capabilities, including at the Bothell facility and the URMC site, could adversely impact the development and potential commercialization of our product candidates. We may encounter difficulties in managing our growth **if and** as we expand **our operations, including** our development and regulatory capabilities, which could disrupt our operations **and otherwise harm our business** . We experienced rapid growth following our inception in July 2018. However, as **described elsewhere in these Risk Factors, we undertook workforce reductions as** part of our November 2022 **and October 2023** ~~restructuring~~ **restructurings** ~~, we reduced our headcount by approximately 15 % by the end of 2022 in order to optimize development of our programs at or nearing clinical development, to continue investments in our core research platforms and innovation, and to maintain a strong balance sheet~~ . ~~As of December 31, 2022, we had 418 full- time employees and three part- time employees. The~~ **These** ~~restructuring and associated~~ workforce ~~reduction~~ **reductions** may yield unintended consequences and costs, including difficulty retaining and motivating remaining employees ~~and~~ **,** difficulty attracting and hiring qualified employees **, and increased reliance on third parties if needed to support our internal capabilities** . Despite our workforce ~~reduction~~ **reductions , if we have success** in ~~connection with the restructuring~~ **our initial clinical trials** , we expect continued growth in the scope of our operations, particularly **if and** as we advance our product candidates into **and through** IND- enabling studies and clinical trials and continue to establish **and develop our** regulatory, quality, and clinical operations and supply chain logistics and manufacturing. To manage our growth, we have implemented and improved, and plan to continue to implement and improve, our managerial, operational, and financial systems, and continue to recruit and train additional qualified personnel. However, due to our limited financial resources and the complexity **of** ~~involved in~~ managing a company with such growth, we may not be able to effectively manage the expansion of our operations or recruit and train **sufficient** additional qualified personnel **to achieve our business objectives within our desired timelines** . The continued expansion of our operations will be costly and may divert our management and business development resources. For example, members of management will have significant added responsibilities in connection with effecting and managing our growth, including identifying, recruiting, integrating, maintaining, and motivating current and future employees, effectively managing our internal development efforts, including the clinical and regulatory (e. g., FDA) review process, while complying with our contractual obligations to third parties, and maintaining and improving our operational, financial, and management controls, reporting systems, and procedures. In addition, as we grow, we may be required to rely more heavily on third- party service providers, which exposes us to risks to which we would not be subject if we performed all work internally, as described elsewhere in these Risk Factors. Our inability to successfully manage our growth could **disrupt our operations and otherwise harm our business, including by** ~~delay~~ **delaying** ~~the~~ execution of our **programs and** business plans ~~or disrupt our operations~~ . We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms, and product candidates that we identify for specific indications. Additionally, we have contractual commitments under certain of our agreements to use commercially reasonable efforts to develop certain programs and, thus, do not have unilateral discretion to vary from such efforts. In addition, we have contractual commitments to conduct certain development plans, and thus may not have discretion to modify such development plans, including clinical trial designs, without agreement from our partners. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. **Additionally, we may be required to invest our resources in a limited number of more advanced programs with higher probabilities of success in the shorter term and, consequently, to reduce our investment in promising earlier stage programs. Such decisions would require us to reduce the breadth and diversity of our product portfolio, which could potentially limit the long- term growth of our pipeline and subject us to greater risk that the failure of any such programs would harm our prospects.** Our spending on current and future research and development programs, therapeutic platforms, and product candidates for specific indications may not yield any commercially viable products ~~. For example, as described elsewhere in these Risk Factors, our prior investments in the Cardiac Program may not result in any commercial products or future sales revenue~~ . If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing, or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights. The use of human stem cells exposes us to a number of risks in the development of our human stem cell- derived products, including inability to obtain suitable donor material from eligible and qualified human donors, restrictions on the use of human stem cells, as well as the ethical, legal, and social implications of research on the use of stem cells, any of which could prevent us from completing the development of or commercializing and gaining acceptance for our products derived from human stem cells. We use human stem cells in our research and development, including induced PSCs (iPSCs) and embryonic stem cells (ESCs), and one or more of our ex vivo cell engineering product candidates may be derived from human stem cells. The use of such cells in our research, or as starting cell lines in the manufacture of one or more of our product candidates, exposes us to numerous risks. These risks include difficulties in securing **viable, appropriate, and** sufficient ~~and viable~~ stem cells as starting material, recruiting patients for our ~~future~~ clinical trials, as well as managing a multitude of **global** legal and regulatory restrictions on the sourcing and use of these cells. **For example, to the extent regulatory requirements differ across jurisdictions, we may face increased difficulty finding cells that meet all applicable jurisdictional requirements, or may be required to develop our product candidates using multiple different types of cells, which could increase the complexity and cost of development.** In ~~particular~~ **addition, certain cells may be subject to restrictions regarding the patient populations in which the resulting products can be used, which could limit the applicability and value of our product candidates. Further** , in some states, use of embryonic tissue as a source of stem cells is prohibited and many research institutions have adopted policies regarding the ethical use of human embryonic tissue. If these **regulations,** policies **,** or restrictions have the effect of limiting the scope of research **or other activities** we can conduct using stem cells, our ability to develop our ex vivo cell engineering product candidates may be significantly impaired, which could have a material adverse effect on our business. ~~Further~~ **Additionally** , the use of stem cells generally, and ESCs, in particular, has social, legal, and ethical implications. Certain political and religious groups continue to voice opposition to the use of human stem cells in drug research, development, and manufacturing. Adverse publicity due to ethical and social controversies surrounding the use of stem cells could lead to negative public opinion, difficulties enrolling patients in our clinical trials, increased regulation, and stricter policies regarding the use of such cells, which could harm our business and may limit market acceptance of any of our product candidates that may receive regulatory approval. In addition, clinical experience with stem cells, including iPSCs and ESCs, is limited. We are not aware of any products utilizing iPSCs or ESCs as a starting material that have received marketing approval from the FDA or a comparable foreign regulatory authority. Therefore, patients in our clinical trials may experience unexpected side effects, and we may experience unexpected regulatory delays prior to or, if approval were to be granted, after regulatory approval. Furthermore, manufacturing and development of our ex vivo stem cell- derived and allogeneic T cell- derived product candidates will require that we obtain suitable donor material from eligible and qualified human donors. If we are unable to obtain sufficient quantities of suitable donor material, or if we are unable to obtain such material in a timely manner, we may experience delays in manufacturing our ex vivo product candidates, which would harm our ability to conduct ~~future~~ clinical trials for or to commercialize these product candidates. Moreover, if the consent, authorization, or process for the donation **and use** of those materials is not obtained or conducted in accordance with applicable legal, ethical, and regulatory requirements, we could face delays in the clinical testing and approval of these product candidates, or, potentially, we could face claims by such human donors **or regulatory authorities** , which could expose us to damages and reputational harm. Negative public opinion and increased regulatory scrutiny of research and therapies involving gene editing or other ex vivo or in vivo cell engineering technologies may damage public perception of our product candidates or adversely affect our ability to conduct our business or obtain regulatory approvals for our product candidates. Certain aspects of our cell engineering platforms rely on the ability to modify the genome, including by editing genes. Public perception may be influenced by claims that genome modification is unsafe, and products using or incorporating genome modification may not gain the acceptance of the public or the medical community. **Similarly, general perceptions of products relying on ex vivo or in vivo cell engineering techniques may be impacted by developments across the pharmaceutical and biotechnology industries, including those affecting or related to other companies, including those developing products that are similar or within adjacent fields or that are being developed in the same indications.** Negative perceptions of genome modification, including gene editing **, or of cell or gene therapy products generally** , may result in fewer physicians being willing to enroll patients into clinical trials of our product candidates or prescribing our treatments, ~~or may~~ reduce the willingness of patients to participate in clinical trials of our product candidates or use our treatments **, or otherwise negatively impact the development of our product candidates** . In addition, given the novel nature of ex vivo and in vivo cell engineering technologies, governments may impose import, export, or other restrictions in order to retain control or limit the use of such technologies. Further, in order to further understand the risks of novel genome modification technologies, regulatory authorities may require us to provide additional data prior to allowing clinical testing or commercialization of product candidates that use such technologies, which may cause us to incur additional costs and delay our development plans for certain of our product candidates. Increased scrutiny, negative public opinion, more restrictive government regulations, or enhanced governmental requirements, either in the United States or internationally, would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of our product candidates or demand for such product candidates ~~. The ongoing COVID- 19 pandemic, or another pandemic, epidemic, or infectious disease outbreak in the United States or worldwide, could materially and adversely affect our preclinical studies and development, our manufacturing capabilities, any clinical trials we may commence, and our business, financial condition, and results of operations. As a result of the COVID- 19 pandemic, or another pandemic, epidemic, or infectious disease outbreak, and related " shelter in place " orders and other public health guidance measures, we have experienced and may in the future experience disruptions that could materially and adversely impact our preclinical studies and development, any clinical trials we may commence, and our business, financial condition, and results of operations. In response to the spread of COVID- 19, beginning in early 2020, we limited operations in our executive offices, with our administrative employees primarily working outside of our offices, and took other precautionary measures, including the periodic testing of our on- site employees and limiting employee travel. Since the initial onset of the COVID- 19 pandemic, consistent with the lifting of certain government orders and guidance, our staff have begun working in the offices more frequently, but many of our administrative employees continue to work outside of our offices on at least a part- time basis. We continue to monitor the effects of COVID- 19 variants and subvariants, along with other infectious disease outbreaks, to assess the safety considerations associated with our employees working onsite and engaging in work- related travel. With the return of employees to our offices, we face an increased productivity risk arising from the potential that they will be exposed to COVID- 19 or other infectious diseases while onsite and will need to take time away from work to recover from any resulting illness. In addition, we require, with limited exceptions, all of our employees to be vaccinated against COVID- 19, which may negatively impact our recruiting and retention efforts. Potential disruptions to our preclinical development efforts resulting from the ongoing COVID- 19 pandemic may include the following: • delays or disruptions in~~

~~preclinical experiments and IND- enabling studies, including due to unforeseen circumstances at our CROs and vendors; • limitations on employee or other resources that would otherwise be focused on the conduct of our preclinical activities, including because of illness of employees or their families; and • delays in necessary interactions with regulatory authorities, ethics committees, and other important agencies and contractors, including due to limitations in employee resources. In addition, we have experienced, and we and our service providers or vendors may continue to experience, delays in the procurement of, or an inability to procure, certain laboratory supplies required for the conduct of our research and preclinical activities, such as cell culture plasticware and single use containers, as a result of factors related to the ongoing COVID- 19 pandemic. The ongoing COVID- 19 pandemic may also adversely affect our manufacturing capabilities. For example, we may experience delays or otherwise experience difficulties in building out and operationalizing the Bothell facility or the URMC site and obtaining key materials, consumables, and equipment necessary to manufacture our product candidates. In addition, if and when we commence clinical trials for any of our product candidates, we may experience delays or disruptions of clinical trial- related activities as a result of the ongoing COVID- 19 pandemic or another pandemic, epidemic, or infectious disease outbreak, including as a result of the following: • interruption of key clinical trial activities, such as clinical trial site data monitoring, efficacy, safety, and translational data collection, processing, and analyses. and clinical trial subject visits, due to limitations on travel imposed or recommended by federal, state, or local governments, employers, and others, which may impact the collection and integrity of the resulting clinical trial data and study endpoints; • delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and staff, and enrolling and retaining patients in our clinical trials; • increased rates of patient withdrawal from our clinical trials following enrollment as a result of contracting COVID- 19 or another disease, developing other health conditions, or being forced to quarantine; • interruption of, or delays in receiving, supplies of our product candidates from our CDMOs due to staffing shortages, production slowdowns, or stoppages and disruptions in delivery systems with respect to materials and reagents; • diversion of healthcare resources away from the conduct of our clinical trials toward efforts to support the COVID- 19 pandemic or other pandemic, epidemic, or infectious disease response, including the diversion of resources, including staff, at hospitals serving as our clinical trial sites and supporting our clinical trials; • interruption or delays in the operations of the FDA and comparable foreign regulatory agencies, including delays in receiving approval to initiate our planned clinical trials; • changes in regulations implemented in response to any pandemic, epidemic, or other outbreak that may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; • limitations on employee resources that would otherwise be focused on the conduct of our clinical trial- related activities, including because of illness of employees or their families or the desire of employees to avoid contact with large groups of people; and • additional delays, difficulties, or interruptions as a result of current or future shutdowns or other restrictions imposed in countries where we or our service providers operate. The COVID- 19 global pandemic continues to evolve, and the extent to which it and any other pandemic, epidemic, or other outbreak may affect our preclinical studies, future clinical trials, business, financial condition, and results of operations will depend on future developments, which continue to be highly uncertain and unpredictable and present material uncertainty and risk to our business~~ . Risks Related to the Development and Clinical Testing of Our Product Candidates We must successfully progress our product candidates through extensive preclinical studies and clinical trials in order to obtain regulatory approval to market and sell such product candidates. Even if we obtain positive results in preclinical studies of a product candidate, these results may not be predictive of the results of future preclinical studies or clinical trials. Before an ~~Investigational New Drug application (~~ IND ~~)~~ or comparable foreign submission can be submitted to the FDA or **a** comparable foreign regulatory authority and be cleared or otherwise become effective, which is a prerequisite for conducting clinical trials on human subjects, a product candidate must successfully progress through extensive preclinical studies, which include preclinical laboratory testing, animal studies, and formulation studies conducted in accordance with good laboratory practices ~~(GLP)~~ . In addition, to obtain the requisite regulatory approvals to ultimately market and sell any of our product candidates, we or any future collaborator for such product candidate must satisfy the FDA' s or a ~~comparably~~ **comparable** foreign regulatory authority' s legal standards with respect to safety, purity, and potency, or efficacy, which may include, among other things, demonstrating through adequate and well- controlled clinical trials that the benefits of the product candidate outweigh its known risks for the intended patient population. Preclinical and clinical testing is inherently unpredictable. We may obtain positive data from early research involving our product candidates but subsequently encounter unexpected or unexplained results in preclinical or clinical studies that may cause such product candidates to be unsuitable for further development. We may also need to perform additional research and preclinical or clinical studies for various reasons, including to determine the cause of any unexpected results, including whether such results were caused by our product candidates or other factors, which could delay our development timelines or prevent us from continuing further development at all. Even if we obtain positive results from preclinical or clinical studies of our product candidates, success in preclinical or clinical studies does not ensure that later preclinical studies or clinical trials will be successful. A number of biotechnology and pharmaceutical companies have suffered significant setbacks in clinical trials, even after positive results in **earlier** preclinical or clinical studies, such as adverse findings observed while clinical trials were underway or safety or efficacy observations during clinical trials, including previously unreported adverse events, and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results have the potential to support approval of a product, and flaws in a clinical trial' s design may not become apparent until the clinical trial is well advanced. In addition, the results of our preclinical animal studies, including our non- human primate **(NHP)** studies, may not be predictive of the results of subsequent clinical trials ~~on~~ **involving** human subjects. Product candidates may fail to show the desired pharmacological properties or safety and efficacy traits in clinical trials despite having successfully progressed through preclinical studies **or earlier clinical trials** . If we fail to obtain positive results in preclinical studies or clinical trials of any product candidate, the development timeline and regulatory approval and commercialization prospects for that product candidate, and, correspondingly, our business and financial prospects, would be negatively impacted. Preclinical **testing of** ~~and clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If preclinical studies or~~ **our product candidates may be delayed or otherwise unsuccessful, which would harm our ability to commence and successfully complete** clinical trials of ~~any of our~~ **, and ultimately commercialize, such** product candidates are prolonged or delayed, we may...... future clinical trials may not be successful . Applicable laws and regulations require us to ~~test~~ **conduct preclinical testing of** our product candidates in animals before initiating clinical trials involving humans **, and the results and timing of such testing are uncertain** . We may experience delays in or difficulty completing studies of our product candidates in animals for various reasons. For example, due to global supply chain issues caused by global geo- political, economic, and other factors beyond our control, as described elsewhere in these Risk Factors, we have experienced and may continue to experience difficulty **and increased costs** in accessing animal models, specifically **certain NHP** ~~non- human primate~~ models, which could delay completion of our preclinical studies involving such models **or harm our ability to conduct or complete such studies at all, and could limit the potential patient population for our product candidates** . In addition, animal testing has been the subject of controversy and adverse publicity. Animal rights groups and others have attempted to stop animal testing by pressing for legislation and regulation and by disrupting such testing through protests and other means. To the extent these attempts are successful, our research and development activities may be interrupted or delayed, become more expensive, or both. We are required to submit an IND or comparable foreign submission to the FDA or comparable foreign regulatory authorities with respect to each product candidate prior to commencing a clinical trial for such product candidate in the applicable jurisdiction. ~~In December 2022, we submitted our first IND to the FDA for our ex vivo allogeneic CD19- directed CAR T cell product candidate, which was allowed to proceed in January 2023.~~ Although we expect our pipeline to yield ~~multiple~~ **additional** INDs and plan to submit INDs for each of our product candidates, we may not be able to submit future INDs in accordance with our expected timelines for various reasons, including due to: • manufacturing **challenges or** delays, including due to challenges associated with scaling up our manufacturing processes and developing and validating assays **or otherwise meeting applicable regulatory requirements** ; • delays in our IND- enabling preclinical studies; or • feedback from the FDA that requires us to conduct additional testing or change the design of a planned clinical trial prior to submitting such IND. Moreover, we cannot guarantee that submission of an IND or comparable foreign submission for a product candidate will result in the FDA or comparable foreign regulatory authorities allowing clinical trials of that product candidate to commence in accordance with our timelines or expectations or at all, or that, once begun, issues will not arise that require suspension or termination of such clinical trials. For example, the FDA **or a comparable foreign regulatory authority** may accept an IND **or comparable foreign** submission for a product candidate but place clinical trials of such product candidate on hold pending the results of additional testing or the development of additional assays **, or may otherwise refuse or terminate the applicable submission. Further, because legal and regulatory requirements for conducting clinical trials vary across jurisdictions, our receipt of authorization to conduct clinical trials in one jurisdiction does not guarantee such authorization will be granted in other jurisdictions. In addition, such legal and regulatory requirements may change over time, including in a manner that could cause us to incur delays or additional expense in order to comply. For example, the regulatory landscape related to clinical trials in the European Union (EU) continues to evolve. The EU Clinical Trials Regulation (CTR), which was adopted in April 2014 and repealed the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike the EU Clinical Trials Directive, which required a separate clinical trial application (CTA) to be submitted to both the competent national health authority and an independent ethics committee in each EU member state in which the clinical trial will be conducted, the CTR provides for a centralized process. The CTR allows sponsors for multi- center trials to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The CTA assessment procedure has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. The decision of each EU member state is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical studies may proceed. The CTR foresees a three- year transition period. Compliance with the CTR requirements by us and our service providers, such as CROs, may impact our development plans. For example, because the CTR requires coordination of application review and processing across multiple member states, our ability to commence clinical trials in accordance with our timelines could be delayed. Further, as discussed elsewhere in these Risk Factors, the United Kingdom (UK) withdrew from the EU in 2020, and uncertainty remains as to whether and to what extent certain UK laws and regulations will be aligned with those of the EU, including the CTR, which does not apply in the UK. Local requirements in the UK and the EU have diverged and may further diverge in the future, which could impact any UK clinical and development activities we may conduct. In addition, clinical trial submissions in the UK must be separate from those submitted to EU member states, adding further complexity, cost, and potential risk to any clinical and development activity in the UK. If we are unable to satisfy applicable legal or regulatory requirements for an IND or comparable foreign submission, or experience delays in doing so, clinical development of our product candidates may be delayed or we may be unable to execute clinical trials of the applicable product candidate in the relevant jurisdiction. For example, we may decide not to submit an IND or comparable foreign submission in certain jurisdictions due to applicable legal or regulatory requirements in such jurisdiction, including based on future changes to such requirements** . Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or a comparable foreign submission, we cannot guarantee that such regulatory authorities will not change their requirements in the future, which could require us to make costly changes to and delay the conduct of our clinical trials or require suspension or termination of such trials entirely. In addition, ~~since~~ **because** the manufacturing of our product candidates, including our ex vivo CAR T cell product candidates, is in its early stages and continues to evolve, we expect that manufacturing- related matters such as chemistry, manufacturing, and controls, including product specifications, will **continue to** be a focus of regulatory review of our INDs or comparable foreign submissions, which may delay ~~allowance~~ **our ability** to proceed with the relevant clinical trials. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or comparable foreign submissions. ~~To date, we have not commenced~~ **Clinical drug development is a lengthy and expensive process with uncertain timelines and outcomes. If clinical trials of** any **of our product candidates** are prolonged or delayed **,or need to be terminated** ,we may be unable to obtain required regulatory approvals and commercialize such product candidates on a timely basis or at all. ~~Preclinical studies and clinical~~ **Clinical** trials are expensive, **complex,and** can take many years to complete,and their outcomes are inherently uncertain and their data subject to varying interpretations and analyses ~~.Failure can occur at any time during preclinical or clinical development~~ .Product candidates in later- stage clinical trials may fail to produce the same results as observed in earlier trials or fail to show the desired safety and efficacy characteristics despite having progressed through preclinical studies **and earlier** clinical trials. We do not know whether ~~planned~~ **our current or future** clinical trials will begin on time, need to be redesigned, enroll patients on time, or be completed on schedule, if at all. Clinical trials may be delayed, suspended, or terminated, or may not be able to be conducted at all, for a variety of reasons, including the following: • delays in or failure to obtain regulatory authorization to commence a trial; • delays in or failure to obtain institutional review board (IRB) or ethics committee (EC) approval ~~at~~ **for** each clinical trial site; • delays in or failure to reach agreement with prospective ~~clinical research organizations (~~ CROs ~~)~~ and **other service providers,** clinical trial sites **, or companion diagnostic development partners** on acceptable terms, or at all ~~, which agreements can be subject to extensive negotiation and may vary significantly among different CROs and trial sites~~ ; • difficulty in recruiting clinical trial investigators **or clinical trial sites** of appropriate competencies and experience **, including due to pre- existing commitments or resource and other infrastructure constraints, including resource allocation to other clinical trials, such as those of our competitors** ; • **delays in or inability to timely manufacture sufficient quantities of a product candidate for use in clinical trials, including due to** lack of sufficient availability of suitable donor material from eligible and qualified donors for the manufacture of ~~product candidates from~~ our ex vivo cell engineering ~~platform~~ **product candidates; • failure of a product candidate to meet acceptable quality or stability standards, or failure to manufacture product candidates in accordance with cGMP and other applicable laws, regulations, and guidelines** ; • delays in establishing the appropriate dosage levels in clinical trials; • delays in or inability to recruit ~~and~~ **,** enroll **, and retain** suitable patients ~~to participate~~ in a trial, ~~including~~ as **discussed elsewhere in** ~~a result of study inclusion and exclusion criteria, patients' prior lines of therapy and treatment, competition with other sponsors' clinical trials, and the~~ **these Risk Factors** ~~availability of other approved therapies; • the difficulty in certain countries in identifying the sub- populations that are the target group for a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results; • lower than anticipated retention rates of patients in clinical trials~~ ; • failure of patients to complete a trial or return for post- treatment follow- up; • **difficulty in identifying the sub- populations that are the target group for a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results; •** clinical sites deviating from trial protocol or dropping out of a trial; • delays caused by the addition of new investigators or clinical trial **sites or replacement of existing investigators or** sites; • safety, efficacy, or other concerns arising out of investigator- sponsored clinical trials (ISTs) involving our product candidates or technologies; • safety or tolerability concerns relating to the product candidate being tested that could cause us or governmental authorities, as applicable, to suspend or terminate a clinical trial or **program or** impose a clinical hold, including if participants are being exposed to unacceptable health or safety risks or experiencing undesirable side effects ~~or~~ **,** there are other unfavorable characteristics of the product candidate, or **regulators deem** ~~if there is evidence that our or~~ **our** ~~third- party~~ product ~~candidates~~ - **candidate** ~~,~~ **to have the potential** ~~or~~ **for comparable** ~~third- party products, are associated with~~ undesirable side effects or risks ~~and regulators deem our~~ **to those of other** product ~~candidate~~ **candidates** ~~to have~~ **, including** ~~the~~ **those** ~~potential~~ **under development by us** ~~for~~ - **or third parties,** ~~comparable side effects or risks~~ due to **compositional,** biologic, mechanistic, sourcing, or other similarities; • the failure of third- party contractors to comply with regulatory requirements or meet their contractual obligations in a timely manner or at all; • changes in regulatory requirements, policies, and guidelines; • ~~inability to manufacture sufficient quantities of a product candidate for use in clinical trials; • the quality or stability of a product candidate falling below acceptable standards, or failure to manufacture product candidates in accordance with cGMP and other applicable laws, regulations, and guidelines; •~~ changes in the treatment landscape for our target indications that **may make it more difficult to initiate or recruit patients for our clinical trials in certain jurisdictions or** may make our product candidates no longer relevant; • claims that the product candidate being tested infringes third- party intellectual property rights, including any resulting injunctions that may prevent further use of such product candidates and interfere with the progress of the trial; and • business interruptions resulting from geo- political actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and fires, or disease ~~, including the ongoing COVID- 19 pandemic~~ . Clinical trials must be conducted in accordance with the FDA' s and comparable foreign regulatory authorities' legal requirements, regulations, and guidelines and are subject to oversight by these governmental authorities and IRBs or ECs of the medical institutions where the clinical trials are conducted. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or ECs of the institutions at which such trial is being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial, or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination, including following an inspection of clinical trial operations or a clinical trial site, for various reasons, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from use of the product candidate being tested, or changes in governmental regulations or administrative actions. **In addition, the complexity and novelty of certain product candidates, the clinical trial design, and the indications for which such product candidates are being developed, as well as the combination of these factors, could negatively affect our ability to successfully execute and complete clinical trials of such product candidates in accordance with our timelines. For**

example, clinical trials involving certain indications, such as autoimmune diseases, may require the involvement and alignment of medical professionals across various specialties. Additionally, we may evaluate certain of our product candidates in multiple indications, including in oncology and B- cell- mediated autoimmune diseases, and across a broad range of diseases in a single clinical trial. Because these diseases can vary significantly, doing so may introduce additional complexities and challenges with executing our clinical trials, any of which could increase the time and expense required to commence and complete the applicable trial. Further, to the extent we develop our product candidates for multiple indications, the occurrence of any potential safety issues or significant side effects with respect to a particular indication or study could negatively affect the development of such product candidate in all indications. We and third parties involved in our clinical trials may not have sufficient resources to adequately address such complexities in accordance with our timelines or at all. If we experience delays in completing, or are required to terminate, any clinical trial of our product candidates, the commercial prospects of the relevant product candidates will be harmed, and our ability to generate product revenues from these product candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, delay our ability to obtain regulatory approval for the relevant product candidate, and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our product candidates, which may impair our ability to commercialize our product candidates and harm our business and results of operations. Furthermore, as described elsewhere in these Risk Factors, we **rely and** will **continue to** rely on third parties that are responsible for executing or supporting our clinical trials, such as CROs and clinical trial sites, including principal investigators, and to the extent they fail to timely and properly perform their obligations, we may experience program delays, incur additional costs, or both, which may harm our business. In addition, we may experience delays and incur additional costs with respect to clinical trials that we conduct in countries outside the United States, including as a result of increased shipment and distribution costs, compliance with additional regulatory requirements, and the engagement of non- United States- based CROs, and may also be exposed to risks associated with clinical investigators who are unknown to the FDA, and different standards of diagnosis, screening, and medical care. We will depend on timely and successful enrollment and retention of patients in our clinical trials for our product candidates. If we experience delays or difficulties enrolling or retaining patients in our clinical trials, our research and development efforts and business, financial condition, and results of operations could be materially adversely affected. Successful and timely initiation and completion of clinical trials will require that we **timely** enroll and retain a sufficient number of patients. Any clinical trials we conduct may be subject to delays for a variety of reasons, including as a result of patient enrollment taking longer than anticipated, patient withdrawal, or the occurrence of adverse events. These types of developments could cause us to delay the trial or halt further development of the relevant product candidate. ~~Our~~ **,** including:• the size and nature of the patient population;• the severity of the disease under investigation ~~,including patients' prior lines of therapy and treatment~~ ;• eligibility and exclusion criteria for the trial;• the number and location of clinical trial sites;• the proximity of patients to clinical sites;• the design of the clinical protocol;• the ability to obtain and maintain patient consents;• competition with other **companies** ~~sponsors or clinical trials~~ for clinical trial sites or patients;• the perceived risks and benefits of the product candidate under evaluation;• the ability to recruit ~~and availability of~~ clinical trial investigators ~~and sites~~ with the appropriate competencies and experience;• the risk that enrolled patients will drop out of the trial before administration of the product candidate or trial completion;• the availability of ~~patients resulting from~~ **competing clinical trials;•** the ~~impact~~ **availability** of **patients during the ongoing COVID- 19 pandemic or** any **other** pandemic,epidemic,or disease outbreak;• the availability of,and clinicians' and patients' satisfaction with,existing and new drugs approved for the indication the clinical trial is investigating;and • clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies,including any new therapies that may be approved for the indications the clinical trial is investigating or the approved label expansion of an existing therapy into the indication the clinical trial **is investigating.These factors** clinical trials will compete with other clinical trials that are in the same therapeutic areas as our product candidates. In addition, because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct at least some of our clinical trials at the same sites as those used by our competitors. ~~This competition~~ **Competition with other clinical trials** may reduce the number and types of patients available to participate in our trials, as 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. Moreover, enrolling patients in clinical trials for diseases ~~in~~ **for** which there is an approved standard of care is challenging, as patients will first receive the applicable standard of care, and many patients who respond positively to the standard of care do not enroll in clinical trials. **In addition, although patients who fail to respond positively to the standard of care treatment may be eligible for clinical trials of our product candidates, treatment with prior regimens may render our product candidates less effective in clinical trials.** As a result, the number of eligible patients who have the potential to benefit from our product candidates could be limited, which could extend development timelines or increase costs for our programs. **The circumstances described above and elsewhere in** ~~In addition, although patients who fail to respond positively to the~~ **these Risk** ~~standard of care treatment may be eligible for clinical trials of our product candidates, treatment with prior regimens may render our product candidates less effective in clinical trials. Patient enrollment in clinical trials depends on many factors~~ **Factors** , including: • the size and...... clinical trial is investigating. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost- effective manner. If we are unable to timely recruit and enroll patients for our clinical trials, enroll a sufficient number of patients to complete our clinical trials as planned, or retain patients in our clinical trials, we may be required to change our trial design, recruit and enroll a different population of patients than we anticipated, or recruit and enroll patients in geographies that are more challenging. We may not be fully prepared to address such challenges, and even if we are able to address such challenges, the results of our clinical trials may be negatively impacted. Delays in the completion of any clinical trial we may conduct will increase our costs, slow down the development and approval process, and delay or potentially jeopardize our ability to commence product sales and generate revenue for the relevant product candidate. In addition, some of the factors that may 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. ~~Future clinical~~ **Clinical** trials may fail to demonstrate that our product candidates, including any future product candidates, or technologies used in or used to develop such product candidates, meet the FDA' s or a comparable foreign regulatory authority' s requirements with respect to safety, purity, and potency, or efficacy, which would prevent, delay, or limit the scope of regulatory approval and commercialization of such product candidates. To obtain the requisite regulatory approvals to market and sell any of our **current or** ~~product candidates and any other~~ future product candidates, we or our potential future collaborators must demonstrate with substantial evidence from adequate and well- controlled clinical trials of the product candidate, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidate meets the FDA' s or such comparable foreign regulatory authorities' legal standards with respect to safety, purity, and potency, or efficacy, which may include, among other things, demonstrating through adequate and well- controlled clinical trials that the benefits of the product candidate outweigh its known risks for the intended patient population. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical development process. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful. Clinical trials of our product candidates or product candidates developed using our technologies (including those conducted by third parties, **such as** in the case of ISTs) may not demonstrate that such product candidates or technologies have efficacy and safety profiles necessary to support regulatory approval. Safety or efficacy results for a particular clinical trial, or between different clinical trials of the same product candidate, can vary significantly due to numerous factors, including differences in the size and type of the patient populations, variety of patients and disease types within a trial, changes in and adherence to the clinical trial protocols and trial procedures, and the rate of dropout among clinical trial participants. If the results of clinical trials are inconclusive with respect to the efficacy of our product candidates or those developed using our technologies, 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 or technologies, we may experience delays in obtaining marketing approval, or we may not obtain approval at all. Additionally, any safety concerns observed in any clinical trial of one of our product candidates, or those developed using our technologies, in our targeted indications could limit the prospects for regulatory approval of such product candidate in those and other indications or the prospects of other product candidates we may develop that are perceived to have the potential for similar safety concerns. Additionally, some of our trials may be open- label trials in which the patient and / or investigator know whether the patient is receiving the investigational product candidate. Data generated from open- label clinical trials may exaggerate any therapeutic effect, as patients and / or investigators are aware when a patient has received the experimental treatment, which may cause investigators to interpret the information of the treated group more favorably. Therefore, positive results observed in open- label trials may not be replicated in later controlled trials. Even if we or our collaborators (or other third parties, in the case of ISTs) successfully complete any future clinical trials, clinical data are often susceptible to varying interpretations and analyses. We cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. Even if positive results are observed in clinical trials, we cannot guarantee that the FDA or comparable foreign regulatory authorities will view our product candidates as having efficacy. Further, the FDA or comparable foreign regulatory authorities may not agree with our manufacturing strategy or may not find comparability between our clinical trial product candidates and proposed commercial product candidates, which may result in regulatory delays or a need to perform additional clinical studies. Moreover, clinical trial results that may be acceptable to support approval of a certain scope in one jurisdiction may be deemed inadequate to support regulatory approval, or may only be deemed sufficient to support a narrower scope of approval, in other jurisdictions. If the FDA or comparable foreign regulatory authorities determine that the results of clinical trials of our product candidates are not adequate to support approval of a marketing application, we may experience delays in obtaining, or fail to obtain, approval of our product candidates, 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. Even if regulatory approval is obtained for a product candidate, the terms of such approval may limit the scope and use of the specific product candidate, which may also limit its commercial potential. Our product candidates may cause serious adverse, undesirable, or unacceptable side effects or have other properties that may delay or prevent marketing approval. If a product candidate receives regulatory approval, and such side effects are identified following such approval, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following such approval. Our product candidates may cause serious adverse, undesirable, or unacceptable side effects, which could cause us or regulatory authorities to interrupt, delay, or halt our future clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign authorities. We ~~have not commenced clinical trials for any of our product candidates, and we~~ do not **currently, and in the future may not,** have ~~any~~ **sufficient** clinical data or other information **to** ~~that would~~ enable us to fully anticipate ~~their~~ -- **the** side effects **of our product candidates** . Accordingly, we may observe unexpected side effects or higher levels of ~~known~~ **expected** side effects in clinical trials of our product candidates, including adverse events known to occur in the same classes of therapeutics, such as infusion reaction, cytokine release syndrome, graft- versus- host disease, neurotoxicities, and certain cancers. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects associated with our product candidates. In such an event, clinical trials of such product candidates could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of such product candidates for any or all targeted indications. ~~The~~ **In addition, the FDA or comparable foreign regulatory authorities may more closely scrutinize any side effects or safety concerns associated with our product**

candidates in the context of the potential benefits observed in diseases that are not immediately life- threatening, such as certain autoimmune diseases, which could harm our ability to develop or obtain regulatory approval for applicable product candidate in such diseases. Moreover, the occurrence of such side effects could negatively affect our ability to recruit and enroll patients in our clinical trials or the ability of enrolled patients to complete the clinical trials, or result in product liability claims **. For example, patients with diseases that are not immediately life- threatening, including certain autoimmune diseases, and their physicians may be less likely to enroll or recommend enrollment in clinical trials of our product candidates if there is a risk of certain side effects or safety concerns and may be more likely to cease their participation in such clinical trials if they experience certain side effects. Similar events may occur if it is determined that there are side effects or safety concerns associated with other products or product candidates that are, or are perceived to be, similar to ours** . Any of these occurrences could significantly harm our business, financial condition, and prospects. Further, clinical trials by their nature involve only a sample of the potential patient population. Because our clinical trials will involve only a limited number of patients and limited duration of exposure to our product candidates, rare and severe side effects of our product candidates may not be apparent during early clinical trials and may only be uncovered once a significantly larger number of patients have been exposed to the product candidate, including during later- stage clinical trials or following commercialization, or when longer- term data is available. As such, even if applicable regulatory authorities initially determine that our product candidates have an acceptable safety profile for their intended use in humans, they may later prove to cause serious side effects in patients that we were unable to observe or predict during their clinical development. In the event that any of our product candidates receives regulatory approval and we or others later determine that such product **may** ~~causes~~ **cause** undesirable or unacceptable side effects, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw or limit approvals of such product and require us to take such product off the market; • regulatory authorities may require the addition of labeling statements, specific warnings, or a contraindication or field alerts to physicians and pharmacies, or issue other communications containing warnings or other safety information about the product; • regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients or that we implement a risk evaluation and mitigation strategy (REMS) plan to ensure that the benefits of the product outweigh its risks; • we may be required to change the therapeutic dose or the way the product is administered, conduct additional clinical trials, or change the labeling of the product; • we may be subject to limitations on how we may promote or manufacture the product; • sales of the product may decrease significantly; • we may be subject to litigation or product liability claims; and • our reputation may suffer. Any of these events could prevent us or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of any products. Interim, topline, or preliminary data from our preclinical studies or ~~future~~ clinical trials that we may announce or publish from time to time may change as more data become available or as we make changes to our manufacturing processes. These data are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose interim, topline, or preliminary data from our preclinical studies or ~~future~~ clinical trials, which are based on a preliminary analysis of then- available data, and the final results and related findings and conclusions are subject to change following a more comprehensive review of the study or trial data. 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 at the time of our initial disclosure of data. Further, modifications or improvements to our manufacturing processes for a product candidate may result in changes to its characteristics or behavior that could cause the product candidate to perform differently and affect the results of our preclinical studies or planned or ongoing clinical trials of such product candidate, and potentially require us to conduct additional preclinical studies or clinical trials. 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 disclosed. As a result, topline data should be viewed with caution until the final data are available. Similarly, preliminary or interim data from clinical trials 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. Additionally, disclosure of preliminary or interim data by us or our competitors, with respect to clinical trials of their product candidates, could result in volatility in the price of our common stock. Further, others, including regulatory authorities, **investors, or analysts,** may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses **,** or may interpret or weigh the importance of data **, including any decisions we may make based on that data, particularly limited or preliminary data,** differently **than we do** , which could impact the value of the particular program, the approvability or commercialization of the particular product candidate, 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, **investors, or analysts,** disagree with the conclusions reached, our ability to obtain approval for and commercialize our ~~potential~~ product candidates ~~may~~ **, as well as our business, operating results, prospects, and financial condition, could** be harmed ~~, which could harm our business, operating results, prospects, or financial condition~~ . Our product candidates or technologies may be involved in investigator- sponsored clinical trials, and we will have limited or no control over the conduct of such trials. ISTs involving our product candidates or technologies pose **or are subject to** similar risks to those set forth elsewhere in these Risk Factors relating to clinical trials that we conduct ourselves. Although ISTs may provide us with clinical data that can inform the development strategy for our product candidates, we will be unable to control the **timing,** design **,** and ~~administration~~ **conduct** of such ISTs or **regulatory matters with respect to such ISTs, including** the submission, clearance or approval, or maintenance of any IND or comparable foreign submission required to conduct such ISTs. In addition, we would not control the ~~timing of~~ data collection and reporting **,**

including timing thereof, with respect to any ~~such~~ ISTs, and may not control the manufacturing of the product candidate or technology to be tested in any such ISTs. A delay in the timely completion of or reporting of data from any potential IST, including as a result of manufacturing complications or delays, ~~difficulty~~ **which could occur for various reasons such as the need to obtain additional licenses, delays in** recruiting, enrolling, or retaining patients, or other potential issues ~~that are~~ **, including those** described in these Risk Factors, could have a material adverse effect on our ability to further develop our product candidates or to advance our product candidates through subsequent clinical trials. Negative results from an IST could have a material adverse effect on our business and prospects and the perception of our product candidates and technologies. Additionally, there is a possibility that ISTs may be conducted under less rigorous clinical standards than those used in company- sponsored clinical trials. Accordingly, the FDA and comparable foreign regulatory authorities may more closely scrutinize the resulting data and may not view these data as providing adequate support for future clinical trials, whether sponsored by us or third parties. In addition, any potential IST could demonstrate marginal efficacy or reveal clinically relevant safety concerns that could delay the further clinical development or regulatory approval of our product candidates. Further, data from a potential IST may fail to demonstrate efficacy for various reasons, including those unrelated to our product candidates or technologies, which may negatively impact the perception of such product candidates and technologies, despite their potential for future success. To the extent that the results of any ISTs raise safety or other concerns regarding our product candidates or technologies, regulatory authorities may question the results of such ISTs or other clinical trials involving the relevant product candidate or technology. Safety concerns arising from any potential ISTs may cause the FDA or comparable foreign regulatory authorities to impose partial or full clinical holds on our product candidates, including product candidates that were developed using the same technology or manufactured using the same reagents and materials as those product candidates that are the subject of such ISTs, which could delay or prevent us from advancing our product candidates into further clinical development and require us to discontinue our development of such product candidates. The occurrence of any of the foregoing would severely harm our business and prospects. The manufacture of our product candidates is complex. We or our CDMOs may encounter difficulties in production, which could delay or entirely halt our or their ability to supply our product candidates for clinical trials or, if approved, for commercial sale. Our product candidates are considered to be biologics, and the process of manufacturing biologics is complex and requires significant expertise and capital investment, including with respect to the development of advanced manufacturing techniques and process controls. As described elsewhere in these Risk Factors, we have entered **into** a long- term lease to establish ~~a~~ manufacturing **capabilities at the Bothell** facility ~~in Bothell, Washington~~ and have entered into an agreement ~~with URMC pursuant~~ to ~~which we have obtained~~ access ~~to~~ manufacturing capabilities within URMC' s cell- based manufacturing facility. We ~~expect that it will take at least several years before we are able to begin manufacturing our product candidates at the Bothell facility, if at all. We~~ currently rely, and expect to continue to rely, on CDMOs for the manufacture of certain of our product candidates for preclinical and clinical studies. We also anticipate that we will continue to rely on CDMOs for at least some portions of our supply chain following commercialization of any product candidates for which we may receive regulatory approval. **As** ~~Moreover, as~~ described elsewhere in these Risk Factors, ~~given our decision to move our planned manufacturing from the Fremont facility to the Bothell facility, it may take us longer to establish and operationalize our internal manufacturing facility than~~ we ~~originally anticipated. We~~ expect that we will also be required to transition certain manufacturing processes and know- how, including **to our CDMOs and** to the Bothell facility and the URMC site, over time, which is a complex process with which we have limited experience. If we experience any delays or issues with the foregoing, our ability to begin manufacturing certain of our product candidates internally could be delayed, and we may need to rely to a greater extent on CDMOs for the manufacture of such product candidates for longer than we currently anticipate. To date, we and our CDMOs have limited experience in manufacturing of cGMP batches of our product candidates. Our CDMOs and, once we begin to operate the Bothell facility and the URMC site, we, must comply with cGMPs and other **complex** regulations and guidelines applicable to the manufacturing of biologics for use in clinical trials and, if approved, commercial sale **, and any inability or failure to comply with such regulations and guidelines could delay our clinical trials or prevent us from being able to commence clinical testing at all** . To date, we have not scaled the manufacturing processes with respect to our product candidates for later- stage clinical trials and commercialization **, and we and our CDMOs may not have sufficient capacity, resources, or capabilities to scale such manufacturing processes in accordance with our desired timelines or at all** . ~~Larger~~ **Further, certain of our product candidates may have characteristics that present increased manufacturing complexity and necessitate longer manufacturing timelines. If we are unable to successfully scale the manufacturing process for these product candidates, including in compliance with cGMP quality requirements, or adapt such manufacturing process to meet late- stage development or commercial quality requirements, we may not be able to manufacture sufficient quantities of compliant product candidates, or manufacture them in a timely manner, which would harm our ability to clinically develop and commercialize such product candidates. In addition, the manufacturing of our product candidates, including large** - scale manufacturing ~~will~~ **, may** require the development of ~~new~~ **novel** processes **for upstream and downstream activities** , including ~~for the removal of impurities that are a normal byproduct of the manufacturing process. The nature of our product candidates requires the development of novel manufacturing processes and~~ analytical technologies, which could cause delays in the scaling of manufacturing, as well as greater costs that could negatively impact the financial viability of our product candidates. We cannot be sure that the manufacturing processes employed by our CDMOs or the technologies that our CDMOs incorporate into our manufacturing processes will result in viable or scalable yields of ex vivo and in vivo cell engineering product candidates that will have acceptable safety, purity, potency, or efficacy profiles and, if approved, meet market demand. Our biologic product candidates are susceptible to product loss or reduced manufacturing success rates at various points during the manufacturing process, including due to contamination, equipment damage or failure, including during shipment or storage, failure of equipment to operate as expected, improper installation or operation of equipment, vendor or operator error, damage to, variability of, or improper use of raw materials or consumables necessary for the manufacturing process, inconsistency in yields, variability in product characteristics, and difficulties in scaling the production process. Any of these issues, and even minor deviations from normal manufacturing processes, could result in reduced production yields, product defects, and other supply disruptions and delays. If microbial, viral, or other contaminations are discovered in our product candidates or in the facilities in which our product candidates are manufactured, including the Bothell facility, the URMC site, or any future manufacturing facilities, or those of our CDMOs, such supply may have to be discarded, our products may be withdrawn from clinical trials and, if approved, the market, and such facilities may need to be closed for an extended period of time to investigate and remedy the contamination. Moreover, if the FDA or comparable foreign regulatory authorities determine that we or our CDMOs, or our or our CDMOs' facilities, are not in compliance with applicable laws and regulations, including cGMPs, the FDA or comparable foreign regulatory authority may not approve a biologics license application (BLA) or comparable foreign marketing authorization until the deficiencies are corrected or we replace the manufacturer in our applications with a compliant manufacturer, and we may ultimately be unable to manufacture our product candidates. The occurrence of any of these issues could delay our ability to commence or timely complete clinical development, obtain regulatory approval of, and commercialize our product candidates. We also may make changes to our manufacturing processes at various points during development, and even after commercialization, for various reasons, such as to control costs, achieve scale, decrease processing time, or increase manufacturing success rate. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could result in changes to a product candidate' s characteristics or behavior or cause our product candidates to perform differently and affect the results of any of our then- ongoing or future preclinical studies or clinical trials, or the performance of the product, once commercialized. In certain circumstances, if we make changes to our manufacturing process for a product candidate, regulatory authorities may require us to perform comparability studies and collect additional preclinical or clinical data prior to undertaking additional clinical trials or obtaining marketing approval for or commercializing the product candidate produced with such modified process. For instance, if we make changes to our manufacturing process for a product candidate during the course of preclinical or clinical development, regulatory authorities may require us to demonstrate the comparability of the product used in preclinical studies, earlier clinical phases, or earlier portions of a trial to the product used in later clinical trials or clinical phases or later portions of a trial, as applicable. **If at any point we switch to a different CDMO or supplier of reagents or materials used in the manufacturing process for a product candidate, including, for example, in order to ensure sufficient supply for later- stage clinical trials and potential commercialization, we may also be required to perform comparability studies in order to demonstrate comparability of the applicable product candidate, reagent, or material from the prior CDMO or supplier to that from the new CDMO or supplier, and otherwise demonstrate that the relevant product candidate, reagents, or materials meet the applicable specifications.** We may be unable to successfully generate comparability data, and even if we are able to generate and provide such data, regulatory authorities may **disagree with the design of our comparability studies or otherwise** determine that the data are insufficient to support a determination of comparability **. Similarly, we may be unable to demonstrate that the relevant materials meet the applicable specifications** . In such an event, we may be required to make further changes to our process or undertake additional preclinical or clinical testing, which could result in manufacturing delays and affect our ability to timely dose patients in our clinical trials, which could delay further development or commercialization of such product candidate **, or we may be unable to continue development of the applicable product candidate at all** . Any adverse developments affecting manufacturing operations for any of our product candidates, including those for which we may obtain regulatory approval, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other supply interruptions that could negatively impact the conduct of our clinical trials or our ability to successfully commercialize any product candidates for which we may obtain regulatory approval. We may also have to take inventory write-offs and incur other charges and expenses for products that fail to meet specifications as a result of defects or storage over an extended period of time, undertake costly remediation efforts, or seek more costly manufacturing alternatives. Any such issues would harm our ability to timely and successfully complete clinical trials and obtain regulatory approval of our product candidates, which could have a significant negative impact on our business, operations, and prospects. We are exposed to a number of risks related to the supply chain for the materials required to manufacture our product candidates. The manufacturing of our product candidates is highly complex and requires sourcing of specialty materials. Many of the risks associated with the complex manufacturing of our final product candidates are applicable to the manufacture and supply of the raw materials required to make such product candidates. In particular, these raw materials are subject to inconsistency in yields, variability in characteristics, contamination, difficulties in scaling the production process, and defects. Similar minor deviations in the manufacturing process for these raw materials could result in supply disruption and reduced production yields for our final product candidates. In addition, we rely on third parties for the supply of these materials, which exposes us to risks associated with dependence on third parties, as described elsewhere in these Risk Factors. Further, we use certain reagents and materials across various programs and initiatives, and any difficulties we experience with such reagents or materials, including with respect to sourcing, quality, or other factors, could have a more significant impact on our portfolio and business than if we used different reagents and materials for each of our programs and initiatives. We must obtain suitable donor material from eligible and qualified donors for the manufacture of product candidates from our ex vivo cell engineering platform. **If we are** ~~We may not be able~~ **unable** to obtain sufficient quantities of suitable donor material in a timely manner or at all, including if we are unable to find donors who meet the eligibility criteria or as a result of geo- political, economic, and other factors beyond our control that may prevent individuals from donating blood ~~. If we are unable to obtain sufficient quantities of suitable donor material, or if we are unable to obtain such material in a timely manner~~ , we may experience delays in manufacturing our ex vivo product candidates, which would harm our ability to conduct ~~future~~ clinical trials of or to commercialize these product candidates. In addition, we require many reagents, which are drug substance intermediates used in our manufacturing processes to bring about chemical or biological reactions, and other specialty raw and intermediate materials, consumables, and equipment, for our manufacturing processes and for quality control testing of our product candidates, some of which are manufactured or supplied by small companies with limited resources and experience with respect to supporting clinical or commercial biologics production. ~~We and our CDMOs currently depend on a limited number of vendors for certain reagents, materials, consumables, and equipment used in the manufacture of our product candidates.~~ Some of these suppliers may not have the capacity **or resources** to support manufacturing of products under cGMP **on our timelines or at all** or may otherwise be ill- equipped to support our needs **, including if and as we expand our manufacturing activities to support later- stage clinical trials and, for any product candidates that may receive regulatory approval, commercialization** . Reagents and other key materials from these suppliers may have inconsistent attributes and introduce variability into our manufactured product candidates, which may contribute to variable patient outcomes and possible adverse events. We also do not have supply contracts with many of these suppliers and may not be able to enter into supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays in receiving key reagents, materials, consumables, and equipment to support clinical or commercial manufacturing, which could delay development and commercialization of our product candidates. For some of these reagents, materials, consumables, and equipment, we and our CDMOs currently rely and may in the future rely on sole source vendors or a limited number of vendors. We may be unable to continue to source reagents, materials, consumables, or equipment from any of these vendors for various reasons, including due to regulatory actions or requirements affecting a vendor, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demand from other customers and supply limitations, or quality issues. Additionally, due to global geo- political, economic, and other factors beyond our control, there has been, and there **are and** may continue to be, a shortage of key materials, consumables, and equipment that are necessary to manufacture our product candidates, including certain consumables such as bags, flasks, and pipette tips, which could affect our or our CDMOs' ability to obtain the materials, consumables, and equipment necessary to manufacture our product candidates. If any of the foregoing events were to occur, we may experience delays in manufacturing our product candidates, which would harm our ability to conduct future clinical trials and, if approved, commercialize our ~~product~~ **products** ~~candidates~~ and generate product revenues in a timely manner or at all. Additionally, as described elsewhere in these Risk Factors, rising rates of inflation **in recent years** have resulted in substantial increases in the costs associated with manufacturing our product candidates, including the costs of materials, consumables, and equipment, that we are unable to offset. Given the unpredictable nature of the current economic climate, including future rates of inflation, it may be increasingly difficult for us to predict and control our future expenses, which may harm our ability to conduct our business. As we continue to develop and scale our manufacturing processes, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of those processes. We may not be able to obtain rights to **or sufficient quantities of** such materials or equipment on commercially reasonable terms, or at all, and our inability to alter our processes in a commercially viable manner to avoid the use of such materials or equipment or find suitable substitutes would have a material adverse effect on our business. Even if we are able to alter our processes so as to use other materials or equipment, such a change may delay our clinical development or commercialization plans. As described elsewhere in these Risk Factors, if such a change occurs for product candidate that is already being tested in clinical trials, the change may require us to perform comparability studies **, demonstrate that the new materials or equipment meet applicable specifications,** and ~~to~~ collect additional data from patients prior to undertaking more advanced clinical trials. We may become exposed to costly and damaging liability claims, either when testing our product candidates in clinical trials or at the commercial stage, and our product liability insurance may not cover all damages arising from such claims. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing, and use of pharmaceutical products. **The** ~~Although we currently have no product candidates for which we have commenced clinical trials or obtained approval for commercial sale, the future~~ use of our product candidates in clinical trials, and the sale of any products for which we may obtain approval in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. Physicians and patients may not comply with any warnings that identify known potential adverse effects or patients who should not use our product candidates. If any of our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. We would require significant financial and management resources to defend against any product liability claims, even if we are successful in such defense. Regardless of the merits or eventual outcome, liability claims may result in decreased demand for our product candidates, negative publicity and injury to our reputation, withdrawal of clinical trial participants, ~~initiation of~~ investigations by regulatory authorities, costs to defend the related litigation, diversion of management' s time and our resources, substantial monetary awards to clinical 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, inability to commercialize our product candidates, and a decline in our share price. Although we maintain product liability insurance for our product candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may be unable to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims, and our business operations could be impaired. Risks Related to Our Dependence on Third Parties We rely **, and expect to continue to expect to rely,** on ~~, and expect to continue to expect to rely on,~~ CDMOs, including third- party testing laboratories, to manufacture our product candidates, as well as materials used in the manufacturing of our product candidates, including testing of such product candidates and materials. Any failure by a CDMO to properly produce acceptable materials or product candidates for us or any failure by us or such CDMO to obtain authorization from the FDA or comparable foreign regulatory authorities or otherwise satisfy regulatory requirements with respect to such manufacturing of our product candidates may delay or impair our ability to initiate or complete our clinical trials, obtain regulatory approvals, or commercialize approved products. We do not currently own or operate any cGMP manufacturing facilities, nor do we have any in- house cGMP manufacturing capabilities. Until we are able to begin manufacturing our product candidates at our ~~Bothell facility, which may occur later than we originally anticipated as a result of our decision to move our planned manufacturing facility from the Fremont facility to the~~ Bothell facility, we will rely in part on CDMOs, including third-party testing laboratories, to manufacture our product candidates for use in preclinical and clinical testing and expect to continue to rely on such CDMOs to manufacture certain of our product candidates thereafter as part of our manufacturing strategy. A limited number of CDMOs specialize in or have the expertise required to manufacture our product candidates or materials used in their manufacture. Moreover, our CDMOs have limited capacity at their facilities and require commitments to secure availability well in advance of manufacturing any products or other materials. Additionally, we face competition from other biopharmaceutical companies to secure manufacturing availability at these facilities. If the CDMOs on which we rely to manufacture our product candidates and other materials do not have sufficient availability at their facilities to do so in accordance with our timelines or are not otherwise able to meet our expected deadlines, we will experience delays in manufacturing our product candidates or other materials necessary for their manufacture. For example, because we rely on, and may continue to rely on, single CDMOs for certain manufacturing activities across multiple programs, any issues we may experience with such a CDMO, including inability to secure manufacturing capacity as and when needed, could result in manufacturing delays across all such programs and harm our ability to timely and successfully complete clinical trials and commercialization of our product candidates. In addition, as described elsewhere in these Risk Factors, we assess and prioritize our programs on an ongoing basis based on various factors. We may not be able to secure manufacturing capacity for certain programs as and when needed **and may be required to prioritize manufacturing activities for certain programs over others** , which could lead to manufacturing delays and harm our ability to further develop the relevant product candidates. We may also experience similar capacity constraints and manufacturing delays in the future with respect to any products we may manufacture at the Bothell facility **. Further, for each new program or CDMO we engage, or in the case of certain changes to the manufacturing process for a product candidate, the relevant manufacturing process and related know- how must be transferred to the CDMO. This technology transfer is time- consuming and complex. If we are required to switch from an existing CDMO to a new CDMO, including to meet cGMP quality requirements or support process lock or larger-scale manufacturing for later- stage clinical trials or potential commercialization, we will need to conduct additional technology transfer activities, which could result in delays in further development of the applicable product candidate** . Our CDMOs also face intense competition to attract and retain qualified personnel. If our CDMOs are unable to attract, retain, and motivate qualified personnel, they may be unable to perform their obligations in a timely manner, or their performance may be substandard or may not meet our quality requirements, which could cause us to experience delays in manufacturing our product candidates. Further, as described elsewhere in these Risk Factors, there are few alternatives for the CDMOs that we currently engage, and even if one of our CDMOs fails to perform according to our expectations and we decide to switch to an alternative CDMO, there is no guarantee that such alternative CDMO will be able to perform its obligations in a timely manner or that its performance will meet our expectations or quality requirements. Any delays in manufacturing our product candidates could materially harm our ability to conduct our clinical trials or commercialize our product candidates in a timely manner or at all and could harm our business. In addition, we rely on multiple CDMOs to produce sufficient quantities of materials required for the manufacture of our product candidates for preclinical testing and ~~future~~ clinical trials ~~,~~ and intend to continue to rely on such CDMOs for the commercial manufacture of certain of our products, if approved. Global supply chain shortages and rising rates of inflation **in recent years** have resulted in substantial increases in the costs of materials, including raw materials, reagents, consumables, and equipment that are required to make or used in the manufacture of our product candidates. If we are unable to obtain such items from third- party sources, or fail to do so on commercially reasonable terms, we may not be able to produce sufficient supply of product candidate or we may be delayed in doing so. Such inability or failure, or any substantial delay in obtaining such items, could materially harm our business. We rely on third parties to produce certain reagents and biological materials that are used in our discovery and development programs. These materials can be difficult to produce and occasionally have variability from our product specifications. If these materials do not comply with our product specifications, or in the event of any other disruption in the supply of these materials, our business could be materially adversely affected. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Our suppliers may also have low yield from manufacturing batches of these materials, which could increase our costs and slow our development timelines. Improper storage of these materials, by us or any third- party suppliers, may require us to destroy some of these materials or product candidates generated using such materials. Reliance on CDMOs entails additional risks to which we would not be subject if we manufactured product candidates ourselves, including those applicable to other third- party service providers, as described elsewhere in these Risk Factors. In particular, such risks include reliance on the CDMO for regulatory compliance and quality control and assurance, including compliance with cGMP requirements and comparable standards relating to methods, facilities, and controls used in the manufacturing, processing, testing, and packing of product candidates, which are intended to ensure that biological products have acceptable safety profiles and that they consistently meet applicable requirements and specifications **, and our CDMOs may be unable to satisfy applicable compliance and quality requirements in accordance with our timelines or at all** . Additional risks include reliance on the CDMO for volume production, the possibility of breach of or inability to perform its obligations under the manufacturing agreement by the CDMO (including a failure to synthesize and manufacture our product candidates in accordance with our product specifications, failure to properly scale- up manufacturing processes, or failure to deliver sufficient quantities of product candidates in a timely manner), and the possibility of termination or nonrenewal of the agreement by the CDMO at a time that is costly or damaging to us. ~~In addition~~ **For example, certain of our CDMOs may be unable to manufacture sufficient supply of our product candidates or materials used in their manufacture, in particular** , if **and as we implement commercial cGMP practices or scale up manufacturing for later- stage clinical trials and potential commercialization. If we experience any issues with respect to the risks described above, we may be required to seek a replacement CDMO, which could require significant internal resources, delay our ongoing manufacturing activities, and ultimately be unsuccessful. If** we were unable to timely find an adequate replacement for our CDMOs or another acceptable solution **when needed** , our clinical trials could be delayed, or our commercial activities could be harmed. In addition, because we depend on our CDMOs, our suppliers, and other third parties for the manufacture, filling, storage, and distribution of our product candidates, we may be unable to prevent or control manufacturing defects in our products, the use or sale of which could seriously harm our business, financial condition, and results of operations. Issues involving any of the foregoing risks could increase our costs, delay our development timelines, and ultimately lead to a delay in, or failure to obtain, regulatory approval of our product candidates. Pharmaceutical manufacturers are required to register their facilities and products manufactured at the time of submission of the marketing application and then annually thereafter with the FDA and certain state and foreign agencies. If the FDA or a comparable foreign regulatory authority does not approve our CDMO' s facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for, or market our product candidates, if approved, on a timely basis or at all. Any discovery of problems with a product, or a manufacturing or laboratory facility used by us or our strategic partners in connection with manufacturing of that product, may result in restrictions on the product or on the relevant facility, including marketed product recall, suspension of manufacturing, product seizure, or a voluntary withdrawal of the drug from the market. We may have little to no control regarding the occurrence of any such incidents at our CDMOs. Pharmaceutical manufacturers are also subject to extensive post- marketing oversight by the FDA and comparable regulatory authorities in the jurisdictions where a product is marketed, including periodic unannounced and announced inspections by the FDA to assess compliance with cGMP requirements. Any failure by one of our CDMOs to comply with cGMP or to provide adequate and timely corrective actions in response to deficiencies identified in a regulatory inspection could result in further enforcement action that could lead to a shortage of products and harm our business, including withdrawal of approvals previously granted, seizure, injunction, or other civil or criminal penalties. The failure of a CDMO to address any concerns raised by the FDA or comparable foreign regulatory authorities could also lead to plant shutdown or the delay or withholding of product approval by the FDA in additional indications or by comparable foreign regulatory authorities in any indication. In addition, because our CDMOs also provide manufacturing services to other companies, including our competitors, there is a risk that our CDMOs may experience the issues described in this Risk Factor with respect to such third parties and their product candidates as well. The occurrence of any such issues could restrict, partially or completely, or otherwise negatively impact such CDMO' s ability to timely and successfully perform its obligations for us with respect to our own product candidates, which would harm our ability to continue manufacturing and commercialize such product candidates. Certain countries may impose additional requirements on the manufacturing of drug products or drug substances, and on manufacturers, as part of the regulatory approval process for products in such countries. The failure by our CDMOs to satisfy such requirements could impact our ability to obtain or maintain approval of our products in such countries. **In addition, as described elsewhere in these Risk Factors, our CDMOs may be subject to various other laws and regulations, compliance with or the effect of which could harm our relationship with such CDMOs and negatively impact our business.** If we are unable to obtain sufficient raw and intermediate materials on a timely basis or if we experience other manufacturing or supply interruptions or difficulties, we may be unable to resume supply of such materials or other manufacturing activities within a reasonable time frame and at an acceptable cost or at all, which could materially adversely affect our business. The manufacture of our product candidates requires the timely delivery of sufficient amounts of raw and intermediate materials. We purchase, and rely on our CDMOs to purchase, certain of these materials from third- party suppliers in order to produce our product candidates for our preclinical studies. There are a limited number of suppliers of these materials, and we may need to assess alternate suppliers to prevent possible disruption of manufacturing of our product candidates for our preclinical studies, our future clinical trials, and if ultimately approved, commercial sale. We ~~intend~~ **rely, and expect** to continue to rely **,** on our CDMOs to purchase materials in order to produce product candidates for ~~any~~ **our** clinical trials ~~that we undertake~~ ; however, we do not have any control over the process or timing of the acquisition of these materials by our CDMOs or the costs of such materials. We work closely with our CDMOs and suppliers, as applicable, to ensure the continuity of supply, but we cannot ensure that these efforts will always be successful. Further, although we strive to diversify our sources of raw and intermediate materials, in certain instances we acquire raw and intermediate materials from a sole supplier. 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 supply these materials for our intended purpose. Alternative sources of supply may exist when we rely on sole supplier relationships, but we cannot ensure that, if needed, we would be able to quickly establish additional or replacement sources for some materials. The lead time needed to establish a relationship with a new supplier can be lengthy, and we may experience delays in the event a new supplier must be used. In addition, 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. Although we generally would not begin a clinical trial unless we believe we have a sufficient supply of a product candidate to complete the clinical trial, any significant delay in the supply of a product candidate, or the raw or intermediate material components thereof, for an ongoing clinical trial due to the need to replace a supplier could considerably delay completion of our clinical trials, product testing, and potential regulatory approval of our product candidates. Moreover, we currently do not have any agreements for the commercial supply of these raw or intermediate materials. A reduction or interruption in supply of raw or intermediate materials combined with an inability of us or our CDMOs to timely establish alternative sources for such supply could adversely affect our ability to manufacture our product candidates or approved products in a timely or cost- effective manner, result in a shortage of product supply, delay the development and any commercial launch of our product candidates, and ultimately impair our ability to generate revenues from sales of any approved products. We rely, and expect to continue to rely, on third parties, including service providers such as CROs, clinical trial sites, including principal investigators, and independent clinical investigators, to conduct or support our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We **rely,** ~~have relied upon~~ and ~~plan~~ **expect** to continue to rely ~~upon~~ **, on** third parties, including service providers such as CROs, independent clinical investigators, and clinical trial sites, to properly and timely execute or support our preclinical studies and clinical trials and related activities, and to monitor and manage data for our ongoing preclinical and clinical programs **and we may rely to a greater extent on such outsourced activities following our October 2023 workforce reduction** . However, we are only able to control certain aspects of ~~their~~ -- **the** activities **of these third parties** to the extent set forth under our contracts with ~~the~~ **these** ~~relevant~~ third parties, and we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards and rules, and our reliance on these third parties does not relieve us of these obligations. With respect to any of our product candidates that may enter clinical development, we and our CROs and other service providers, as well as our clinical trial sites, including principal investigators, are required, and we rely on them, to comply with good clinical practices (GCP) requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities. Regulatory authorities enforce GCPs through periodic inspections of clinical trial sponsors and clinical trial sites, including principal investigators. If we or any of our CROs or other service providers, or any clinical trial sites or principal investigators involved in our trials, fail to comply with applicable GCPs, the clinical data generated from these clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot be certain that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP. In addition, to the extent third parties executing or otherwise supporting our clinical trials, including CROs and clinical trial sites, including principal investigators, fail to conduct such clinical trials in accordance with GCP, fail to timely and successfully enroll patients in our clinical trials, or experience significant delays in the execution of our trials, including delays in achieving full enrollment or clinical trial data collection and analysis, we may experience program delays, incur additional costs, or both, which may harm our business. Our clinical trials must also be conducted using product produced in compliance with cGMP regulations, and our failure to do so may require us to repeat clinical trials, which would delay the regulatory approval process for the relevant product candidate. Further, third parties that support our preclinical and clinical programs, such as service providers, including CROs, independent clinical investigators, and clinical trial sites, including principal investigators, are not our employees, and we are unable to control, other than by contract, the amount of resources, including time, that they devote to our product candidates, preclinical studies, and clinical trials. If such third parties, including our CROs or other service providers, are unable to attract, retain, and motivate qualified personnel, they may be unable to perform their obligations in a timely manner, or their performance may be substandard. If such third parties fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard or does not meet our quality requirements, it may delay or compromise the prospects for approval and commercialization of any such product candidates. In addition, in order for these third parties to perform under their contracts with us, we regularly disclose or plan to disclose to these third parties confidential or proprietary information, which increases the risk that this information will be misappropriated. Additionally, disruptions caused by global geo- political, economic, and other factors beyond our control may increase the likelihood that these third parties encounter difficulties or delays in performing their obligations to us, including with respect to initiating, enrolling, conducting, or completing our planned clinical trials. There is a limited number of third parties, including service providers such as CROs ~~,~~ and clinical trial sites, that specialize in or have the expertise required to achieve our business objectives. These third parties generally have the right to terminate their agreements with us in the event of our uncured material breach, and may have the right to terminate under other circumstances, including if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties or do so in a timely manner or on commercially reasonable terms. 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 data they obtain is compromised due to the failure to adhere to our preclinical or clinical protocols, regulatory requirements, or for other reasons, our preclinical studies or clinical trials may be extended, delayed, or terminated, the results thereof could be negatively impacted, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. Switching from existing to alternative service providers or clinical trial sites, or adding new service providers or clinical trial sites, may involve significant cost and requires management time and focus. In addition, there is a natural transition period when a new service provider commences work, which could lead to delays and materially impact our ability to meet our desired development, including clinical development, timelines. Additionally, even if our service providers perform as required, they may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with these service providers, including our contracted laboratories and CROs, there can be no assurance that we will not encounter these types of 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. Risks Related to Intellectual Property and Information Technology ~~We~~ **Our success depends on our ability to protect our intellectual property rights and proprietary technologies, and we** may not be able to protect our intellectual property rights throughout the world. Patent rights are national or regional rights. The filing, prosecution, maintenance, and defense of patent rights on our platform technologies and product candidates worldwide would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may have a different scope and strength than do those in the United States. In addition, the laws of some foreign countries, particularly certain developing countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our intellectual property rights in all countries outside the United States or from making, using, selling, or importing products made using our intellectual property rights in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained intellectual property rights, including patent protection, to develop their own products and may also export otherwise infringing products to territories where we have intellectual property rights, including patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products and our patent or other intellectual property rights may not be effective or adequate to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property, particularly those relating to biopharmaceutical products, which could make it difficult in those jurisdictions for us to stop the infringement or misappropriation of our patents or other intellectual property rights, or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent and other intellectual property rights in foreign jurisdictions are expensive, especially in jurisdictions where we have no local presence, and could result in substantial costs and divert our efforts and attention from other aspects of our business. Furthermore, such proceedings could put our patents at risk of being invalidated, held unenforceable, or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims of infringement or misappropriation against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Similarly, if our trade secrets are disclosed in a foreign jurisdiction, competitors worldwide could have access to our proprietary information, and we may be without satisfactory recourse. Such disclosure could have a material adverse effect on our business. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third- party, which could materially diminish the value of those patents. In addition, many countries limit the enforceability of patents against government agencies or government contractors. This could limit our potential revenue opportunities. 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. Because of the expense and uncertainty of litigation, we may conclude that, even if a third party is infringing our issued patents, or any patents that may be issued as a result of our pending or future patent applications, or other intellectual property rights, the risk- adjusted cost of bringing and enforcing such a claim or action, which typically lasts for years before it is concluded, may be too high or not in the best interest of our company or our stockholders, or it may be otherwise impractical or undesirable to enforce our intellectual property against some third parties. Our competitors or other third parties may be able to sustain the costs of complex patent litigation or proceedings more effectively than we can because of their greater financial resources and / or more mature and developed intellectual property portfolios. In such cases, we may decide that the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we may receive as a result of the proceedings and that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. In addition, the uncertainties associated with litigation could compromise our ability to raise the funds necessary to initiate or continue our future clinical trials, continue our internal research programs, in- license needed technology or other product candidates, or enter into development partnerships that would help us bring our product candidates to market. We depend on intellectual property licensed from third parties, and our rights to develop and commercialize our product candidates are subject to, in part, the terms and conditions of the applicable license agreements. If we breach our obligations under these agreements or if any of these agreements is terminated, we may be required to pay damages, lose our rights to such intellectual property and technology, or both, which would harm our business. We depend on patents, know- how, and proprietary technology, both that we own and that we license from others, to research, develop, and commercialize our product candidates. We are a party to a number of intellectual property license agreements and acquisition agreements pursuant to which we have acquired certain of our core intellectual property rights. Moreover, we rely upon licenses to certain intellectual property rights and proprietary technology from third parties that are important or necessary for the development of our technologies and products, including technology related to our manufacturing processes and our product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use or in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in such fields of use or territories. These licenses may also require us to grant back certain intellectual property rights to our licensors and to pay certain amounts relating to sublicensing patent and other rights. We have entered into, and we expect to enter into in the future, license agreements and other agreements pursuant to which we may obtain access to or acquire intellectual property rights and technologies. These license and acquisition agreements impose, and we expect that future license and acquisition agreements will impose, various diligence, milestone and royalty payment, and other obligations on us. If we fail to comply with our obligations under these agreements, we may be required to pay damages, and the licensor may have the right to terminate the agreement. Any termination of these licenses could result in the loss of significant rights and could harm our ability to develop or advance one of our cell engineering platforms, or develop, manufacture, or commercialize one of our product candidates. See the subsection titled " Business — Key Intellectual Property Agreements " in Part I, Item 1 of this Annual Report for additional information regarding these key agreements. Licensing of intellectual property is of critical importance to our business, involves complex legal, business, and scientific issues and is complicated by the rapid pace of scientific discovery in our industry. Disputes may arise between us and our licensors regarding intellectual property subject to a license agreement, including those relating to: • the scope of rights granted under the license agreement and other issues related to interpretation of the agreement, certain provisions of which may be susceptible to multiple interpretations; • whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement; • our right to sublicense the patent and other rights granted to us under the license agreement to third parties as part of collaborative development relationships; • whether we are complying with our diligence obligations with respect to the use of the licensed intellectual property rights in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; • the priority of invention of patented technology; • the amount and timing of payments owed under license agreements; and • the allocation of ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners. The resolution of any contract interpretation disagreement that may arise could change what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Our business may also suffer if any current or future licensors fail to abide by the terms of the applicable agreement, if such licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be unpatentable, invalid, or unenforceable, or if we are unable to enter into or maintain necessary license agreements on acceptable terms or at all. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current or future licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. In addition, although we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in product candidates that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize any product candidates, we may be unable to achieve or sustain profitability. If we are unable to successfully maintain the intellectual property rights we currently have pursuant to agreements with third parties, or those we may in- license or acquire in the future, we may have to abandon development of the relevant research programs or product candidates, which could harm our ability to commercialize our products, and our business, financial condition, results of operations, and prospects could be materially adversely affected. We depend, in part, on our licensors to file, prosecute, maintain, defend, and enforce certain patents and patent applications that are material to our business. Certain patents relating to our product candidates are owned or controlled by certain of our licensors. Each of our licensors generally has rights to file, prosecute, maintain, and defend the patents we have licensed from such licensor in their name, generally with our right to comment on such filing, prosecution, maintenance, and defense, with some obligation for the licensor to consider or incorporate our comments, for our exclusively licensed patents. We generally have the first right to enforce our exclusively licensed patent rights against third parties, although our ability to settle such claims often requires the consent of the licensor. If our licensors, third parties from whom they license or have obtained the relevant patents, or any future licensees having rights to file, prosecute, maintain, and defend our patent rights fail, or have in the past failed, to properly and timely conduct these activities for patents or patent applications covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, or selling competing products. We cannot be certain that such activities have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Pursuant to the terms of the license agreements with some of our licensors, these licensors may have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents and, even if we are permitted to pursue such enforcement or defense, we cannot ensure the cooperation of our licensors. We cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it could cause us to lose rights to intellectual property that we may need to operate our business or could cause us to lose the ability to exclude our competitors from using the intellectual property rights. In addition, even when we have the right to control patent prosecution of licensed patents and patent applications, enforcement of licensed patents, or defense of claims asserting the invalidity of those patents, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to or after our assuming control. In the event we breach any of our contractual obligations to our licensors related to such prosecution, we may incur significant liability to our licensors. We may not be successful in obtaining or maintaining necessary rights to product candidates, product candidate components, or processes for our product development pipeline, which may require us to operate our business in a more costly or otherwise adverse manner than we anticipated. We may not be successful in obtaining or maintaining exclusive rights to owned and in- licensed patents or patent applications or future patents to the extent they are co- owned by us and third parties. We own or license from third parties certain intellectual property rights necessary to develop our product candidates. The growth of our business will likely depend in part on our ability to acquire or in- license additional proprietary rights, including to advance our research or allow commercialization of our product candidates. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development or delay commercialization of one or more product candidates and our business and financial condition could suffer. If we are unable to obtain or maintain necessary third- party intellectual property rights, we may be required to expend considerable time and resources to develop or license replacement technology. For example, our programs may rely upon technologies or product candidates that require the use of additional proprietary rights held by third parties. Furthermore, other pharmaceutical companies and academic institutions may have filed or may plan to file patent applications potentially relevant to our business. In order to work effectively and efficiently, or for other reasons, our product candidates may also require specific formulations, reagents, materials, components, or other technology, which may be covered by intellectual property rights held by others. In order to avoid infringing third- party patents, we may be required to license technology from these third parties to further develop or commercialize our product candidates. We may be unable to acquire or in- license third- party intellectual property rights that we identify as necessary or important to our business operations, including composition, method of use, method of making, or other intellectual property rights required to make, use, or sell our product candidates. Such licenses or other rights may not be available at a reasonable cost or on reasonable terms, or at all, and, as a result, we may be unable to develop or commercialize the affected product candidates, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights. In addition, we may need to seek to develop alternative approaches that do not infringe on such intellectual property rights, which, if we were successful in developing such alternatives, may entail additional costs and lead to delays in development. In certain cases, it may not be feasible for us to develop such alternatives, which would harm out ability to continue development of the affected product candidates. Even if we are able to obtain a license to such intellectual property rights, any such license may be non- exclusive, which may allow our competitors to access to the same technologies licensed to us. Additionally, we sometimes collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. However, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may license the intellectual property rights to other parties, potentially blocking our ability to pursue any of our programs to which such rights relate. The licensing and acquisition of third- party intellectual property rights is competitive, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete negotiations and ultimately license or acquire the intellectual property rights necessary or useful for the development of our product candidates. Any delays in entering into, or inability to enter into, license or other agreements pursuant to which we obtain rights related to our product candidates could delay or halt the development and commercialization of our product candidates in certain geographies, which could harm our business prospects, financial condition, and results of operations. Moreover, some of our owned and in- licensed patents or patent applications or future patents are or may be co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owner' s interest in such patents or patent applications, such co- owner may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technologies. In addition, such co- owner may not provide the cooperation necessary to enforce such patents against third parties. Furthermore, our owned and in- licensed patents may be subject to a reservation of rights by one or more third parties. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. We may depend on intellectual property licensed or sublicensed to us from, or for which development was funded or otherwise assisted by, government agencies, such as the National Institutes of Health, for development of our technology and product candidates. Government agencies have provided, and may in the future provide, funding, facilities, personnel, or other assistance in connection with the development of the intellectual property rights owned by or licensed to us. Such government agencies may have retained rights in such intellectual property, including the right to grant or require us to grant mandatory licenses or sublicenses to such intellectual property to third parties under specified circumstances, including if it is necessary to meet health and safety needs that we are not reasonably satisfying or if it is necessary to meet requirements for public use specified by federal regulations, or to manufacture products in the United States. Any exercise of such rights, including with respect to any such required sublicense, could result in the loss of significant rights and could harm our ability to commercialize or continue commercializing products that are subject to government rights. For example, at least one of our in- licensed patent cases related to each of our ex vivo and in vivo cell engineering platforms has been funded at least in part by the United States government. As a result, these patent cases are subject to certain federal regulations pursuant to the Bayh- Dole Act of 1980 (Bayh- Dole Act). In particular, the federal government retains a " nonexclusive, nontransferable, irrevocable, paid- up license " for its own benefit to inventions produced with its financial assistance. The Bayh- Dole Act also provides federal agencies with " march- in rights, " which allow the government, in specified circumstances, to require the contractors or successors in title to the patent to grant a " nonexclusive, partially exclusive, or exclusive license " to a " responsible applicant or applicants. " If the patent owner refuses to do so, the government may grant the license itself. Intellectual property rights discovered under government- funded programs are also subject to certain reporting requirements, compliance with which may require us or our licensors to expend substantial resources and failure to comply may lead to loss of rights. Such intellectual property is also subject to a preference for United States industry, which may limit our ability to contract with foreign product manufacturers for products covered by such intellectual property rights. Moreover, we cannot be sure that any intellectual property we may co- develop with academic institutions in connection with preclinical research or development activities will be free from government rights pursuant to the

Bayh- Dole Act. If, in the future, we co- own or in- license technology that is critical to our business and is developed in whole or in part with federal funds subject to the Bayh- Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected. If we are unable to obtain and maintain sufficient intellectual property protection for our platform technologies and product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our platform technologies and product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business. We have filed numerous patent applications and anticipate that we will file additional patent applications both in the United States and in other countries, as appropriate. However, we cannot predict: • if and when any patents will issue from our owned and in- licensed patent applications, and whether the claims of any such issued patent will cover our product candidates and platforms or uses thereof in the United States or in other foreign countries; • the degree and range of protection any issued patents will afford us against competitors, including whether third parties will find ways to invalidate or otherwise circumvent our patents; • whether others will apply for or obtain patents claiming inventions similar to those covered by our patents and patent applications; or • whether we will need to initiate litigation or administrative proceedings to defend our patent rights, which may be costly whether we win or lose. Obtaining and enforcing patents is expensive and time- consuming, and we may not be able to file, and we and our licensors may not be able to prosecute, all necessary or desirable patent applications or maintain, defend, or enforce patents that may issue based on our patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection or before another party files a patent application covering the relevant inventions. Although we enter into confidentiality agreements with parties that have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors, and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Composition of matter patents for biological products such as ex vivo and in vivo cell engineering product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. We cannot be certain, however, that the claims in our pending patent applications covering the composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office (USPTO) or by patent agencies in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products " off- label " for those uses that are covered by our method of use patents. Although off- label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement may be difficult to prevent or prosecute. One aspect of the determination of patentability of inventions depends on the scope and content of the " prior art, " which is information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our inventions or, if issued, affect the validity or enforceability of a patent claim. Further, we may not be aware of all third- party intellectual property rights potentially relating to our product candidates or their intended uses, and as a result, the impact of such third- party intellectual property rights on the patentability of our own patents and patent applications, as well as upon our freedom to operate, is highly uncertain. Because patent applications in the United States and most other countries are typically confidential for a period of 18 months after filing, or may not be published at all, we cannot be certain that we were **or will be** the first to file any patent application related to our product candidates. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Furthermore, for United States patent applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be instituted by a third party or the USPTO to determine who was the first to invent any of the subject matter covered by the relevant patent claims. For United States patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law in view of the passage of the Leahy- Smith America Invents Act (the Leahy- Smith Act), which introduced significant changes to the United States patent laws, including new procedures for challenging pending patent applications and issued patents. The strength of patents in the biotechnology and pharmaceutical fields can be uncertain and evaluating the scope and validity of such patents involves complex legal, factual, and scientific analyses, which may vary based on the jurisdiction in which the analyses are performed. Patents have in recent years been the subject of much litigation in the United States and worldwide, resulting in court decisions, including United States Supreme Court decisions, that have increased uncertainties as to the patentability of certain inventions as well as the enforceability of patent rights in the future. The patent applications that we own or in- license may fail to result in issued patents with claims that cover our platform technologies or our product candidates or uses thereof in the United States or in other foreign countries. Even if patents do successfully issue, third parties may challenge the patentability, validity, enforceability, or scope thereof, which may result in such patents being narrowed, invalidated, revoked, or held unenforceable. In the event of litigation or administrative proceedings involving our issued patents, we cannot be certain that the claims of any such patent will be considered patentable by administrative bodies or valid by courts in either the United States or foreign countries. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately cover our platform technologies or product candidates or prevent others from designing their products to avoid being covered by our patent claims. If the breadth or strength of protection provided by our patent filings is threatened, companies may be dissuaded from collaborating with us to develop, and could threaten our ability to successfully commercialize, our product candidates. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, or vice versa. Further, as patent rights are time limited, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope, or expiration of a third- party patent, which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope or validity of patent claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application worldwide, including in the United States, that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. The scope of a patent' s claims is determined by an interpretation of the laws of the country in which the patent has been granted, the written disclosure in the patent, and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent worldwide, including in the United States, that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. Intellectual property rights do not necessarily protect us from all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • we may not develop proprietary technologies that are patentable; • we may choose not to file a patent in order to maintain certain rights as trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property; • our pending patent applications may not lead to issued patents for various reasons; • we or our licensors or future collaborators might not have been the first to make the inventions covered by, or the first to file, certain issued patents or pending patent applications that we own or have exclusively licensed, which may jeopardize our or our licensors' or future collaborators' ability to obtain an issued patent or the validity of any issued patents; • the scope of protection of any patent that may issue from our own or our in- licensed patent applications is unpredictable and may not cover our product candidates or uses thereof in the United States or in other foreign countries; • the claims of any patent that may issue based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties; • others may develop product candidates or technologies that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed; • others may independently develop similar or alternative technologies or duplicate our technologies without infringing our intellectual property rights; • our competitors may 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 need to initiate litigation or administrative proceedings to enforce or defend our patent rights, which will be costly regardless of outcome; • issued patents that we own or have exclusively licensed may be revoked or may be held invalid, unpatentable, unenforceable, or not infringed, including as a result of efforts to enforce our patents and legal challenges; • we may fail to adequately protect and police our trade secrets and trademarks; and • third- party patent rights may have an adverse effect on our business, including **if** these rights claim subject matter similar to or improving that covered by our patents and patent applications. Should any of these events occur, they could significantly harm our business, results of operations, and prospects. Confidentiality agreements with employees and third parties may not prevent ~~unauthorized~~ disclosure of trade secrets and other proprietary information. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, subject matter for which patents are difficult to enforce, and other elements of our product candidates, technology, and product discovery and development processes that involve proprietary know- how, information, or technology that we do not cover through patent protection. Any disclosure, either intentional or unintentional, by our current or former employees, contractors, collaborators, or those of third parties, including those with whom we share our facilities and consultants and vendors that we engage to perform research, clinical trials, or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary or confidential information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we **rely and** expect **to continue** to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Trade secrets and confidential information, however, can be difficult to protect. We seek to protect our trade secrets, know- how, and confidential information, including our proprietary processes, in part, by entering into confidentiality agreements with our employees, consultants, outside scientific advisors, contractors, ~~and~~ collaborators **, and other third parties** . We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. In addition, we enter into agreements with our consultants, contractors **, service providers** , and outside scientific collaborators that typically include invention assignment obligations. 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 or confidential information, including our technology and processes. Although we use reasonable efforts to protect our trade secrets and confidential information, our employees, consultants, outside scientific advisors, contractors, ~~and~~ collaborators **, and other third parties** might intentionally or inadvertently disclose such information to competitors **or other third parties** , including, as to consultants and advisors, to their primary employers, in breach of our agreements with such parties, and adequate remedies for such breaches may be unavailable. In addition, competitors may otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques **. Further, we may be required to disclose trade secrets and other confidential information to governmental authorities, including in connection with regulatory filings related to our product candidates, and such authorities may make certain documentation or information contained therein available to the public. If we are unable to or otherwise fail to take advantage of any opportunity to protect such trade secrets or other confidential information, our competitors could use such information to compete with us, which would significantly harm our business** . Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time- consuming, and the outcome is unpredictable. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties or misappropriation of our intellectual property by third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results, and financial condition. Third- party claims of intellectual property infringement against us or our collaborators may prevent or delay our product discovery, development, or commercialization efforts. Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. We cannot be certain that our platform technologies, product candidates, and other proprietary technologies we may develop will not infringe existing or future patents owned by third parties. The legal and administrative landscape related to infringement of the patents and proprietary rights of third parties is fluid as there is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents. These include interference, derivation, inter partes review, post- grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Litigation and other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time- consuming and, even if resolved in our favor, are likely to divert significant resources from our core business and distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to enter into or compete in the marketplace. Furthermore, patent reform and changes to patent laws add uncertainty to the possibility of challenge to our patents in the future. Numerous issued patents and pending patent applications owned by third parties may exist worldwide in the fields in which we are developing our platform technologies and product candidates. We cannot provide any assurances that third- party patent filings that might be enforced against the making, use, or sale of our current product candidates or future products do not exist, which, if they did exist, would result in either an injunction prohibiting our sales, or an obligation to pay royalties on product sales or other forms of compensation to third parties. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates will be subject to claims of infringement of the patent rights of others. Third parties may assert that we infringe their patents or other intellectual property, or that we are otherwise employing their proprietary technology without authorization, and may sue us. There may be third- party patent filings of which we are currently unaware with claims, including claims to compositions, formulations, methods of manufacture, or methods of use or treatment, that cover our product candidates. It is also possible that patent filings owned by third parties of which we are aware, but which we do not believe are relevant to our platform technologies, product candidates, or other proprietary technologies we may develop, could be found to be infringed by our product candidates. Because patent applications can take many years to issue, there may be pending patent applications, including those of which we are unaware, that may later result in issued patents that our product candidates may infringe. In addition, third parties, including our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may obtain patents in the future that may prevent, limit, or otherwise interfere with our ability to make, use, and sell our product candidates, and may claim that use of our technologies or the manufacture, use, or sale of our product candidates infringes upon these patents. If any such third- party patents were held by a court of competent jurisdiction to cover our technologies or product candidates, or if we are found to otherwise infringe a third party' s intellectual property rights, the holders of any such patents may be able to block, including by court order, our ability to develop, manufacture, use, sell, or commercialize the applicable product candidate unless we obtain a license under the applicable patents or other intellectual property, or until such patents expire or are finally determined to be held unpatentable, invalid, or unenforceable. Such a license may not be available on commercially reasonable terms or may not be available at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, our ability to commercialize our product candidates may be impaired or delayed, which could significantly harm our business. The pharmaceutical and biotechnology industries have produced a considerable number of patents, and it may not always be clear to industry participants, including us, which patents cover the making, use, or sale of various types of products or methods of use. The scope of patent coverage is subject to interpretation by both administrative bodies and the courts, and the interpretation is not always predictable or uniform. If we were sued for patent infringement, we would need to demonstrate that the making, use, or sale of our product candidates, products, or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, which we may not be able to do.

Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents, and there is no assurance that a court would invalidate the claims of any such patent. Third parties asserting their patent or other intellectual property rights, such as confidential information or trade secrets, against us may also seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates or force us to cease some of our business operations. We may not have sufficient resources to bring any these actions to a successful conclusion. Defense against any of these claims, regardless of their merit and whether we are successful or not, would require us to incur substantial costs and could divert management and other employee resources from our business, cause development delays, and impact our reputation, which could have a material adverse effect on our business and operations. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties, or redesign our infringing products, which may be impossible to do on a cost- effective basis or require substantial time and monetary expenditure. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Our issued patents and patent applications could be found unpatentable, invalid, or unenforceable if challenged in courts or before an administrative body, and we may be involved in lawsuits to protect or enforce our patents or other intellectual property or the intellectual property of our licensors. Our participation in any such action could be expensive, time- consuming, and unsuccessful. Our issued patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, our patent applications may be subject to a third- party pre- issuance submission of prior art to the USPTO, or we may become involved in post- grant review proceedings, opposition or derivation proceedings, reexaminations, or inter partes review proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. In addition, interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions or the correct inventorship of the inventions claimed in our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. An adverse determination in any such proceeding may result in loss of exclusivity or in our patent claims being narrowed, invalidated, held unpatentable, or held unenforceable, in whole or in part, which could limit our ability to exclude others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products, and otherwise no longer protect our product candidates. In addition, competitors may infringe our issued patents or other intellectual property or the intellectual property of our licensors. To cease such infringement or unauthorized use, we may be required to file patent infringement claims, which can be expensive and time- consuming and could divert the time and attention of our management and personnel. If we or one of our licensors initiates legal proceedings against a third party to enforce a patent covering one of our platform technologies or product candidates, the defendant could counterclaim that we infringe their patents or that the patent covering our product candidate is invalid or unenforceable, or both. In patent litigation in the United States or abroad, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent, including lack of novelty, obviousness, non- enablement, or insufficient written description, or that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation, using post- grant proceedings such as re- examination, inter partes review, post- grant review, opposition, or derivation proceedings. The outcome following legal assertions of unpatentability, invalidity, or unenforceability is unpredictable. In a proceeding before an administrative body, there is a risk that the body will decide that a patent is unpatentable or will be revoked, in whole or in part. In any patent infringement proceeding or declaratory judgment action, there is a risk that a court will decide that a patent of ours or our licensors is invalid or unenforceable, in whole or in part. In the event of either decision, we would no longer have the right to stop another party from using the invention covered by the relevant patent. There is also a risk that, even if the validity of such a patent is upheld, the court or administrative body 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 our patent claims do not cover the invention. The court could also decide that the other party' s use of our patented technology falls under the safe harbor to patent infringement under 35 U. S. C. § 271 (e) (1). With respect to the validity and patentability of our patents, for example, we cannot be certain that there is no invalidating prior art of which we, our patent counsel, and the patent offices were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for the relevant product candidate, which could limit our ability to assert our patents against those parties or other competitors and prevent us from excluding third parties from making, using, or selling similar or competitive products. Even if we establish infringement of our or our licensors' intellectual property, the remedies may be insufficient. For example, the court may decide not to grant an injunction against further infringing activity 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 in the course of litigation. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the price of our common stock could be substantially adversely affected. Litigation, interference, derivation, or other proceedings involving our or our licensors' patents may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. Any failure to obtain or maintain patent protection with respect to our product candidates and other technologies, including as a result of such proceedings, could have a material adverse effect on our business, financial condition, results of operations, and prospects. The terms of our patents may not be sufficient to effectively protect our products and business. Patents have limited terms, and in many jurisdictions worldwide, including the United States, if all maintenance fees are timely paid, the natural expiration of a patent' s term is generally 20 years after its first effective non- provisional filing date. Although various extensions may be available, the term of a patent, and the protection it affords, is limited. Given the significant amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. Further, if we encounter delays in our clinical trials, the period of time during which we could market our product candidates under patent protection would be reduced. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic therapies. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing product candidates similar or identical to ours. Our patents issued as of ~~February~~ **January** ~~2023~~ **2024** have terms expected to expire on dates ranging from ~~2023~~ **2028** to 2042, subject to any patent term extensions that may be available. If patents are issued on our patent applications pending as of ~~February~~ **January** ~~2023~~ **2024** , the resulting patents are projected to expire on dates ranging from ~~2023~~ **2028** to 2044. In addition, although upon issuance in the United States a patent' s term can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. A patent term extension based on regulatory delay may also be available in the United States and in certain other foreign jurisdictions. However, in the United States, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension in the United States does not extend to the full scope of the patent' s claims, but instead only as to the scope of the product as approved. The laws governing analogous patent term extensions in foreign jurisdictions vary widely and many differ from the process in the United States. Additionally, we may not receive a patent term extension if we fail to exercise due diligence during the testing phase or regulatory review process, fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. If we are unable to obtain a patent term extension for any particular patent, or the term of any such extension is less than we request, the period during which we will have the right to exclude others from using the patent rights will be shortened. Our competitors may be able to obtain approval of competing products following our patent expiration and take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data to launch a biosimilar product earlier than might otherwise be the case, which could reduce our revenue, possibly materially. In general, if we do not have sufficient patent term to protect our platform technologies and product candidates, our business and results of operations will be adversely affected. Third parties may challenge the inventorship or ownership of or otherwise assert rights in our patent and other intellectual property rights. We may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patents or other intellectual property, including as a result of being an inventor or co-inventor. In the United States, the failure to name the proper inventors on a granted patent can result in the patent being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions made to an invention by the individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates, or as a result of questions regarding co- ownership of potential joint inventions. For example, inventorship disputes may arise from conflicting obligations of consultants or others who are involved in developing our platform technologies or product candidates or related intellectual property. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. Litigation may be necessary to defend against claims challenging or relating to inventorship and ownership of intellectual property rights. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or the right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distract management and other employees. We or our licensors may have relied on third- party consultants or collaborators or on funds from third parties, such as the United States government, such that we or our licensors are not the sole and exclusive owners of the patents that we own or that we have in- licensed. If third parties have ownership rights or other rights to our patents, including in- licensed patents, they may be able to license such patents to our competitors, and our competitors could make, use, or sell competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects. In addition, although it is our policy to require our employees ~~and~~ **,** contractors **and other third parties** who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. As described elsewhere in these Risk Factors, such claims could be expensive and time- consuming to litigate or defend and could divert the time and attention of our management and other personnel, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ and engage individuals who were previously employed by or have otherwise provided services for other organizations, including at other biotechnology or pharmaceutical companies or at academic institutions. We may be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or organizations. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could cause us to incur substantial costs and distract our management and employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of these third parties or organizations. Moreover, any such litigation or the threat thereof may adversely affect our reputation and our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors, or hire employees or consultants, each of which would have an adverse effect on our business, results of operations, and financial condition. Our internal computer systems, or those used by third parties involved in our operations, such as research institution collaborators, CROs, CDMOs, and other service providers, contractors, or consultants, may fail or suffer security breaches **or incidents** . We and third parties involved in our operations are increasingly dependent upon information technology systems, infrastructure, and data to operate our business. In the ordinary course of business, we currently and will continue to collect, store, and transmit confidential information (including trade secrets or other intellectual property, proprietary business information, including data from our research **, preclinical studies,** and clinical trials ~~we plan to conduct~~ , and personal information). It is critical that we and these third parties do so in a secure manner to maintain the confidentiality, integrity **,** and availability of such information. For example, we have outsourced elements of our operations to third parties, and as a result we manage a number of third- party vendors that have access to our confidential information, including those that provide information technology and data security systems and services ~~. Although~~ **, and** we ~~generally~~ **do not** have ~~agreements requiring such vendors to use industry standard practices for data security, we have no~~ operational control over ~~them~~ **these third- party vendors** . In addition, we currently and may in the future share or exchange confidential information with other third parties, such as collaborators, licensors, or strategic partners, none of which we have control over and all of which are subject to similar security risks as we are. As such, we are subject to risks not only from security incidents involving our own systems and networks, but also those of third parties with whom we work. Despite the implementation of security measures (including edge technology designed to identify and protect our network from infiltration by third- party systems), our internal computer systems and those of any third parties involved in our operations, including our third- party research institution collaborators, CROs, CDMOs, and other service providers, contractors, and consultants, including vendors of information technology and data security systems and services, are vulnerable to damage and interruptions from cyberattacks, security breaches **and incidents** , computer viruses, ransomware, fraud, and ~~similar~~ **other compromises and** incidents involving ~~the loss of~~ or **leading to** unauthorized access to **or loss, modification, unavailability, use, disclosure, or other processing of** confidential information. **In addition, certain systems or components thereof require enhanced or otherwise different security measures, which may require us to invest additional resources and may leave such systems more vulnerable to security compromises or incidents.** These **compromises and incidents** may involve acts by current or former employees, service providers (including providers of information technology- specific services), nation states (including groups associated with or supported by foreign intelligence agencies), organized crime organizations, " hacktivists, " or others. For example, SolarWinds Corporation (SolarWinds), a provider of information technology monitoring and management products and services that we ~~use~~ **used** , experienced a cyberattack in 2020 that was likely the result of a supply chain attack by an outside nation state. We took steps to mitigate the vulnerabilities identified within these products and, following our investigations, concluded that our confidential information was not materially accessed, lost, or stolen as a result of this cyberattack. However, there may be unknown effects from this or other cyberattacks that have occurred or may occur in the future, any of which could have a material negative impact on our business. In addition, **in certain cases, we may rely on or incorporate third- party software, code, or other similar materials into our systems, processes, and operations, such as in the case of internal software development, which exposes us to various risks, including that such third- party materials may have harmful components that could enable access and harm to our systems and confidential information. If we are unable to or otherwise do not detect these harmful components, or are unable to manage their effects, our business could be significantly harmed. In addition,** the current geo- political climate and tensions between the United States and certain countries, including Russia and China, may increase our vulnerability to such cybersecurity attacks. For example, ~~following~~ **the conflict between** Russia **and** ~~' s invasion of~~ Ukraine **may create heightened threats of** ~~in late February 2022, there is an increased risk that Russia' s cyber activities, including in particular,~~ ransomware attacks ~~, will expand~~ and **other cybersecurity** ~~affect organizations worldwide, with a particularly heightened threat~~ **threats** for certain industries, including healthcare and pharmaceuticals. We continue to monitor and take steps to mitigate this risk ~~, including by following guidance of the Cybersecurity & Infrastructure Security Agency (CISA) and the Federal Bureau of Investigation (FBI) and exchanging information with third party organizations and attending briefings to learn more about actual and potential cyber threats~~ , but we cannot ensure that such efforts will be sufficient to protect us from any such cyberattacks or other incidents. In addition, in July 2022, the heads of the FBI and MI5 issued joint warnings regarding the threat posed by China to national security ~~in the United States, United Kingdom (UK), and allies in Europe and globally~~ due to the Chinese government' s increasing use of cyber espionage to steal technology from Western corporations and disrupt Western business. Moreover, the biotechnology industry is one of the top industries that China has targeted for domestic growth and development, and it therefore may be a primary target for such cyber espionage efforts. We continue to monitor our systems and upgrade our security capabilities in order to mitigate risk. However, any access to or loss or theft of our confidential information in connection with a future cyberattack could have a material adverse effect on our business. Threats involving the misuse of access **to** our network, systems, and information by our current or former employees or third parties involved in our operations, including service providers, contractors, vendors, or partners, whether intentional or unintentional, also pose a risk to the security of our network, systems, and information, including data. For example, we are subject to the risk that employees may inadvertently share confidential information with unintended third parties, or that departing employees may take, or create their own information based on, our confidential information upon leaving the company. In addition, any such insiders may be the victims of social engineering attacks that enable unauthorized third parties to access our network, systems, and information using an authorized person' s credentials. We and our network, systems, and information are also vulnerable to malicious acts by insiders, including leaking, modifying, or deleting confidential information, or performing other acts that could materially interfere with our operations and business. Although we provide regular training to our employees regarding cybersecurity threats and best practices, we cannot ensure that such training or other efforts will prevent unauthorized access to or sabotage of our network, systems, and information. Although we have not, to our knowledge, experienced any material system failure, accident, or security breach to date, because techniques used to obtain unauthorized access to or to sabotage systems are constantly evolving and generally are not recognized until they are launched against a target, we cannot be sure that our ~~continued~~ **current practices, including our** security and data protection efforts and investment in information **security and** technology will **detect or** prevent future significant breakdowns, data leakages, breaches in our systems or the systems of third parties involved in our operations, such as ~~services~~ - **service** providers, contractors, and collaborators, or other ~~cyber~~ **compromises or** incidents that could have a material adverse effect upon our reputation, business, operations, or financial condition. If such an event were to occur, it could materially disrupt our operations and programs, ~~and~~ the development of our product candidates could be delayed or otherwise negatively impacted **, and our business could be significantly harmed** . Any such event that leads to unauthorized access **to or loss, modification, unavailability** , use, ~~or~~ disclosure **, or other processing** of personal information, including personal information regarding our clinical trial subjects or employees **, or any reporting or belief that any such event or impact has occurred** , could delay further development and commercialization of our product candidates, harm our reputation directly, require us to comply with federal or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information. As a result, we could incur significant legal and financial exposure and reputational harm that could have a material adverse effect on our business. In any case, if we experience a cyberattack or ~~other~~ security **breach or** incident, we could incur significant costs to remedy the resulting damage, including costs to deploy additional personnel and security and protection technologies, train employees, and engage third- party experts and consultants **. We and the third parties involved in our operations may face difficulties and delays in identifying, responding to, and remediating security breaches and incidents, and we may find it necessary or appropriate to put in place additional measures designed to identify, protect against, and otherwise address cyberattacks and security breaches and incidents** . 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 commercially reasonable terms or at all **. Further, our personnel, and those of any third parties involved in our operations, including vendors, service providers, collaborators, contractors, and consultants, may develop and use artificial intelligence technologies in the course of performing work for us, including generative artificial intelligence technologies (GenAI) that have the ability to output new content and information based on user inputs. GenAI has the potential to benefit our business and operations, possibly significantly, including by potentially creating efficiencies and enabling powerful research and development that may otherwise not be possible, and we may be at a competitive disadvantage if we do not or are unable to use GenAI, or only use it for limited purposes. However, use of GenAI in connection with our confidential, proprietary, or otherwise sensitive information, including personal data, may result in leaks, disclosure, or otherwise unauthorized or unintended access to or use or other processing of such information, including incorporation of such information into the applicable GenAI system or use of such information to further refine and train the GenAI models. Any such access or use, or any improper or inappropriate use, of GenAI could, for example, reveal trade secrets or other confidential information that may enable third parties to replicate or improve upon our technologies and programs, advance their technologies or programs more rapidly than we do, or otherwise negatively impact the value of, or our ability to obtain or maintain, intellectual property rights. Access to and use and other processing of personal data may subject us to risks and potential liability and obligations under applicable data privacy laws, as described elsewhere in these Risk Factors. Further, we may use the output of GenAI in our technologies, programs, and other aspects of our business, and such output could incorporate third party intellectual property, or we may otherwise be unable to own, protect, further develop, or ultimately use such output, which could significantly harm our business to the extent such technologies, programs, or other aspects of our business rely upon such output. Such output may also be false, non- sensical, biased, or otherwise harmful to our operations and business if incorporated therein. Further, our ability to use GenAI or further develop or use its output may depend on access to specific third- party software and infrastructure, such as processing hardware or third- party artificial intelligence models, and we cannot control the availability or pricing of such software and infrastructure, especially in a highly competitive environment. We may also face novel and urgent cybersecurity risks and emerging ethical risks relating to the use of GenAI, which could adversely affect our operations, assets, including intellectual property and data, and reputation, as well as those of any third parties involved in our operations. Use of artificial intelligence technologies in general, and GenAI in particular, in our business could subject us to additional costs and expenses, litigation, regulatory actions and investigations, and other negative consequences. There is significant uncertainty with respect to the nature of the laws and regulations that have been and may in the future be adopted, including how such laws and regulations will be interpreted and applied, both within and outside of the U. S., with respect to the use of artificial intelligence technologies in general, and GenAI in particular, including the ownership of or right to use the output of GenAI. We may need to expend significant resources to modify and maintain our business practices to comply with such laws and regulations and to otherwise ensure appropriate and lawful use of artificial intelligence technologies, including GenAI and its output, in our technologies, programs, and other aspects of our business** . In addition, we have entered into and expect to continue to enter into collaboration, license, contract research, and manufacturing relationships with organizations that operate in certain countries that are at heightened risk of technology, data, and intellectual property theft through direct intrusion by private parties or foreign actors, including those affiliated with or controlled by state actors. If any theft or intrusion affects our technology, data, or intellectual property, the value of such technology, data, or intellectual property to our company may be diminished and our competitive position could be harmed. In such a case, our efforts to protect and enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from such intellectual property, and we may be at heightened risk of losing our proprietary intellectual property rights around the world, including outside of such countries, to the extent such theft or intrusion destroys the proprietary nature of our intellectual property. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. We currently and in the future will need to maintain and protect our trademarks and trade names to ensure, among other things, name recognition by potential partners and, if our products receive regulatory approval, customers in our markets of interest. We may not be able to protect our rights in our current or future trademarks and trade names or may be forced to stop using these trademarks or trade names, including as a result of such trademarks and trade names being challenged, infringed, circumvented, or declared generic or descriptive, or being determined to infringe on other marks. In any such case, we may no longer be able to enforce or use our rights in these trademarks and trade names. During trademark registration proceedings, our applications may be rejected by the USPTO or comparable foreign agencies. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in many comparable foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to collaborators or to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these guidelines or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Moreover, any name we may propose to use as a trade name for any of our product candidates in the United States must be approved by the FDA, regardless of whether we have applied to register it as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or a comparable foreign regulatory authority objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would be registerable under applicable trademark laws, not infringe the existing rights of third parties, and be acceptable to the FDA or comparable foreign regulatory authority. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. At times, competitors or other third parties may adopt trademarks or trade names similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trademark or trade name infringement claims brought against us by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. If we assert trademark infringement claims against third parties, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Changes in United States and foreign patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, and patent rights in particular. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time- consuming, and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs associated with protection of, and may diminish our ability to protect, our inventions and our ability to obtain, maintain, and enforce our intellectual property rights and, more generally, could adversely affect the value of our intellectual property or narrow the scope of our owned and licensed patents. ~~Recent patent~~ **Patent** reform legislation in the United States and other countries, including the Leahy- Smith Act signed into law on September 16, 2011, could increase uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy- Smith Act introduced a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, and provide more efficient and cost- effective avenues for competitors to challenge patents. These include allowing third- party submission of prior art to the USPTO during patent prosecution and additional procedures to attack patents by USPTO- administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. In addition, under the Leahy- Smith Act, the United States transitioned to a first inventor to file system for filings made after March 2013, under which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. As a result, we must be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our platform technologies, product candidates, and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or our licensors' patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention if the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. The Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition, in 2012, the ~~European Union (EU) Patent Package (~~ EU Patent Package ~~)~~ regulations were passed with the goal of providing a single pan- European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. **The** ~~Implementation of the~~ EU Patent Package **was implemented on June 1,** ~~will likely occur in the first half of~~ 2023. ~~At that time~~ **As a result** , all European patents, including those issued prior to ratification of the European Patent Package, ~~will~~ **now** by default automatically fall under the jurisdiction of the UPC. The UPC ~~will provide~~ **provides** third parties, including our competitors, with a new forum to seek to centrally revoke our European patents and to seek to obtain pan-European injunctions. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. Under the current EU Patent Package, we ~~will~~ have the right to opt our patents out of the UPC ~~over~~ **for** the first seven years of the UPC' s existence, but doing so may preclude us from realizing the benefits of this new unified court. Furthermore, the patent position of companies in the biopharmaceutical industry is particularly uncertain. Various courts, including the United States Supreme Court, have rendered decisions that could negatively affect the actual or perceived value of patents, such as recent federal district and appellate court rulings that have narrowed the scope of patent protection available in certain circumstances, weakened the rights of patent owners in certain situations, and in certain cases invalidated patents entirely. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents once obtained. Depending on decisions by Congress, the federal courts, the USPTO, and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the 2013 case Assoc. for Molecular Pathology v. Myriad Genetics, Inc., the United States Supreme Court held that certain claims to naturally occurring substances are not patentable. Although we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by Congress, the federal courts, ~~or~~ the USPTO **, or the relevant law- making bodies in other countries** may impact the value of our patents. Accordingly, evolving ~~case law~~ **laws** in the United States and other countries may adversely affect our and our licensors' ability to obtain new patents or to enforce existing patents and may facilitate third- party challenges to any of our owned or licensed patents. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for ~~non- compliance~~ **noncompliance** with these requirements. The USPTO and foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar requirements during the patent application process. Additionally, periodic maintenance fees on any issued patent must be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. ~~Although~~ **We employ reputable law firms and other professionals to help us comply, and in many cases,** an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules **. However** , there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in a failure to perfect a priority claim, abandonment, or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, **failure to pay** ~~non- payment of~~ fees, and failure to properly legalize and submit formal documents. In any such event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Risks Related to Our Regulatory Environment The development and commercialization of biopharmaceutical products is subject to extensive regulation, and the regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time- consuming, and inherently unpredictable. If we are unable to obtain regulatory approval for our product candidates on a timely basis, or at all, our business will be substantially harmed. The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post- marketing information and reports, and other activities we may engage in relating to our product candidates are subject to extensive regulation. In the United States, marketing approval of biologics requires the submission of a BLA to, and approval of such BLA by, the FDA, before a party can market any product candidate in the United States. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing, and controls. Outside the United States, many comparable foreign regulatory authorities employ similar approval processes **. Any issues encountered by such regulatory authorities, including as a result of any prolonged government shutdown, could delay or otherwise negatively impact the development and commercialization of our product candidates. For example, closures of government agencies or staffing shortages or furloughs could increase the time required for interactions with regulatory authorities, including with respect to the review, acceptance, or approval of regulatory applications or other correspondence or submissions related to our product candidates, as well as our patent or other intellectual property applications, and could also result in delays in the interpretation and implementation of important laws and regulations relevant to our business** . To date, we have not submitted a BLA to the FDA or similar applications to comparable foreign regulatory authorities for any product candidate, and we cannot be certain that any of our product candidates will receive regulatory approval once a BLA or similar application has been submitted. The process of obtaining regulatory approval is expensive, uncertain, often takes many years following the commencement of clinical trials, and can vary substantially based upon the type, complexity, and novelty of the product candidates involved, as well as the target indications, patient population, and regulatory authority involved. As a company, we have no experience with the preparation and submission of a BLA or any other application for marketing approval. Further, the FDA has not yet granted approval for a therapeutic derived from stem cells, which we believe may increase the complexity, uncertainty, and length of the regulatory approval process for certain of our product candidates developed using our ex vivo cell engineering platform. In addition, the FDA has the authority to require a REMS plan as part of a BLA approval or after BLA approval, which may impose further requirements or restrictions on the distribution or use of an approved biologic, such as limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe- use criteria, and requiring treated patients to enroll in a registry. Our product candidates could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; • we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate satisfies the FDA' s or such comparable foreign regulatory authorities' legal standards with respect to safety, purity, and potency, or efficacy, for its intended patient population; • the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; • we may be unable to demonstrate that a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; • the data collected from clinical trials may not be sufficient to support the submission of a BLA or other comparable foreign submission or to obtain regulatory approval in the United States or elsewhere, or regulatory authorities may not accept a submission due to, among other reasons, the content or formatting of the submission; • the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities or those of CDMOs with which we contract for clinical and commercial product supply; and • the approval policies or regulations of the FDA or comparable foreign regulatory authorities may change in a manner that renders our clinical data insufficient for approval, including, for example, as a result of positive or negative data from third parties regarding other products or product candidates. The lengthy approval process, as well as the unpredictability of ~~future~~ clinical trial results, may prevent us from obtaining regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and prospects. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining whether and when regulatory approval will be granted for any product candidates, including those that we may submit for approval in the future. For example, regulatory authorities in various jurisdictions have in the past had, and may in the future have, differing requirements for, interpretations of, and opinions on preclinical and clinical data ~~. As a result~~ , ~~we~~ **and certain regulatory authorities may more closely scrutinize our data, including our processes for maintaining the integrity of and disseminating such data, in particular, as our product candidates advance into later stages of development. We** may be required to conduct additional preclinical studies, alter our proposed clinical trial designs, or conduct additional clinical trials to satisfy the regulatory authorities in each of the jurisdictions in which we hope to conduct clinical trials and develop and, if approved, market our products. ~~Further~~ **In addition** , ~~even if we believe the data collected~~ from **time** ~~clinical trials of our product candidates are promising, such data may not be sufficient~~ to **time,** ~~support approval by~~ the FDA **and** ~~or any~~ comparable foreign regulatory ~~authority~~ **authorities may adopt guidance in areas applicable to various aspects of our research and development programs, compliance with which could increase the time and expense required, or make it more difficult, to complete development activities and ultimately obtain regulatory approval** for **our product candidates** ~~various reasons, including those discussed elsewhere in these Risk Factors~~ . In addition, even if we obtain approval for any of our product candidates, regulatory authorities may grant such approval for fewer or more limited indications than we request, may not approve the price we intend to charge for such product, may grant approval contingent on the performance of costly post- marketing clinical trials, or may approve such product with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product. Notably, to date, the FDA has required that any patient receiving a gene therapy be followed for 15 years post- treatment. This post- treatment follow- up **, and any other requirements that the FDA or other regulatory authorities may impose for gene or cell therapy products,** increases the cost and complexity of developing and ultimately commercializing **such** ~~gene therapy~~ products. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates **. Certain of our product candidates, including SC262, may require or otherwise benefit from use of a companion diagnostic to such product candidate for efficacy, safety, or other reasons. If we or our collaborators are unable to successfully develop and obtain regulatory approval for any necessary companion diagnostics for these product candidates, or experience significant delays in doing so, we may be unable to obtain regulatory approval for, commercialize, and generate revenue from such product candidates or be unable to realize their full commercial potential. Certain of our product candidates, including SC262, may require or otherwise benefit from use of a companion diagnostic to such product candidate for efficacy, safety, or other reasons. In such cases, the FDA and comparable foreign regulatory authorities may require the development and regulatory approval or clearance of at least one companion diagnostic as a condition to approving such product candidate for use in the relevant patient population. We do not have experience in or capabilities for developing or commercializing companion diagnostics and expect that, if companion diagnostics are needed for our product candidates and satisfactory companion diagnostics are not commercially available, we will need to collaborate with third- party diagnostic development collaborators to perform these functions. The process of identifying suitable collaborators and developing and obtaining approval or clearance for companion diagnostics is lengthy, costly, uncertain, and time- consuming. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as medical devices and may require separate regulatory approval prior to commercialization. The approval or clearance of a companion diagnostic as part of a therapeutic product' s further labeling limits the use of the therapeutic product to only those patients who express the specific characteristic that the companion diagnostic was developed to detect. For any companion diagnostic developed for use with one of our product candidates, we or our collaboration partners may experience delays in obtaining or may be unable to obtain regulatory approval or clearance for or be able to continue marketing of such companion diagnostic for various reasons, such as difficulties in manufacturing, technology transfer activities, or obtaining adequate third- party reimbursement, which**

could harm our business. If we or our collaboration partners are unable to obtain necessary regulatory approvals or clearance for companion diagnostics necessary for our product candidates or experience delays in doing so, we may suffer significant negative consequences, including: • we may be unable to successfully complete clinical trials of the applicable product candidate; • the applicable product candidate may not receive marketing approval on a timely basis or at all, if its safe and effective use depends on use of a companion diagnostic; or • we may not realize the full commercial potential of the applicable product candidate. The occurrence of any of these events could harm our business, possibly materially . We may attempt to secure approval from the FDA or comparable foreign regulatory authorities through accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical or clinical studies, or additional data analysis from prior studies, beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive approval through the FDA' s accelerated approval pathway, if our confirmatory trials or additional analysis do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained. We may in the future seek accelerated approval for ~~our~~ one or more of our product candidates. Under the FDA' s Accelerated Approval Program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life- threatening condition that is reasonably likely to provide a meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is typically contingent on the sponsor' s agreement to conduct, in a diligent manner, additional confirmatory studies or additional data analysis from prior studies to verify and describe the drug' s clinical benefit. If such post- approval confirmatory studies or additional analyses fail to confirm the drug' s clinical benefit or are not completed in a timely manner or at all, the FDA may withdraw its approval of the drug on an expedited basis. In response to certain concerns regarding the current accelerated approval pathway, Congress has considered and may in the future consider legislation that could change aspects of the accelerated approval pathway, including in ways that may have uncertain outcomes. For example, in December 2022, President Biden signed an omnibus appropriations bill to fund the United States government through fiscal year 2023, included in which is the Food and Drug Omnibus Reform Act of 2022, which, among other things, introduced reforms intended to expand the FDA' s ability to regulate products receiving accelerated approval, including by increasing the FDA' s oversight over the conduct of confirmatory studies **, such as requiring the FDA to specify conditions for post- approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non- compliance with post- approval requirements. To the extent the FDA requires us to amend the design of our clinical trials or requires additional trials to meet changes in the data requirements for approval, our clinical timelines and approval will be delayed, which could have an adverse effect on our business and operations** . However, the ultimate impact of these reforms remains unclear. In addition, there is uncertainty regarding the extent to which reimbursement will be available for products that receive approval through this pathway. As a result, even if we obtain approval for a product candidate through this pathway, we may not receive reimbursement at the levels we expect, which could harm our ability to generate revenue and achieve or sustain profitability. The future of the Accelerated Approval Program is uncertain, and we cannot predict which, if any, additional changes Congress, the FDA, or other governmental authorities will make, when such changes will be adopted, or how existing or future changes will affect our business. These changes may alter the accelerated approval requirements in ways that make it more difficult or otherwise negatively impact our ability to obtain accelerated approval for our product candidates, and could increase the burden of compliance with post- marketing requirements, each of which could increase our costs and harm our ability to commercialize our products and achieve and sustain profitability. Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that, after our evaluation of the feedback and other factors, we will decide to pursue or submit a BLA for accelerated approval or any other form of expedited development, review, or approval, or that, if we decide to pursue any such pathway, ~~that~~ our applications will be granted on a timely basis or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. In addition, even if we are able to obtain accelerated approval or any other form of expedited approval for any of our product candidates, we may not obtain such approval in a timely manner or otherwise in accordance with our timelines, and the costs of obtaining such approval and performing any additional studies or analysis may be higher than we currently anticipate. Further, if the results of any such additional studies or analysis do not ultimately support full regulatory approval of the applicable product, it may be withdrawn from the market, which could harm our ability to generate revenue and otherwise negatively impact our business and financial prospects. A failure to obtain, or delay in obtaining, accelerated approval or any other form of expedited development, review, or approval for any of our product candidates would extend the period of time until commercialization, if any, of such product candidate, could increase the cost of development of such product candidate beyond what we anticipate, and could harm our competitive position in the marketplace. Even if our product candidates receive regulatory approval, we and such products will be subject to ongoing obligations and continued regulatory review, which may require us to incur significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal, and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, testing, labeling, packaging, distribution, import, export, adverse event reporting, storage, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing legal and regulatory requirements. These requirements include submission of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and GCP regulations for any clinical trials that we may conduct post- approval. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the approved product. Compliance with the requirements and limitations described in this paragraph, or any issues that arise in connection with such compliance, may require us to incur significant expense and limit our ability to timely and successfully commercialize our products. Manufacturers and their facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations, as well as, for the manufacture of certain of our product candidates, the FDA' s cGTP regulations for the use of human cellular and tissue products to prevent the introduction, transmission, or spread of communicable diseases. As such, we and our CDMOs will be subject to continual review and inspections to assess compliance with cGMP and cGTP regulations and adherence to commitments made in any approved marketing application. Accordingly, we and third parties that we engage or with which we conduct business must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, quality control, and distribution. In addition, if we obtain approval for any of our product candidates, our product labeling, advertising, and promotion will be subject to stringent legal and regulatory requirements and continuing regulatory review. In the United States, the FDA and the FTC strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false in any particular way, and adequately substantiated by clinical data. The promotion of a drug product in a manner that is false, misleading, unsubstantiated, or for unapproved (or off- label) uses may result in enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA or the FTC. In particular, a product may not be promoted for uses that are not approved by the FDA, as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may be subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant sanctions and false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid, and other federal and state healthcare programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If there are changes in the application of legislation or regulatory policies, or a regulatory authority subsequently discovers problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the manufacturing of such product, including the facility where it is manufactured, or disagrees with the promotion, marketing, or labeling of a product, such regulatory authority may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we or one of our distributors, licensees, or co- marketers fail to comply with applicable legal or regulatory requirements, a regulatory authority may, among other things: • issue warning or untitled letters; • issue, or require us to issue, safety- related communications, such as safety alerts, field alerts, " Dear Doctor " letters to healthcare professionals, or import alerts; • impose civil or criminal fines or penalties; • suspend, limit, or withdraw regulatory approval, which could require us to conduct additional clinical trials, change our product labeling, or submit additional applications for regulatory approval; • suspend any of our preclinical studies and clinical trials; • refuse to approve our pending applications or supplements to approved applications; • conduct inquiries investigations, which could require us to expend significant time and resources in response and generate negative publicity; • impose restrictions on our operations, the product, or its manufacture, including requiring us to close our and our CDMOs' facilities; or • impose regulatory sanctions, seize or detain products, refuse to permit the import or export of products, or require us to conduct a product recall or remove the product from the market. If any of these events were to occur or if we otherwise fail to comply with ongoing legal and regulatory requirements, our ability to commercialize and generate revenue from our product candidates could be significantly impaired and we may incur substantial additional expense, which could materially adversely affect our business, financial condition, results of operations, and the overall value of our company. Moreover, the policies of the FDA and ~~of~~ comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit, or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain, or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved, or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products may be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s ability to hire and retain key personnel, including personnel with the expertise necessary to evaluate product candidates such as ours, and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the FDA have fluctuated in recent years. Moreover, these and other factors have increased the uncertainties associated with interpreting the FDA' s guidance and predicting its areas of focus and responses to various issues. In addition, government funding of other government agencies 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 extend the time necessary for new biologics or modifications to licensed biologics to be reviewed or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the United States government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. ~~Separately, in response to the ongoing COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it has adapted to the evolving pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the ongoing COVID- 19 pandemic.~~ If a prolonged government shutdown occurs, or if global health concerns ~~continue to~~ **, staffing shortages, budget restrictions, or other changes in government policies** prevent the FDA or comparable foreign regulatory authorities from conducting their **normal operations, such as** regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Our business operations and current and future relationships with healthcare professionals, healthcare facilities and institutions, clinical investigators, consultants, vendors, customers, and third- party payors in the United States and elsewhere are subject to applicable anti- kickback, fraud and abuse, false claims, physician payment transparency, and other healthcare laws and regulations, which could expose us to substantial penalties, contractual damages, reputational harm, administrative burdens, and diminished profits. Healthcare providers, healthcare facilities and institutions, physicians, and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare professionals, healthcare facilities and institutions, clinical investigators, consultants, customers, and third- party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including the federal Anti- Kickback Statute and the federal False Claims Act, that may constrain the business or financial arrangements and relationships through which we research, sell, market, and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and regulation by the federal and state governments and by foreign jurisdictions in which we conduct our business. The applicable federal, state, and foreign healthcare laws that affect our ability to operate include, but are not limited to, the following: • the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving, or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, or recommendation of, any good, facility, item, or service, for which payment may be made, in whole or in part, under any United States federal healthcare program, such as Medicare and Medicaid. The term " remuneration " has been broadly interpreted to include anything of value, including stock options. The federal Anti- Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. Any arrangements with prescribers must be for bona fide services and compensated at fair market value. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the United States federal civil and criminal false claims laws, including the civil False Claims Act, which can be enforced by private citizens on behalf of the United States federal government through civil whistleblower or qui tam actions, and the federal civil monetary penalties law which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the United States federal government, claims for payment or approval that are false or fraudulent, knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease, or conceal an obligation to pay money to the United States federal government. Pharmaceutical manufacturers can cause false claims to be presented to the United States federal government by, among other things, engaging in impermissible marketing practices, such as the off- label promotion of a product for an indication for which it has not received FDA approval. Further, pharmaceutical manufacturers can be held liable under the civil False Claims Act even when they do not submit claims directly to government payors if they are deemed to " cause " the submission of false or fraudulent claims. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act; • the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing, or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items, or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation; • the Federal Food, Drug, and Cosmetic Act ~~(FDCA)~~ , which prohibits, among other things, the adulteration or misbranding of drugs, biologics, and medical devices; • the United States Public Health Service Act, which prohibits, among other things, the introduction into interstate commerce of a biological product unless a biologics license is in effect for that product; • the United States Physician Payments Sunshine Act ~~(Sunshine Act)~~ and its implementing regulations, which require, among other things, certain manufacturers of drugs, devices, biologics, and medical supplies that are reimbursable under Medicare, Medicaid, or the Children' s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare and Medicaid Services (CMS) information related to certain payments and other transfers of value to physicians, as defined by statute, certain non- physician practitioners (including physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse- midwives), and teaching hospitals, as well as ownership and investment interests held by such physicians and their immediate family members; • analogous United States state laws and regulations, including: state anti- kickback and false claims laws, which may apply to our business practices, including research, distribution, sales and marketing arrangements, and claims involving healthcare items or services reimbursed by any third- party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the United States federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state and local laws requiring the registration of pharmaceutical sales representatives; and • similar healthcare laws and regulations in foreign jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. We have entered into, and expect to enter into in the future, consulting and scientific and clinical advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our product candidates, if approved. Compensation under some of these arrangements may include the provision of stock or stock options in addition to or in lieu of cash consideration. Because of the complex and far- reaching nature of these laws, it is possible that governmental authorities could conclude that our payments to physicians may not be fair market value for bona fide services or that our business practices do not comply with current or future statutes, regulations, agency guidance, or case law involving applicable fraud and abuse or other healthcare laws and regulations. For example, these relationships and any related compensation could result in perceived or actual conflicts of interest, or the FDA' s determination that the financial relationship affected the conduct or interpretation of one of our preclinical studies or clinical trials. In such a case, the integrity of the data generated from such preclinical study or clinical trial may be questioned and the utility of the preclinical study or clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of any regulatory submissions related to our product candidates. Any such delay or rejection could prevent us from commercializing our product candidates. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal, and administrative penalties, damages, fines, exclusion from government- funded healthcare programs, such as Medicare and Medicaid, or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of noncompliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits, and the curtailment or restructuring of our operations. Further, defending against any governmental actions can be costly and time- consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions, our business may be impaired. In addition, if any of the physicians or other providers or entities with whom we expect to do business are found to violate applicable laws or regulations, they may be subject to criminal, civil, or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Our employees, independent contractors, principal investigators, consultants, vendors, commercial partners, and other third parties that we engage or with which we collaborate may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud and other misconduct committed by our personnel and third parties that we engage or with which we collaborate in the course of our operations, including our employees, independent contractors, principal investigators, consultants, vendors, and commercial partners. It is not always possible to identify and deter misconduct or business noncompliance by such parties. We cannot ensure that precautions we take to detect and prevent inappropriate conduct, including our compliance controls, policies, and procedures, will in every instance protect us or be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from unlawful acts committed by such parties in the jurisdictions in which we operate, including trade restrictions and sanctions and employment, foreign corrupt practices, environmental, competition, and patient privacy and other data privacy and protection laws and regulations. Misconduct by any such third parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we may establish, report financial information or data accurately, comply with federal and state healthcare fraud and abuse laws and regulations, including prohibitions on pricing, discounting, labeling, marketing and promotion, sales commission, customer incentive programs, and other business arrangements, or disclose unauthorized activities to us. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. If any actions are instituted against us as a result of such misconduct or noncompliance, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, we may be subject to or experience significant civil, criminal, and administrative penalties, damages, monetary fines, individual imprisonment, disgorgement of profits, possible exclusion from participation in Medicare, Medicaid, and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional reporting or oversight obligations if we become subject to a corporate integrity agreement or other agreement to resolve allegations of noncompliance with the law, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and pursue our strategy. Current and future legislation may increase the difficulty and cost for us and any future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may charge for such product candidates. In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, the Patient Protection and Affordable Care Act (the ACA) was enacted in 2010, which substantially changed the way healthcare is financed by both governmental and private payors. Among the provisions of the ACA of importance to the pharmaceutical and biotechnology industries, which includes biologics, are the following: • an increase in the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15. 1 % to 23. 1 % of the average manufacturer price; • expansion of the manufacturer Medicaid rebate obligation to drugs paid by Medicaid managed care organizations; • a requirement for manufacturers to participate in a coverage gap discount program, under which they must agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; • a non- deductible annual fee on pharmaceutical manufacturers or importers who sell " branded prescription drugs " to specified federal government programs; • a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; • establishment of a Center for Medicare and Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and • a licensure framework for follow- on biologic products. Since its enactment, there have been judicial, executive, and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the United States Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in force in its current form. Other legislative changes have been proposed and adopted in the United Stated since the ACA was enacted, including aggregate reductions of Medicare payments to providers through 2032. In addition, on March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, beginning January 1, 2024. Most significantly, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010. Among other things, the IRA requires, beginning in 2026, manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap; imposes rebates, first due in 2023, under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation; and, beginning in 2025, replaces the Part D coverage gap discount program with a new discounting program. The IRA permits the Secretary of the Department of Health and Human Services **(HHS)** to implement many of these provisions through guidance, as opposed to regulation, for the initial years. ~~For~~ **HHS has issued and will continue to issue and update guidance as these programs are implemented. On August 29, 2023, HHS announced the list of the first ten drugs** that ~~and~~ **will be subject to price negotiations, although** ~~other~~ -- **the** ~~reasons, it~~ **Medicare drug price negotiation program** is currently ~~unclear how~~ **subject to legal challenges. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of** the IRA **are unconstitutional. The** ~~will be effectuated, and while the~~ impact of the IRA **and these judicial challenges** on the pharmaceutical industry and our business cannot yet be fully determined, **but** it is likely to be significant. **If** ~~In any case, if~~ we obtain regulatory approval for any of our product candidates, the IRA could substantially and negatively impact the prices we may charge for such products, which could harm our ability to generate revenue and achieve and sustain profitability **. In addition, in response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Center for Medicare and Medicaid Innovation, which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future** . Additionally, individual states in the United States have passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing and costs. Similar developments have occurred outside of the United States, including in the EU where healthcare budgetary constraints have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. To obtain reimbursement or pricing approval in some EU member states, we may be required to conduct studies that compare the cost- effectiveness of our product candidates to other therapies that are considered the local standard of care. Further, there have been a number of, and there may in the future be, other policy, legislative, and regulatory proposals aimed at changing the pharmaceutical industry. The United States government, state legislatures, and foreign governmental entities have shown significant interest in implementing cost containment programs to limit the growth of government- paid healthcare costs, including price controls, restrictions on reimbursement and coverage, **drug importation programs and proposals,** and requirements for substitution of generic products for branded prescription drugs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit our product candidates from coverage and limit payments for pharmaceuticals. In addition, the policies of the FDA and of comparable foreign regulatory authorities may change and additional laws, regulations and government actions 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, either in the United States or abroad **. For example, if the Supreme Court reverses or curtails the Chevron doctrine, which gives deference to regulatory agencies in litigation against these agencies, including the FDA, more companies may bring lawsuits against the FDA to challenge its**

longstanding decisions and policies, which could undermine its authority, lead to uncertainties in the industry, and disrupt its normal operations, which could delay its review of any marketing applications we may submit for our product candidates . Moreover, currently enacted legislation may not be renewed once it expires, which may make it more difficult for us to obtain regulatory approval for and commercialize our product candidates. For example, the Prescription Drug User Fee Act (PDUFA) was enacted by Congress in 1992 to allow the FDA to collect fees from parties that produce certain human drug and biological products. Among other things, the fees collected under PDUFA provide for the timely review of regulatory submissions, such as BLAs. PDUFA has been renewed multiple times since its enactment, including at the end of September 2022, which will allow the FDA to continue collecting prescription drug user fees in future fiscal quarters. However, there is no guarantee that future renewals will occur in a timely manner, if at all. In addition, there may be amendments to PDUFA that could significantly affect how regulatory submissions are reviewed, and we cannot predict the extent of such amendments and how they will affect our business. If PDUFA is not renewed or its renewal is delayed, or if PDUFA is amended in certain ways, the FDA' s ability to review any regulatory submissions and related correspondence for our product candidates may be materially adversely impacted, which could negatively impact our development timelines and ability to obtain regulatory approval of our product candidates. In the EU, similar developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever- increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. On December 13, 2021, Regulation 2021 / 2282 on Health Technology Assessment (HTA) amending Directive 2011 / 24 / EU (the Regulation), was adopted in the EU. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once the Regulation becomes applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and providing the basis for cooperation at the EU level for joint clinical assessments in these areas. The Regulation will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non- clinical (e. g., economic, social, and ethical) aspects of health technology, and making decisions on pricing and reimbursement. In the UK, the Voluntary Scheme for Branded Medicines Pricing and Access (VPAS) currently returns a portion of funds to the National Health Service (NHS) based on the sales of branded prescription medicines (innovative brands, branded generics, and biosimilars) when a maximum sales growth rate is exceeded. The 2019 VPAS caps the growth of NHS branded medicine spending at a nominal rate of 2 % per year, with the industry returning any spending beyond the cap. However, the 2019 VPAS is due to come to an end in December 2023. It is possible that a future VPAS will include higher payback rates which could have a negative impact on our future potential NHS-based revenues. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative or executive action in the United States or any other jurisdiction. If we or any third parties we may engage or with which we collaborate are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may be unable to obtain regulatory approval or lose any regulatory approval that may have been obtained, and we may not achieve or sustain profitability. Even if we are able to commercialize any product candidate, coverage and adequate reimbursement may not be available or such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business. The regulations that govern regulatory approvals, pricing, and reimbursement for drug products vary widely from country to country. Some countries require approval of the sale price of a drug product before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription drug product pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval. Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third- party payors, such as government authorities, private health insurers, and other organizations **, which consider various factors in determining the level of coverage and reimbursement, including the nature of the disease to be treated, the availability and cost of other therapies for the same disease, and the size of the patient population that could benefit from such treatment** . Even if we succeed in bringing one or more products to the market, these products may not be considered cost- effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis **. For example, the cost of treatment with our product candidates may be expensive or more costly than other available treatment options, in particular, because such product candidates may require only a single or minimal number of administrations. Even if treatment costs are partially offset by coverage from third- party payors, required co- payments or deductibles may cause treatment with such product candidates to be too expensive for certain patients** . Because our product candidates are in the early stages of development, we are currently unable to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third- party payors that reimburse patients or healthcare providers are requiring that drug companies provide these payors with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts reimbursed for drug products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected. There may be significant delays in obtaining reimbursement for newly- approved drug products, and coverage may be more limited than the purposes for which the drug product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any product for which we receive regulatory approval will be reimbursed in all cases or at a rate that covers our costs, including for research, development, manufacture, sale, and distribution. Interim reimbursement levels for new drug products, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drug products that are already reimbursed, may be incorporated into existing payments for other services, and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drug products may be reduced by mandatory discounts or rebates required by third- party payors and by any future relaxation of laws that presently restrict imports of drug products from countries where they may be sold at lower prices than in the United States. Obtaining coverage and adequate reimbursement for our product candidates may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Similarly, because our product candidates are physician- administered injectables, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may or may not be reimbursed for providing the treatment or procedure in which our product is used. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. Third- party payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. As a result, the coverage determination process is often time- consuming and costly and will likely require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor- by- payor basis. One payor' s determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third- party payor' s decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. As discussed elsewhere in these Risk Factors, there have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal, and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict what initiatives 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 or impose price controls may adversely affect: • the demand for any of our product candidates that may receive regulatory approval; • our ability to set a price that we believe is fair for our approved products; • our ability to obtain coverage and reimbursement approval for an approved product; • 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. **Additionally, companion diagnostic tests that we or our collaborators may develop require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biologics products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biologics products, will apply to companion diagnostic tests.** Our inability to promptly obtain coverage and adequate reimbursement from third- party payors for the product candidates that we may develop and for which we obtain regulatory approval **or any companion diagnostics that we or our collaborators may develop** could have a material and adverse effect on our business, financial condition, results of operations, and prospects. We face potential liability related to the privacy of personal information, including health information we utilize in the development of products developed from our ex vivo cell engineering platform, as well as information we may obtain from research institutions participating in our clinical trials and directly from individuals. We and our partners and vendors are subject to various federal, state, and foreign data protection and privacy laws and regulations. If we fail **, or are alleged to fail,** to comply with these laws and regulations, we may be subject to litigation, regulatory investigations, enforcement notices, enforcement actions, fines, and criminal or civil penalties, as well as negative publicity, reputational harm, and potential loss of business. In the United States, our and our partners' and vendors' operations are subject to numerous federal and state laws and regulations, including state data breach notification laws and federal and state data privacy laws and regulations that govern the collection, use, disclosure, and protection of health information and other personal information. For example, most healthcare providers, including research institutions from which we obtain patient health information, are subject to data privacy and security regulations promulgated under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH). Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. For example, under HIPAA, we could potentially face substantial criminal or civil penalties if we knowingly receive protected health information from a HIPAA- covered healthcare provider or research institution that has not satisfied HIPAA' s requirements for disclosure of such health information, or otherwise violate applicable HIPAA requirements related to the protection of such information. Even when HIPAA does not apply, failure to take ~~appropriate~~ **reasonable** steps to keep consumers' personal information secure may constitute a violation of the Federal Trade Commission Act. Certain of the ~~research~~ materials we use in our therapeutic research and development efforts, as well as stem cell lines used as starting material in our ex vivo cell engineering product candidates, are derived from human sources, which may contain sensitive identifiable personal information regarding the donor. In addition, ~~once we commence clinical trials,~~ we or our partners or vendors may maintain or otherwise have access to sensitive identifiable personal information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who may enroll in our patient assistance programs **, if any** . We may become subject to further obligations under HIPAA as a result of our access to such information. In addition, our collection of personal information generally, including information of our employees **, human donors,** or ~~future~~ patients, may subject us to state data privacy laws governing the processing of personal information and requiring notification to affected individuals and state regulators in the event of a data breach involving such personal information. For example, we may be subject to state laws such as the California Consumer Privacy Act (CCPA) and its related regulations, and the California Privacy Rights Act (CPRA) ~~amending the CCPA~~ , which establish data privacy rights for **California** residents ~~of the State of California~~ , with corresponding obligations on businesses related to transparency, deletion, and opt- out of the selling of personal information, and grant a private right of action for individuals in the event of certain security breaches **that has increased the likelihood of, and risks associated with, data breach litigation** . The CPRA, which became effective on January 1, 2023, significantly ~~modifies~~ **modified** the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information **and imposing new audit requirements for higher risk data** . The CPRA also ~~creates~~ **created** a new state agency that is vested with authority to implement and enforce the CCPA and the CPRA ~~. New legislation relating to data~~ **, which could result in increased** privacy and **information** security **enforcement. Additional compliance investment and potential business process changes may also be required. Numerous similar laws, and other laws governing privacy and information security, such** ~~has~~ - **as Washington' s My Health, My Data Act, have** been **passed and continue to be** proposed ~~or enacted in various other states and~~ at the **state and** federal level ~~. Such~~ **, reflecting a trend toward more stringent privacy** legislation **in** ~~will continue to shape~~ the **United States** ~~data privacy environment nationally~~ . Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to confidential, sensitive, and personal information than federal, international, or other state laws, and such laws may differ from each other and have potentially conflicting requirements that would make compliance challenging, require us to expend significant resources **to** achieve compliance, and restrict our ability to process certain personal information. Any clinical trial programs **, including related regulatory filings,** and research collaborations that we engage in outside the United States may implicate international **laws and regulations concerning** data protection ~~laws~~ **and privacy** , including **those governing various aspects of clinical research and** , in the EU, the General Data Protection Regulation (GDPR). The GDPR imposes obligations in relation to the collection, **use, sharing, disclosure, transfer, and other** processing ~~, sharing, disclosure, transfer, and other use~~ of data relating to an identifiable living individual **within the European Economic Area (EEA)** , or " personal data, " including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training, and audit. The GDPR imposes stringent operational requirements for data controllers and data processors of personal data. Among other things, the GDPR requires that detailed notices be provided to clinical trial subjects and investigators, as well as maintenance of certain security levels for personal data and notification of data breaches or security incidents to appropriate data protection authorities or data subjects. Further, as a result of the **UK** ~~United Kingdom~~ ' s withdrawal from the EU effective as of December 31, 2020, we **are** ~~will be~~ required to comply with both the GDPR and the GDPR as incorporated into **UK** ~~United Kingdom~~ national law (UK GDPR) with respect to any clinical trial data generated from the EU and the **UK** ~~United Kingdom~~ , respectively, which may have differing requirements. We may be subject to diverging requirements under EU member state laws and **UK** ~~United Kingdom~~ law, such as whether consent can be used as the legal basis for processing of clinical trial data and the roles, responsibilities, and liabilities and respective data protection obligations as between CROs, clinical trial sites, and sponsors. As these laws develop and the rules diverge, we may need to make operational changes to adapt, which could increase our costs and adversely affect our business. The GDPR and UK GDPR regulate cross- border transfers of personal data out of the ~~European Economic Area (~~ EEA ~~)~~ and the United Kingdom, respectively. Recent legal developments in Europe have created complexity and uncertainty regarding the legality of and requirements with respect to transfers of personal data from the EEA and United Kingdom to the United States and other countries in which we or our partners or service providers may operate. **Case law from** ~~For example, on July 16, 2020,~~ the Court of Justice of the European Union (CJEU) ~~invalidated the EU- US Privacy Shield Framework (Privacy Shield), under which personal data could previously be transferred from the EEA and United Kingdom to United States~~ **states** ~~entities~~ that **reliance on** ~~had self- certified under~~ the ~~Privacy Shield scheme. The CJEU decision also created additional obligations and uncertainty regarding the use of~~ standard contractual clauses **, which are a standard** ~~for~~ **form** ~~such~~ **of contract approved by the European Commission as an adequate personal data transfer mechanism, alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case- by- case basis. We currently rely and expect to rely in the future on the EU standard contractual clauses, the UK Addendum to the EU standard contractual clauses, and the UK International Data Transfer Agreement, as applicable, to transfer personal data outside of the EEA and the UK, including to the United States. Following a period of legal complexity and uncertainty regarding international personal** data transfers ~~. In March 2022~~ , **particularly to** the United States ~~and EU announced a new~~ **, we expect that the** regulatory ~~regime intended~~ **guidance and enforcement landscape will continue** to **develop in** ~~replace the invalidated regulations~~ --- **relation to transfers to the** ~~; however, this new EU- US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for~~ United States ~~Signals Intelligence Activities. Subsequent European court~~ and ~~regulator decisions~~ **elsewhere. As a result, we may** have ~~taken a restrictive approach~~ to **make certain** ~~international~~ - **operational changes and implement revised standard contractual**

clauses and other relevant documentation for existing data transfers **within required time frames** ~~. As government authorities issue further guidance on personal data export mechanisms or start aggressively taking enforcement action based on such guidance or the CJEU decision, we could be subject to additional costs, complaints, regulatory investigations, or fines~~. If we are unable to transfer personal data between and among countries and regions in which we or our partners ~~or~~ **, collaborators,** vendors **, or clinical trial sites** operate, it could adversely affect the manner in which we operate our business, affect the geographical location or segregation of our relevant systems and operations, and adversely affect our financial results. These laws and regulations may also apply to service providers and vendors that store or otherwise process personal data on our behalf, such as CROs and other service providers that may support the conduct of our clinical trials and information technology or other vendors. If our data privacy or security measures fail to comply with applicable data privacy laws, or if a service provider or vendor misuses data we have provided to it or fails to safeguard such data, or otherwise fails to comply with such laws, we may be subject to litigation, regulatory investigations, enforcement notices, or enforcement actions imposing fines or requiring us to change the way we use personal data, as well as negative publicity, reputational harm, and potential loss of business. Failure to comply with the GDPR could result in penalties. Since we may be subject to the supervision of relevant data protection authorities under both the GDPR and the UK GDPR, we could be fined under each of those regimes independently in respect of the same breach. Penalties for certain breaches are up to the greater of € 20 million (£ 17. 5 million) or 4 % of our global annual turnover. In addition to fines, GDPR noncompliance may result in regulatory investigations, reputational damage, orders to cease or change our data processing activities, enforcement notices, assessment notices for a compulsory audit, or civil claims, including class actions **. As we continue to expand certain of our operations into other foreign countries and jurisdictions, we may be subject to additional laws and regulations that may affect how we conduct business** . We expect that we will need to expend significant capital and other resources to ensure ongoing compliance with applicable data privacy and security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations related to data privacy and security, even if we are not found liable, could be expensive and time- consuming to defend and could result in negative publicity that could harm our business. Moreover, even if we take all necessary action to comply with legal and regulatory requirements, we could be subject to a data breach or other unauthorized access of personal information, which could subject us to fines and penalties, as well as litigation and reputational damage. If we fail to keep apprised of and comply with applicable international, federal, state, or local **legal and** regulatory requirements and changes thereto, we could be subject to a range of **legal or** regulatory actions that could affect our or any collaborators' ability to **develop and** seek to commercialize our product candidates. Any threatened or actual government enforcement action, or litigation when private rights of action are available, could also generate negative publicity, damage our reputation, result in liabilities, fines, and loss of business, and require that we devote substantial resources that could otherwise be used in support of other aspects of our business. **We and third parties involved in our operations are subject to United States and certain foreign laws and regulations relating to export and import controls, sanctions, embargoes, anti- corruption, and anti- money laundering. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which would harm our business. We are subject to export control and import laws and regulations, including the United States Export Administration Regulations, United States Customs regulations, various economic and trade sanctions regulations administered by the United States Treasury Department' s Office of Foreign Assets Controls, the United States Foreign Corrupt Practices Act of 1977, as amended (FCPA), the United States domestic bribery statute contained in 18 U. S. C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. International trade, tariff, and import / export laws and regulations may require us to obtain licenses or permits in order to complete certain activities necessary for the research, manufacture, and development of our product candidates. Moreover, we expect such laws and regulations, along with associated guidance and interpretations, to evolve over time in ways that may impact various aspects of our business. The process for obtaining any necessary licenses or permits may be lengthy and time- consuming, and if we are not able to obtain any such licenses or permits in a timely manner, we may experience delays in our ability to manufacture, develop, and commercialize our product candidates. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, collaborators, and other third parties from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell products, if any, for which we receive regulatory approval outside the United States, to conduct clinical trials, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. In the ordinary course of our business, we may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We may be held liable for the corrupt or other illegal activities of our employees, agents, contractors, collaborators, and other third parties, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross- border operations. The United States government has and continues to make significant additional changes in United States trade policy and may continue to take future actions that could negatively impact United States trade. For example, as discussed elsewhere in these Risk Factors, legislation has been introduced in Congress to limit certain interactions with certain Chinese biotechnology companies. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what interactions, including**

products or services, may be subject to such actions, or what actions may be taken by the other countries in retaliation. If our interactions with parties affected by any such actions are limited or no longer possible, our business, liquidity, financial condition, or results of operations could be materially and adversely affected. Third parties involved in our operations, including CDMOs and other service providers, partners, and collaborators, may also be also impacted by various laws and regulations, including those described above, compliance with or the effect of which could negatively impact the ability of these third parties to perform their obligations under our agreements with or otherwise harm our relationships with such third parties. For example, recently proposed legislation and acts by United States lawmakers have called for limitations on certain genetic information that may be shared with certain Chinese biotechnology firms and review of certain of these firms for sanctions due to potential threats to United States national security. To the extent that this or similar legislation becomes law or reviews or other actions are initiated, and any third parties involved in our operations are the subject of these laws or actions, then our relationships with these third parties, and our programs and business generally, could be materially negatively impacted. Risks Related to Our Limited Operating History, Financial Condition, and Need for Additional Capital We ~~are a preclinical- stage biotechnology company and~~ have incurred significant losses since our inception, and we expect to incur losses for the foreseeable future. We have no products approved for commercial sale and may never achieve or maintain profitability. We **have** ~~are a preclinical- stage biotechnology company with~~ a limited operating history. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We have incurred significant losses since inception, have not generated any revenue from product sales, and have financed our operations historically through private placements of our convertible preferred stock and, more recently, through our **initial public offering (** IPO **)** . We expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. We had net losses of $ **283. 3 million, $** 269. 5 million, **and** $ 355. 9 ~~million, and 285. 3~~ million for the years ended December 31, **2023,** 2022, **and** 2021 ~~, and 2020~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ 1. ~~1~~ **3** billion, which includes cumulative non- cash charges related to the revaluation of our success payment liabilities and contingent consideration of $ ~~18~~ **10** . ~~6~~ **3** million and $ ~~99~~ **58** . ~~1~~ **3** million, respectively. Our losses have resulted principally from expenses incurred for the research and development of our ex vivo and in vivo cell engineering platforms, management and administrative costs, and other expenses incurred while building our business infrastructure. We expect our operating losses and expenses will ~~remain relatively flat~~ **decline in 2024, excluding one- time items, as a result of our strategic repositioning in October 2023, and likely increase** over the ~~next few years. If~~ **longer term from the 2024 level if** our clinical trials are successful, ~~our operating losses~~ and **if** ~~expenses will likely increase over the longer term as~~ we expand our research and development efforts. Our operating losses and expenses are, and will in the future likely be, driven by our ongoing operations and our potential future expanded operations, including if and as we: • expand our research and development efforts; • advance and expand the capabilities of our ex vivo and in vivo cell engineering platforms; • identify additional product candidates; • advance preclinical development of our current product candidates and initiate additional preclinical studies, including with respect to future product candidates; • commence and advance through clinical studies of our current and future product candidates; • establish our manufacturing capabilities, including through CDMOs and building our internal manufacturing facilities; • acquire and license technologies aligned with our ex vivo and in vivo cell engineering platforms; • seek regulatory approval of our current and future product candidates; • **collaborate with third parties to support the development and regulatory approval of companion diagnostics to our product candidates; •** engage in commercialization activities, including product manufacturing, marketing, sales, and distribution for any of our product candidates for which we obtain marketing approval; • expand our operational, financial, and management systems and increase personnel, including those required to support our preclinical and clinical development, manufacturing, and potential future commercialization efforts; • continue to develop, prosecute, and defend our intellectual property portfolio; and • continue to incur legal, accounting, and other expenses necessary to operate our business, including the costs associated with operating as a public company. We have devoted a significant portion of our financial resources and efforts to building our organization, developing our ex vivo and in vivo cell engineering platforms, identifying and developing potential product candidates, executing preclinical studies, establishing manufacturing capabilities, preparing for **and commencing** clinical trials of our product candidates, acquiring technology, organizing and staffing the company, business planning, establishing and maintaining our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. We are in the early stages of development of our product candidates ~~, have not yet commenced any clinical trials for any of our product candidates,~~ and have not completed development or commercialization of any product candidate. To become and remain profitable, we must succeed in identifying, developing, obtaining regulatory approval for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our product candidates, continuing to discover and develop additional product candidates, obtaining regulatory approval for any product candidates that successfully complete clinical trials, accessing manufacturing capacity, establishing marketing capabilities, and commercializing and ultimately selling any products for which we may obtain regulatory approval. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain profitability or meet outside expectations for our profitability. If any of the foregoing events were to occur, the value of our shares of common stock could be materially adversely affected. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or increases in the amount of expenses we will incur or when, or if, we will be able to achieve profitability. If we are required by the FDA or comparable foreign regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in commencing or completing our clinical trials or the development of any of our product candidates, our expenses could increase and our ability to obtain commercial revenue could be further delayed and become more uncertain, which will have a material adverse impact on our business. We will require additional funding to finance our operations. If we are unable to raise capital when needed, or on acceptable terms, we could be forced to delay, reduce, or eliminate our product development programs or commercialization efforts. Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive, and uncertain process that takes years to complete. As described above, our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase ~~in connection with~~ **if and as** our ongoing activities **grow in scope and breadth** . Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce, or eliminate our research and development programs or any future commercialization efforts, and our business, results of operations, and financial condition would be adversely affected. As of December 31, ~~2022~~ **2023** , we had $ ~~434~~ **205** . ~~0~~ **2** million in cash, cash equivalents, and marketable securities **, which does not include approximately $ 179. 9 million of net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses, from our Follow- On Offering (as defined below) completed on February 12, 2024** . Based on our current business plans, we believe that our existing cash, cash equivalents, and marketable securities as of December 31, ~~2022~~ **2023** will be sufficient to fund our operating expenses and capital expenditure requirements for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources more quickly than we currently expect, which could require us to seek additional funds sooner than planned, including through public or private equity or debt financings or other sources, such as strategic collaborations. **Furthermore, we hold significant balances of cash and cash equivalents, including as necessary to conduct our day- to- day operations, some of which are held in deposit accounts at commercial banks in excess of the government- provided deposit insurance.** In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. For example, in August 2022, we entered **into** a sales agreement with Cowen and Company, LLC (Cowen), acting as sales agent, pursuant to which we may offer and sell through Cowen shares of our common stock having an aggregate offering price of up to $ 150. 0 million from time to time in a series of one or more at the market equity offerings (collectively, the ATM facility). As of December 31, ~~2022~~ **2023** , we had raised ~~approximately~~ $ ~~0~~ **27** . 6 million in net proceeds under the ATM facility **. Further, on February 12, 2024, we completed an underwritten public offering pursuant to which we sold 21. 8 million shares of our common stock, including 4. 5 million shares pursuant to the full exercise of the underwriters' option to purchase additional shares, and pre- funded warrants to purchase 12. 7 million shares of our common stock (the Follow- On Offering)** . Attempting to secure additional financing may divert our management from our day- to- day activities, which may adversely affect our ability to develop our product candidates. Our future capital requirements will depend on many factors, including: • the scope, timing, progress, costs, and results of discovery, preclinical development, and clinical trials for our current or future product candidates **, including the development of companion diagnostics to such product candidates** ; • the number and scope of clinical trials required for regulatory approval of our current or future product candidates; • the costs, timing, and outcome of regulatory review of our current or future **product candidates and any companion diagnostics to such** product candidates; • the cost associated with building our manufacturing capabilities, as well as costs associated with the manufacturing of clinical and commercial supplies of our current or future product candidates; • the costs and timing of future commercialization activities, including manufacturing, marketing, sales, and distribution, for any of our product candidates for which we receive marketing approval; • the costs and timing of preparing, filing, and prosecuting patent applications, maintaining and enforcing our intellectual property rights, and defending any intellectual property- related claims, including any claims by third parties that we are infringing upon their intellectual property rights; • our ability to maintain existing, and establish new, strategic collaborations, licensing, or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty, or other payments due under any such agreement; • the revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval; • the expenses required to attract, hire, and retain skilled personnel; • the costs of operating as a public company; • our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party, including government, payors; • potential interruptions or delays resulting from global geo- political, economic, and other factors beyond our control; • the effect of competing technological and market developments; and • the extent to which we acquire or invest in businesses, products, and technologies. Our ability to raise additional funds will depend on financial, economic, geo- political, and market conditions and other factors over which we may have no or limited control. Market volatility, including as a result of **bank failures, including Silicon Valley Bank (SVB) and Signature Bank (Signature) in 2023, and measures taken in response thereto, and** the ~~ongoing~~ **resulting impact on the broader banking sector, geo-political and economic instability resulting from the escalation in conflict between Russia and Ukraine, the conflict in the Middle East, tensions in US- China relations, and the aftermath of the** COVID- 19 pandemic, ~~the recent escalation in conflict between Russia and Ukraine,~~ or other factors **,** could also adversely impact our ability to access capital as and when needed. Additional funds may not be available when we need them, on terms and at a cost that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, or on terms and at a cost that are acceptable to us, we could be required to: • delay, limit, reduce, or terminate preclinical studies, clinical trials, or other research and development activities, or eliminate one or more of our development programs altogether, or otherwise restructure our operations or reduce our workforce; or • delay, limit, reduce, or terminate our efforts to access manufacturing capacity or establish and operationalize our manufacturing facility, establish sales and marketing capabilities, or other activities that may be necessary to commercialize any product candidates for which we obtain regulatory approval, or reduce our flexibility in developing or maintaining our sales and marketing strategy with respect to any product candidates for which we obtain regulatory approval **. For example, as described elsewhere in these Risk Factors, we implemented the October 2023 strategic repositioning and associated workforce reduction in order to focus our resources on our ex vivo cell therapy product candidates, and correspondingly, reduce**

our near- term investment in our fusogen platform, which involves shifting our focus on fusogen to research activities. We will require additional funding and other resources in order to expand preclinical development and initiate clinical development for product candidates derived from our fusogen platform . Raising additional capital may cause dilution to our stockholders, restrict our operations, or require us to relinquish rights to our technologies or product candidates. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations with our existing cash, cash equivalents, and marketable securities, proceeds from any future equity or debt financings, and upfront, milestone, and royalty payments received under any future licenses, collaborations, or other arrangements. Additional capital may not be available on terms that are reasonable or acceptable to us, if at all. If we raise additional capital through the sale of equity or debt securities, existing stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our stockholders. In addition, **any** ~~the possibility of~~ such issuance **, or the possibility of such issuance,** may cause the market price of our common stock to decline. Debt financing, if available, may result in increased fixed payment obligations and the existence of securities with rights that may be senior to those of our common stock, and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or acquiring, selling, or licensing intellectual property rights or assets, which could adversely impact our ability to conduct our business. If we raise additional funds through collaborations, strategic alliances, or marketing, distribution, or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams, or product candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results, and prospects. Our success payment and contingent consideration obligations in our license and acquisition agreements may result in dilution to our stockholders, drain our cash resources, or require us to incur debt to satisfy the payment obligations. We agreed to make success payments, payable in cash, pursuant to our license agreement with Harvard and contingent consideration and success payments, payable in cash or stock, pursuant to our acquisition agreement with Cobalt. Pursuant to the terms of our license agreement with Harvard, we may be required to make up to an aggregate of $ 175. 0 million in success payments to Harvard (Harvard Success Payments), payable in cash, based on increases in the per share fair market value of our common stock. The potential Harvard Success Payments are based on multiples of increasing value ranging from 5x to 40x based on a comparison of the per share fair market value of our common stock relative to the original issuance price of $ 4. 00 per share at ongoing pre- determined valuation measurement dates. The Harvard Success Payments can be achieved over a maximum of 12 years from the effective date of the agreement. If a higher success payment tier is met at the same time a lower tier is met, both tiers will be owed. Any previous Harvard Success Payments made are credited against the Harvard Success Payment owed as of any valuation measurement date so that Harvard does not receive multiple success payments in connection with the same threshold. As of December 31, ~~2022~~ **2023** , a Harvard Success Payment had not been triggered. See Note 4, License and collaboration agreements to our consolidated financial statements included elsewhere in this Annual Report for more details on the various per share common stock values that trigger a Harvard Success Payment. In connection with the Cobalt acquisition, we are obligated to pay to certain former Cobalt stockholders contingent consideration (Cobalt Contingent Consideration) of up to an aggregate of $ 500. 0 million upon our achievement of certain pre- defined development milestones and a success payment (Cobalt Success Payment) of $ 500. 0 million, each of which is payable in cash or stock. The Cobalt Success Payment is payable if, at pre- determined valuation measurement dates, our market capitalization equals or exceeds $ 8. 1 billion, and we are advancing a program based on the fusogen technology in a clinical trial pursuant to an IND, or have filed for, or received approval for, a BLA or new drug application for a product based on the fusogen technology. **The Cobalt Success Payment can be achieved over a maximum of 20 years from the date of the acquisition, but this period could be shorter upon the occurrence of certain events.** A valuation measurement date would be triggered upon a change of control if at least one of our programs based on the fusogen technology is the subject of an active research program at the time of such change of control. If there is a change of control and our market capitalization is below $ 8. 1 billion as of the date of the change of control, the amount of the potential Cobalt Success Payment will decrease, and the amount of potential Cobalt Contingent Consideration will increase. As of December 31, ~~2022~~ **2023** , a Cobalt Success Payment had not been triggered. See Note 3, Acquisitions, to our consolidated financial statements included elsewhere in this Annual Report for details on the amount of the potential Cobalt Success Payment and potential Cobalt Contingent Consideration if there is a change of control based on various thresholds for our market capitalization on such change of control date. In order to satisfy our obligations to make these success payments, if and when they are triggered, we may issue equity or convertible debt securities that may cause dilution to our stockholders, or we may use our existing cash or incur debt to satisfy the success payment obligations in cash, which may adversely affect our financial position. In addition, these success payments may impede our ability to raise money in future public offerings of debt or equity securities or to obtain a third- party line of credit. The contingent consideration and success payment obligations in our license and acquisition agreements may cause our operating results, net losses, and financial condition as reported by United States generally accepted accounting principles to fluctuate significantly from quarter to quarter and year to year, which may reduce the usefulness of our financial statements. Our success payment and contingent consideration obligations under our license and acquisition agreements are recorded as liabilities on our balance sheets. Under United States generally accepted accounting principles (GAAP), we are required to estimate the fair value of these liabilities as of each quarter end, with changes in the estimated fair value recorded in research and development- related success payments and contingent consideration. Factors that may lead to increases or decreases in the estimated fair value of the success payment liabilities include, among others, changes in the value of our common stock and market capitalization, changes in volatility, the estimated number and timing of valuation measurement dates, the term of the success payments, and changes in the risk- free interest rate. Factors that may lead to increases or decreases in the estimated fair value of our contingent consideration obligations include, among others, the estimated likelihood and timing within which milestones may be achieved and the estimated discount rates. A small change in the inputs and related assumptions with respect to our success payment **liabilities** and contingent consideration ~~liabilities~~ may result in a relatively large change in the estimated valuation and associated liabilities and resulting expense or gain. As a result, our operating results, net losses, and financial condition as reported by GAAP may fluctuate significantly from quarter to quarter and year to year for reasons unrelated to our operations, which may reduce the usefulness of our GAAP financial statements. For example, as of December 31, **2023 and** 2022 ~~and 2021~~, the estimated aggregate fair value of the Cobalt Success Payment and Harvard Success Payment liabilities was $ **12. 8 million and $** 21. 0 ~~million and $ 102. 5~~ million, respectively, and the estimated fair value of the Cobalt Contingent Consideration was $ **109. 6 million and $** 150. 4 ~~million and $ 153. 7~~ million, respectively. For the three and twelve months ended December 31, ~~2022~~ **2023** , we recorded ~~gains~~ **an expense** of $ ~~14~~ **0** . ~~7~~ **4** million and **a gain of** $ ~~81~~ **8** . ~~5~~ **2** million, respectively, related to the aggregate change in the estimated fair value of the Cobalt Success Payment and Harvard Success Payment liabilities. For the three and twelve months ended December 31, ~~2022~~ **2023** , we recorded **an** expense of $ ~~9~~ **6** . ~~2~~ **4** million and a gain of $ ~~3~~ **40** . ~~4~~ **8** million, respectively, related to the change in the estimated fair value of the Cobalt Contingent Consideration. We have incurred net losses since our inception and expect to continue to incur net losses for the foreseeable future. It is possible that future fluctuations in the price of our common stock and market capitalization and the resulting change in the estimated fair value of our success payment liabilities could lead us to record net income in a future period despite us incurring operating losses and negative cash flows during such period. Alternatively, significant stock appreciation during a future period could lead to a significant increase in our recorded GAAP net loss. Our limited operating history may make it difficult to evaluate our prospects and likelihood of success. We **have** ~~are a preclinical- stage biopharmaceutical company with~~ a limited operating history upon which to evaluate our business and prospects. Since our inception in July 2018, we have devoted substantially all of our resources and efforts to building our organization, developing our ex vivo and in vivo cell engineering platforms, identifying and developing potential product candidates, executing preclinical studies, establishing manufacturing capabilities, preparing for **and conducting** clinical trials of our product candidates, acquiring technology, organizing and staffing the company, business planning, establishing and maintaining our intellectual property portfolio, raising capital, and providing general and administrative support for these operations. **We** ~~Since all of our product candidates are still in preclinical development, we~~ have not yet demonstrated our ability to successfully ~~commence or~~ complete any clinical trials, including Phase 3 or other 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 product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from period to period due to a variety of factors, many of which are beyond our control. Consequently, predictions about our future success or viability are difficult to make and may not be as accurate as they could be if we had a longer operating history. Risks Related to Commercialization of Our Product Candidates We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing, or commercializing competing products before or more successfully than we do. The biotechnology and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop, and obtain marketing approval for new and innovative products on a cost- effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large pharmaceutical companies, biotechnology companies, academic institutions, government agencies, and other public and private research organizations. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and marketing of products that compete with our product candidates. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources, including intellectual property that may be necessary or useful for the development and commercialization of our product candidates, being concentrated in our competitors and becoming unavailable to us on commercially reasonable terms or at all. 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. With the proliferation of new drugs and therapies for our target indications, and as new technologies become available, we expect to face increasingly intense competition. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any product candidates that we successfully develop and **are able to** commercialize **, including those for the treatment of various cancers, B- cell- mediated autoimmune diseases, and type 1 diabetes,** will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our product candidates or our technologies obsolete, less competitive, or uneconomical. Our competitors may, among other things: • have significantly greater financial, manufacturing, marketing, drug development, technical, and human resources than we have; • develop and commercialize products that are safer, more effective, less expensive, more convenient, or easier to administer, or have fewer or less severe side effects **than any products for which we may obtain regulatory approval** ; • obtain quicker regulatory approval; • establish proprietary positions covering our products and technologies; • implement more effective approaches to sales and marketing; or • form more advantageous strategic alliances. Our business, financial condition, and results of operations could be materially adversely affected by any of the foregoing events. In addition, our potential future collaborators may decide to market and sell products that compete with the product candidates that we have agreed to license to them, which could have a material adverse effect on our future business, financial condition, and results of operations. Smaller and other early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. As described elsewhere in these Risk Factors and in the subsection titled " Business — Competition " in this Annual Report, we currently and in the future will compete with ~~these~~ third parties in ~~recruiting~~ **the development** and **commercialization of**

~~retaining qualified scientific and management personnel, establishing clinical trial sites, and recruiting patients for clinical trials, as well as in acquiring technologies complementary to, or~~ **our product candidates** ~~necessary for, our programs~~ . Market opportunity and market growth for our product candidates may prove to be smaller than we initially estimated, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates ~~,~~ or at all **, or we may otherwise be unable to capitalize on this opportunity** . We intend to initially focus our product candidate development on treatments for various diseases caused by missing or damaged cells. Our projections of addressable patient populations within any particular disease state that may benefit from treatment with our product candidates are based on our estimates. Market opportunity estimates and growth forecasts are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates **, including if the cost of treatment with our product candidates, including any required co- payments, is expensive or higher than other available therapies** . Our market opportunity may also be limited by future competitor therapies that enter the market. If any of our estimates proves to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished, which would have an adverse material impact on our business. In particular, certain of our product candidates are intended to treat cancer, and, in particular, B cell malignancies. Cancer therapies are sometimes characterized as first- line, second- line, or third- line and beyond, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first- line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first- line therapy, which usually consists of chemotherapy, antibody drugs, tumor- targeted small molecules, hormone therapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second- line therapy may be administered. Second- line therapies often consist of more chemotherapy, antibody drugs, tumor- targeted small molecules, radiation therapy, or a combination of these. Third- line therapies can include chemotherapy, antibody drugs, and small molecule tumor- targeted therapies, more invasive forms of surgery, and new technologies. The use of certain classes of therapies, including CAR T therapies, has been limited to a subset of patients with relapsed or refractory disease. Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers who are in a position to receive a particular line of therapy and who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. Consequently, even if our product candidates are approved for a later line of therapy, the number of patients that may be eligible for treatment with our product candidates may turn out to be much lower than expected. **In addition, even if the market opportunity for our product candidates achieves or exceeds the level and growth we anticipate, we may be unable to grow our business at the rate or in the manner necessary to successfully capitalize on this opportunity, including due to limited financial, personnel, and other resources. Our ability to successfully commercialize our product candidates will also be affected by numerous factors beyond our control, including limitations on third- party resources and infrastructure and other factors discussed in these Risk Factors.** We currently have no marketing, sales, or distribution infrastructure and we intend to either establish a sales and marketing infrastructure or outsource this function to a third party. Each of these commercialization strategies carries substantial risks to us. We currently have no marketing, sales, or distribution capabilities because all of our product candidates are ~~still~~ in ~~preclinical~~ **the early stages of** development. If one or more of our product candidates complete clinical development and receive regulatory approval, we intend to either establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our product candidates in a legally compliant manner, or to outsource this function to a third party, both of which involve significant risks. If we elect to establish our own sales and marketing capabilities, we will incur significant additional costs, including to hire and retain qualified personnel to build out the organization, and we may be unable to build out this organization in a way that will enable us to successfully market our products and generate revenues. If we elect to enter into arrangements with third parties to perform sales and marketing with respect to our product candidates, we may be unable to identify suitable partners, and even if we do identify such partners, we may be unable to negotiate the terms of such arrangement in a timely manner or at all, which could delay our marketing efforts and our ability to generate revenues. To the extent that we are able to enter into collaboration agreements with respect to marketing, sales, or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. Such collaborative arrangements with partners may place the commercialization of our products outside of our control and would subject us to a number of risks, including that we may not be able to control the amount or timing of resources that our collaborative partner devotes to our products or that our collaborator' s willingness or ability to complete its obligations, and our ability to complete our obligations under these arrangements, may be adversely affected by business combinations or significant changes in our collaborator' s business strategy. If we are unable to enter into these arrangements on acceptable terms, or at all, we may not be able to successfully commercialize any products for which we receive regulatory approval. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our ability to generate product revenue will suffer and we may incur significant additional losses, which would have a material adverse effect on our business, financial condition, and results of operations. Our product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA), which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a highly similar or " biosimilar " product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the applicant' s own preclinical data and data from adequate and well- controlled clinical trials to demonstrate substantial evidence that such product provides benefits that outweigh its known and potential risks for the intended patient population, as well as data that demonstrate that such product can be manufactured to a pre- defined standard. We believe that any of our product candidates that may be approved 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 our product candidates to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Jurisdictions outside the United States have also established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2004. However, biosimilars can only be authorized once the period of data exclusivity on the reference biological medicine has expired. The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. As a result of this and uncertainties regarding patent protection, we are not currently able to predict with certainty the length of market exclusivity for any particular product candidate that may receive marketing approval based solely on the expiration of the relevant patent (s) or the current forms of regulatory exclusivity. There may also be future changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for any product for which we receive regulatory approval could materially and negatively affect or prevent our ability to generate revenues, which could prevent us from achieving or sustaining profitability. Risks Related to Ownership of Our Common Stock Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. As of December 31, ~~2022~~ **2023** , our executive officers, directors, holders of 5 % or more of our capital stock, and their respective affiliates, **beneficially** owned **, in the aggregate,** approximately ~~64~~ **62. 5** % of our **common** ~~outstanding voting~~ stock. Therefore, these stockholders have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments to 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 other stockholders may feel are in their best interests. Future sales of our ~~common stock~~ **securities by us** in the public market could cause our common stock price to fall. ~~Our~~ **At any time in the future we may sell a large number of shares of our common stock or rights to acquire a large number of shares of our common stock. Such sales, or the perception that such sales could occur, could cause our** common stock price ~~could~~ **to** decline as a result of **, among other things, dilution from these** sales **, including pursuant to the exercise or conversion** of **rights to acquire our common stock, or discounts to the trading price of our common stock associated with such sales. In addition, transactions involving** a large number of shares of **our** common stock ~~or the perception that these sales could occur. These sales~~ , or the possibility that these ~~sales~~ **transactions** may occur, ~~might~~ **may** also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate **We expect that we will need significant additional capital in the future to support our planned operations, including conducting clinical trials, manufacturing, and other research and development activities, commercializing any product candidates for which we may obtain regulatory approval, and continuing to operate as a public company. To raise capital, we may sell shares of our common stock, warrants, convertible securities, or other securities in one or more transactions at prices and in a manner we determine from time to time. For example, as described elsewhere in these Risk Factors, we have sold shares of common stock in the ATM facility and shares of common stock and pre- funded warrants in the Follow- On Offering. If we sell additional securities in the future, whether in the ATM facility, in future public offerings, or otherwise, you could experience material dilution. In addition, such sales could result in new investors gaining rights, preferences, and privileges senior to the holders of our common stock. In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline Sales of a substantial number of shares of our common stock by our existing stockholders in the public market, or the perception that such sales could occur, could cause our stock price to fall. If our existing stockholders sell, indicate an intention to sell, or there is a perception in the market that they intend to sell, a large number of shares of our common stock, the trading price of our common stock could decline** . As of December 31, ~~2022~~ **2023** , ~~191~~ **197** . ~~0~~ **9** million shares of our common stock were outstanding ~~. Substantially all~~ **, which excludes the shares of common stock issued or issuable pursuant to pre- funded warrants sold in the Follow- On Offering as well as** shares of common stock sold in **the ATM facility and** ~~our IPO (excluding any~~ shares ~~sold to our directors or officers~~ **of common stock issued upon exercise of outstanding equity awards,** in ~~the directed~~ **each case, after December 31, 2023, and 57. 3 % of such** ~~share~~ **shares** ~~program)~~ **were beneficially owned by holders of 5 % or more of our common stock. In addition, shares of common stock that** are ~~freely tradable without restriction~~ **either subject to outstanding options or reserved** ~~or~~ **for** ~~further registration~~ **future issuance under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, applicable lock- up agreements, and Rule 144 and Rule 701** under the Securities Act of 1933, as amended (Securities Act) **. If these additional shares of common stock are sold** , ~~unless held by our~~ **or** ~~" affiliates " as defined~~ **there is a perception that they will be sold,** in ~~Rule 144~~ **the public market, the trading price of our common stock could decline. Further, certain holders of shares of our common stock are entitled to**

rights with respect to the registration of their shares under the Securities Act. **Registration** ~~Additionally, as~~ of **these shares** ~~December 31, 2022, we had raised approximately $ 0. 6 million in net proceeds~~ under the ~~ATM facility. All~~ **Securities Act would result in the** shares **becoming** ~~of common stock sold in the ATM facility are~~ freely tradable without restriction ~~or further registration~~ under the Securities Act, ~~unless~~ **except for shares** held by ~~our "~~ affiliates ~~"~~ **,** as defined in Rule 144 under the Securities Act. **Any** ~~Shares issued upon the exercise of stock options outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale~~ **sales of securities** ~~in the public market to the extent permitted~~ by ~~the~~ **these stockholders could have a material adverse effect on** ~~provisions of applicable vesting schedules, as well as Rules 144 and 701 under~~ the **trading price** ~~Securities Act. We also register the offer and sale~~ of **our** ~~all shares of~~ common stock ~~that we may issue under our equity compensation plans. Accordingly, these shares may be sold in the public market upon issuance. In addition, in the future, we may issue additional shares of common stock, or other equity or debt securities convertible into common stock, in connection with a financing, acquisition, employee arrangement, or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our common stock to decline~~ . We do not currently intend to pay dividends on our common stock and, consequently, our stockholders' ability to achieve a return on their investment will depend on appreciation of the value of our common stock. We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. We do not intend to declare or pay any cash dividends on our capital stock in the foreseeable future. As a result, any investment return on our common stock will depend upon increases in the value of our common stock, which is not certain. Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and Delaware law might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things: • establish a staggered Board divided into three classes serving staggered three- year terms, such that not all members of the Board are elected at one time; • authorize our Board to issue new series of preferred stock without stockholder approval and create, subject to applicable law, a series of preferred stock with preferential rights to dividends or our assets upon liquidation, or with superior voting rights to our existing common stock; • eliminate the ability of our stockholders to call special meetings of stockholders; • eliminate the ability of our stockholders to fill vacancies on our Board; • establish advance notice requirements for nominations for election to our Board or for proposing matters that can be acted upon by stockholders at our annual stockholder meetings; • permit our Board to establish the number of directors; • provide that our Board is expressly authorized to make, alter, or repeal our bylaws; • provide that stockholders can remove directors only for cause and only upon the approval of not less than 66 2 / 3 % of all outstanding shares of our voting stock; • require the approval of not less than 66 2 / 3 % of all outstanding shares of our voting stock to amend our bylaws and specific provisions of our certificate of incorporation; and • limit the jurisdictions in which certain stockholder litigation may be brought. As a Delaware corporation, we are subject to the anti- takeover provisions of Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in a business combination specified in the statute with an interested stockholder (as defined in the statute) for a period of three years after the date of the transaction in which the person first becomes an interested stockholder, unless the business combination is approved in advance by a majority of the independent directors or by the holders of at least two- thirds of the outstanding disinterested shares. The application of Section 203 of the Delaware General Corporation Law could also have the effect of delaying or preventing a change of control of our company. Our certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum, to the fullest extent permitted by law, for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of a fiduciary duty owed by any director, officer, or other employee to us or our stockholders, (iii) any action asserting a claim against us or any director, officer, or other employee arising pursuant to the Delaware General Corporation Law, (iv) any action to interpret, apply, enforce, or determine the validity of our second amended and restated certificate of incorporation or amended and restated bylaws, or (v) any other action asserting a claim that is governed by the internal affairs doctrine, shall be the Court of Chancery of the State of Delaware (or another state court or the federal court located within the State of Delaware if the Court of Chancery does not have or declines to accept jurisdiction), in all cases subject to the court' s having jurisdiction over indispensable parties named as defendants. In addition, our amended and restated certificate of incorporation provides that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, but that the forum selection provision will not apply to claims brought to enforce a duty or liability created by the Securities Exchange Act of 1934, as amended (Exchange Act). Although we believe these provisions benefit us by providing increased consistency in the application of Delaware law for the specified types of actions and proceedings, the provisions may have the effect of discouraging lawsuits against us or our directors and officers. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, and operating results. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock will be deemed to have notice of and consented to this exclusive forum provision, but will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. Under the Tax Cuts and Jobs Act of 2017 (Tax Act), **as modified by the Coronavirus Aid, Relief, and Economic Stability Act (CARES Act),** our federal net operating losses (NOLs) generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs is limited to 80 % of taxable income. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended **(the Code)** , if a corporation undergoes an " ownership change, " generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period, the corporation' s ability to use its pre- change NOL and other pre- change tax attributes, such as research and development tax credits, to offset its post- change income or taxes may be limited. We may have experienced ownership changes in the past and may experience ownership changes as a result of subsequent shifts in our stock ownership, some of which are outside our control. As a result, our ability to use our pre- change NOLs and tax credits to offset post- change taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use and gain the benefit of a material portion of our NOLs and tax credits. **Changes in U. S. and foreign tax laws could have a material adverse effect on our business, cash flow, results of operations, or financial conditions. We are subject to tax laws, regulations, and policies of the United States federal, state, and local governments and of comparable taxing authorities in foreign jurisdictions. Changes in tax laws, and in the administration of such laws, could adversely affect our effective tax rate, our cashflow, our operating results, or our reported financial condition. For example, the Tax Act eliminated the option to deduct research and development expenditures currently and requires taxpayers to capitalize and amortize those expenditures over five or fifteen years pursuant to Code Section 174. If and when we come profitable, these changes may cause us to pay federal income taxes earlier under the revised tax law than under the prior law and may increase our total federal tax liability attributable to orphan drug programs and other research and development activities. There can be no assurance that our effective tax rate, tax obligations, tax credits, including the orphan drug designation credit, or incentives will not be adversely affected by these or other developments or changes in law.** General Risk Factors Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including: • timing and variations in the level of expense related to the current or future development of our programs; • timing and status of enrollment for our ~~future~~ clinical trials; • changes or fluctuations in our stock price and market capitalization, which could impact the value of our contingent obligations and cause fluctuations in our operating expenses as a result of these non- cash adjustments; • impact of geo- political, economic, and other factors beyond our control ~~, including the ongoing COVID- 19 pandemic,~~ on us or third parties with which we collaborate or that we engage; • results of ~~future~~ clinical trials, or the addition or termination of such clinical trials or funding support by us or potential future partners or other third parties; • our execution of any collaboration, licensing, or similar arrangements, and the timing of payments we may make or receive under such arrangements or the termination or modification of any such arrangements; • any intellectual property infringement, misappropriation, or violation lawsuit or opposition, interference, post- grant proceeding, or cancellation proceeding in which we may become involved; • additions and departures of key personnel; • strategic decisions by us or our competitors, such as acquisitions, divestitures, spin- offs, joint ventures, strategic investments, or changes in business strategy; • the impact of global supply chain issues and ~~rising rates of~~ inflation on the costs of laboratory consumables, supplies, and equipment required for our ongoing operations; • if any product candidate we may develop receives regulatory approval, the timing and terms of such approval and market acceptance and demand for such product candidate; • the timing and cost of establishing a sales, marketing, and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with current or future collaborators; • regulatory developments affecting current or future product candidates or those of our competitors; • the amount of expense or gain associated with the change in value of the success payments and contingent consideration; and • changes in general market and economic conditions. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. Our stock price may be volatile or may decline regardless of our operating performance, which may result in substantial losses for investors and may potentially subject us to securities class action litigation, which is expensive and could divert management' s attention. The market price of our common stock **, as well as investor perceptions of our business and its value,** may be highly volatile and may fluctuate substantially as a result of a variety of factors, some of which are related in complex ways, and many of which are beyond our control, including the factors listed below and other factors describe in these Risk Factors: • the commencement of, enrollment in, or results of current and future preclinical studies and clinical trials we may conduct, or changes in the development status of our product candidates; • any delay in 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 the issuance by the FDA of a " refusal to file " letter or a request for additional information; • adverse results or delays in clinical trials **; • perceptions regarding the significance of data from our clinical trials, particularly preliminary data** ; • 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 actions taken by regulatory agencies with respect to our preclinical studies or clinical trials, manufacturing supply chain, or sales and marketing activities, including failure to receive regulatory approval of our product candidates **or companion diagnostics to such product candidates** ; • changes in laws or regulations, including preclinical study or clinical trial requirements for regulatory approvals worldwide; • adverse changes to our relationship with manufacturers or suppliers; • manufacturing, supply, or distribution shortages; • our failure to successfully commercialize our product candidates; • changes in the structure of healthcare payment systems; • additions or departures of key scientific or management personnel; • unanticipated serious safety concerns related to the use of our product candidates; • disputes or other developments relating to proprietary rights, including patent rights, trade secrets, litigation matters, and our ability to obtain patent protection for our technologies or product candidates; • variations in our results of operations; • 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 ex vivo and in vivo cell engineering products in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts; • announcements made by us or our competitors about new product **candidates** and **programs** ~~service offerings~~, success ~~or~~ **,** setbacks **, or other updates** related to product ~~or service offerings~~ **candidates and programs** that exist or are under development, **strategic transactions and relationships, such as** acquisitions **collaborations** , **and** ~~strategic relationships,~~ joint ventures, or capital commitments; • our inability to establish **or successfully maintain any** collaborations **or other strategic relationships** , if needed; • our ability to effectively manage our growth; • the size and growth of our initial target markets; • changes in the market valuations of similar companies; • press reports, whether or not true, about our business; • sales or perceived potential sales of our common stock by us or our stockholders ~~in the future~~ ; • overall fluctuations in the equity markets; • ineffectiveness of our internal controls; • changes in accounting practices or principles; • changes or developments in the global legal and regulatory environment, including any new laws or regulations, or amendments to existing laws or regulations, that may impact the commercial environment for our product candidates; • litigation involving us, our industry, or both, or investigations by regulators into our operations or those of our competitors; • general political and economic conditions both within and outside the United States, including changes in interest rates, ~~rising~~ inflation, geo- political and economic instability resulting from the ~~recent~~ escalation in conflict between Russia and Ukraine **, the conflict in the Middle East, tensions in US- China relations** , and economic and tax policies announced by foreign countries; and • other events or factors, many of which are beyond our control. The stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. If the market price of our common stock does not exceed your purchase price, you may not realize any return on, and may lose some or all of, your investment. In addition, because the biotechnology industry is complex and subject to heightened risks as compared to many other industries, investors may be reluctant to place value in and invest in our company and choose instead to prioritize investment in other companies and industries, including those that may be perceived as more stable or that prioritize initiatives that may not be relevant to our industry or practical for us to prioritize at this stage in our development. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. The market price of our common stock has fluctuated since our IPO and may continue in the future to be volatile. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results, or financial condition. Market and economic conditions may negatively impact our business, financial condition, and share price. Concerns about inflation, interest rates, energy costs, geo- political issues, the United States mortgage market and a declining real estate market, unstable global credit markets and financial conditions, and volatile oil prices have led to periods of significant economic instability, diminished liquidity and credit availability, declines in **investment in industries perceived as complex or higher risk, such as biotechnology, declines in** consumer confidence and discretionary spending, diminished expectations for the global economy and expectations of slower global economic growth going forward, increased unemployment rates, and increased credit defaults in recent years. Our general business strategy may be adversely affected by any such economic downturns, volatile business environments, and continued unstable or unpredictable economic and market conditions ~~.~~ **, including as a result of a prolonged government shutdown,** ~~For~~ - **or** ~~example~~ **the perception or possibility that such a shutdown may occur. The closures of SVB and Signature in 2023 and their placement into receivership with the Federal Deposit Insurance Corporation created bank- specific and broader financial institution liquidity risk and concerns. Although government intervention ultimately provided depositors at SVB and Signature with access to their funds** , **adverse developments with respect to specific financial institutions or the broader financial services industry that have occurred or may occur in the future may lead to market- wide liquidity shortages, impair our ability to access near- term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur, and we cannot predict the impact or follow- on effects of these insolvencies more broadly or on our business in particular. Further, there is no guarantee that the government will intervene to provide depositors with access to funds if similar events occur in the future. If other banks and financial institutions with which we have commercial relationships enter receivership or become insolvent in the future, our ability to access our existing cash, cash equivalents, and investments may be threatened, which could adversely affect our business and financial condition.** ~~given~~ **Given** the depth and breadth of our portfolio, we assess and prioritize our programs on an ongoing basis based on various factors, including internal and external opportunities and constraints, which may result in our decision to advance certain programs ahead or instead of others. Given the volatility in our stock price and the increased difficulty in accessing global credit markets **and raising capital** due to the market and economic conditions described above **,** we have adjusted our pipeline prioritization strategy and resource allocation in order to enable the success of our most advanced product candidates. In particular, we have gated investment in our programs, with future investment dependent on our achievement of certain milestones. ~~As a result, even~~ **Even** if our programs achieve the required milestones, development and potential commercialization of our product candidates may be delayed, which could harm our competitive position. In **order to**

manage resource constraints, we may be required to make decisions regarding how to prioritize our programs based on limited data. As a result, we may be required to delay or halt the development of potentially promising earlier stage programs to focus our resources on a limited number of more advanced programs with higher probabilities of success in the shorter term. Such decisions have, and in the future would, reduce the breadth and diversity of our portfolio and investments therein, potentially limit the long- term growth of our pipeline, and increase the risk and extent of the negative impact on our business if such programs are not successful. In addition, **if any of the events described occur, or** if the market and economic conditions described above continue to deteriorate or do not improve, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance, and stock price. As a result, we may be required to further adjust our pipeline prioritization strategy and resource allocation in order to extend our cash runway and enable the success of certain of our product candidates, which may require ~~us to~~ **that we make adjustments based on limited information and** slow or stop the development of ~~other~~ **certain** product candidates. Additionally, rising rates of inflation **in recent years** have increased the costs associated with conducting our business, including by causing substantial increases in the costs of materials, including raw materials and consumables, equipment, services, and labor. Given that we do not currently generate revenue from sales of any of our product candidates, we do not have an ability to offset these increases in our costs. Moreover, given the unpredictable nature of the current economic climate, including future changes in rates of inflation, it may be increasingly difficult for us to predict and control our future expenses, which may harm our ability to conduct our business. We or the third parties upon whom we depend may be adversely affected by natural disasters, including earthquakes, fires, typhoons, and floods, public health epidemics, ~~such as the ongoing COVID- 19 pandemic,~~ telecommunications or electrical failures, geo- political actions, including war and terrorism, political and economic instability, and other events beyond our control, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. We or our partners, CROs, CDMOs, or other service providers, may experience interruptions to our operations, including the conduct of our research and development programs, clinical trials, and manufacturing operations, due to natural disasters, including earthquakes, fires, typhoons, and floods, public health epidemics, such as the ~~ongoing~~ COVID- 19 pandemic, hardware, software, telecommunication or electrical failures, geo- political actions, including war and terrorism, or political and economic instability, which could significantly disrupt or harm our business. Our corporate headquarters and other facilities, including the site of our planned manufacturing facility, are located in areas that have experienced significant natural disasters, including the San Francisco Bay Area and Seattle, Washington, each of which have experienced severe effects from wildfires and, in the case of the San Francisco Bay Area, severe earthquakes. We do not carry earthquake insurance. Earthquakes, wildfires, or other natural disasters could severely disrupt our operations, and could materially and adversely affect our business, financial condition, results of operations, and prospects. If a natural disaster, electrical failure, or other event occurs that prevents us from using all or a significant portion of our headquarters, damages critical infrastructure, or otherwise disrupts operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For example, a prolonged electrical failure could result in damage to or destruction of materials that are critical for our research and manufacturing operations, including our master cell banks, which would delay the advancement of our programs and materially harm our business, operating results, prospects, or financial condition. In addition, a failure of our computing systems could result in the loss of research or preclinical data important to our research or development programs, interrupt the conduct of ongoing research, or otherwise impair our ability to operate, which could delay the advancement of our programs or cause us to incur costs to recover or reproduce lost data. In addition, if in the future a natural disaster, power outage, or other event occurred that prevented us from using all or a significant portion of our manufacturing capabilities, we may not be able to manufacture sufficient supply of our product candidates required to conduct our clinical trials or commercialize our products in accordance with our timelines or at all. The disaster recovery and business continuity plans we currently have in place are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, together with our lack of earthquake insurance in particular, could have a material adverse effect on our business. Integral parties in our supply chain are similarly vulnerable to natural disasters or other sudden, unforeseen, and severe adverse events. In addition, our supply chain is vulnerable to changes in the geo- political and economic climate, including changes in relationships between the United States and countries from which we may need to source materials and other resources necessary for the preclinical evaluation of our product candidates, including animal models, and specifically non-human primate models, or to manufacture our product candidates, including raw and intermediate materials and consumables. If any such event or change were to affect our supply chain, it could have a material adverse effect on our business. **As a result of the COVID- 19 pandemic and related public health guidance measures, we experienced and may in the future experience disruptions that could materially and adversely impact our preclinical and clinical studies and development and our business, financial condition, and results of operations. Potential disruptions resulting from the COVID- 19 pandemic or another pandemic, epidemic, or infectious disease outbreak may include delays or disruptions in our research, preclinical, clinical, manufacturing, and regulatory activities, including due to limitations on employee or other resources both internally and at third parties, including government agencies, or delays in procuring, or inability to procure, necessary supplies, materials, and equipment. The extent to which the impact of the COVID- 19 pandemic and any other pandemic, epidemic, or other outbreak may affect our preclinical studies, clinical trials, business, financial condition, and results of operations will depend on future developments, which continue to be highly uncertain and unpredictable.** Furthermore, geo- political actions, **such as the conflicts in Ukraine and the Middle East, trade restrictions,** and the resulting political and economic instability, could negatively impact our operations ~~. For example, in response to Russia' s military actions against Ukraine, the United States and certain other countries have imposed significant sanctions and trade~~

~~actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions if the conflict continues or worsens. It is not possible to predict the broader consequences of the conflict between Russia and Ukraine, including related geo- political tensions, and the measures and retaliatory actions that will be taken by the United States and other countries in respect thereof, as well as any countermeasures or retaliatory actions Russia may take in response, are likely to cause regional instability and geo- political shifts and could materially adversely affect global trade, currency exchange rates, regional economies, and the global economy~~ . Although it is difficult to anticipate the impact of any of the foregoing on our company in particular, ~~the conflict~~ **such geo- political actions,** and **any** actions taken in response **thereto,** ~~to the conflict~~ could increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations ~~. We are subject to United States and certain foreign laws and regulations relating to export and import controls, sanctions, embargoes, anti- corruption, and anti- money laundering. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We could face criminal liability and other serious consequences for violations, which would harm our business. We are subject to export control and import laws and regulations, including the United States Export Administration Regulations, United States Customs regulations, various economic and trade sanctions regulations administered by the United States Treasury Department' s Office of Foreign Assets Controls, the United States Foreign Corrupt Practices Act of 1977, as amended (FCPA), the United States domestic bribery statute contained in 18 U. S. C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, collaborators, and other third parties from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell products, if any, for which we receive regulatory approval outside the United States, to conduct clinical trials, or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. In the ordinary course of our business, we may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We may be held liable for the corrupt or other illegal activities of our employees, agents, contractors, collaborators, and other third parties, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. The withdrawal of the United Kingdom from the European Union, commonly referred to as " Brexit, " may adversely impact our ability to obtain regulatory approvals of our product candidates in the United Kingdom or European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the United Kingdom or European Union, and may require us to incur additional expenses in order to develop, manufacture, and commercialize our product candidates in the United Kingdom or European Union. Following the result of a referendum in 2016, the United Kingdom (UK) left the EU on January 31, 2020, commonly referred to as " Brexit. " Pursuant to the formal withdrawal arrangements agreed between the UK and the EU, the UK was subject to a transition period until December 31, 2020 (the Transition Period), during which time EU rules continued to apply. Negotiations between the UK and the EU continue in relation to the customs and trading relationship between the UK and the EU following the expiry of the Transition Period. The transition period provided time for the UK and EU to negotiate a framework for partnership for the future, which was ultimately crystallized in the Trade and Cooperation Agreement (TCA) and became effective on January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, including the mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. Since a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU directives and regulations, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval, and commercialization of our product candidates in the UK or the EU. For example, following the referendum, as required by EU law, the EMA relocated to Amsterdam from London. As of January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (MHRA) is the UK' s standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules apply in Northern Ireland than in Great Britain; broadly, Northern Ireland continues to follow the EU regulatory regime, but its national competent authority remains the MHRA. The MHRA has published guidance on how various aspects of the UK regulatory regime for medicines will operate in Great Britain and in Northern Ireland following the expiry of the Transition Period. The guidance addresses clinical trials, importing, exporting, and pharmacovigilance and is relevant to any business involved in the research, development, or commercialization of medicines in the UK. Following the Transition Period, the UK is no longer covered by the centralized procedures for obtaining EU- wide marketing authorization from the EMA and companies established in the UK must follow one of the UK national authorization procedures or one of the remaining post- Brexit international cooperation procedures to obtain marketing authorization to commercialize a product in the UK. The MHRA may rely on a decision taken by the European Commission with respect to the approval of a new (centralized procedure) marketing authorization when making a determination with respect to an application for a Great Britain marketing authorization, or use the MHRA' s decentralized or mutual recognition procedures, which enable marketing authorizations approved in EU member states (or Iceland, Liechtenstein, or Norway) to be granted in Great Britain. Any delay in obtaining, or an inability to obtain, any marketing approvals in the UK or EU, as a result of Brexit or otherwise, could prevent us from commercializing our product candidates in the UK or the EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other requirements, some of which could be significant, in connection with the importation of our product candidates into the UK or EU, or we may incur expenses in establishing a manufacturing facility in the UK or EU in order to circumvent such requirements. If any of these outcomes occur, we may be forced to restrict~~

~~or delay efforts to seek regulatory approval for our product candidates in the UK or the EU or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability. Any further changes in international trade, tariff, and import / export regulations, as a result of Brexit or otherwise, may impose unexpected duty costs or other non- tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK~~ . If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business, our market, or our competitors, or if they adversely change their recommendations regarding our common stock, the trading price or trading volume of our common stock could decline. The trading market for our common stock is influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market, or our competitors. We do not have any control over the analysts or the content and opinions included in their research and reports. If one or more of these analysts issue an unfavorable rating or downgrade our common stock, provide a more favorable recommendation about our competitors, or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If any analyst who may cover us were to cease such coverage or fail to regularly publish reports on us, we could lose visibility in the financial markets and demand for our common stock could decrease, which could cause the trading price or trading volume of our common stock to decline. We are an emerging growth company, and any decision on our part to comply only with certain reduced reporting and disclosure requirements applicable to emerging growth companies could make our common stock less attractive to investors. We are an " emerging growth company " as defined in the JOBS Act, and, for as long as we continue to be an emerging growth company, we may choose to take advantage of exemptions from various reporting requirements applicable to other public companies but not to emerging growth companies, including: • not being required to have our independent registered public accounting firm audit our internal control over financial reporting under Section 404 of the Sarbanes- Oxley Act of 2002 (the Sarbanes- Oxley Act); • reduced disclosure obligations regarding executive compensation in our periodic reports and annual reports on Form 10- K; and • exemptions from the requirements of holding non-binding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. Our status as an emerging growth company will end as soon as any of the following takes place: • the last day of the fiscal year in which we have more than $ 1. 235 billion in annual revenue; • the date we qualify as a " large accelerated filer, " with at least $ 700 million of equity securities held by non- affiliates; • the date on which we have issued, in any three- year period, more than $ 1. 0 billion in non- convertible debt securities; or • the last day of the fiscal year ending after the fifth anniversary of the completion of our **IPO** ~~initial public offering~~ , which is December 31, 2026. We cannot predict if investors will find our common stock less attractive as a result of our decision to rely on any of the exemptions afforded to emerging growth companies. If some investors find our common stock less attractive because we rely on any of these exemptions, there may be a less active trading market for our common stock and the market price of our common stock may be more volatile. 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 any new or revised accounting standards during the period in which we remain an emerging growth company (or we affirmatively and irrevocably opted out of the extended transition period); however, we may adopt certain new or revised accounting standards early. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates. The requirements of being a public company may strain our resources, result in an increased risk of litigation, and divert management' s attention. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time-consuming, or costly, and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and operating results. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet the requirements of the Sarbanes- Oxley Act, significant resources and management oversight may be required. As a result, management' s attention may be diverted from other business concerns, which could adversely affect our business and operating results. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure **create** ~~are creating~~ uncertainty for public companies, ~~increasing~~ **increase** legal and financial compliance costs, and ~~making~~ **make** some activities more time- consuming. These laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to continue to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from potential revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations, and standards fail to meet the requirements of the applicable regulatory or governing bodies, including due to ambiguities related to their application in practice, regulatory authorities may initiate legal proceedings against us, and our business may be adversely affected. New laws, rules, and standards and our efforts necessary to comply may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our ~~Board~~ **board of**

directors, particularly to serve on our audit committee and compensation **and talent** committee, and qualified executive officers. Additionally, the dramatic increase in the cost of such insurance may cause us to opt for lower overall policy limits or to forgo insurance that we may otherwise rely on to cover defense costs, settlements, and damages awarded to plaintiffs in connection with any securities litigation. By disclosing information in the periodic filings required of a public company, our business and financial condition are more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management' s resources and seriously harm our business. If we fail to maintain proper and effective internal controls over financial reporting, our ability to produce accurate and timely financial statements could be impaired. Pursuant to Section 404 of the Sarbanes-Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting. When we lose our status as an " emerging growth company ~~" and become an " accelerated filer " or a " large accelerated filer~~, " our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we have implemented and may need to continue to implement additional financial and management controls, reporting systems, and procedures, and may need to hire additional accounting and finance staff. We cannot guarantee that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations, or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement with a related party, which could cause us to fail to make a required related party transaction disclosure. Additionally, controls can, depending on the circumstances, be circumvented by the acts of a single individual, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. ~~133~~ **The withdrawal of the United Kingdom from the European Union, commonly referred to as " Brexit, " may adversely impact our ability to obtain regulatory approvals of our product candidates in the United Kingdom or European Union, result in restrictions or imposition of taxes and duties for importing our product candidates into the United Kingdom or European Union, and may require us to incur additional expenses in order to develop, manufacture, and commercialize our product candidates in the United Kingdom or European Union. The UK left the EU on January 31, 2020, commonly referred to as " Brexit. " Pursuant to the formal withdrawal arrangements agreed between the UK and EU, the UK and EU negotiated a framework for partnership for the future in their Trade and Cooperation Agreement (TCA), which became effective on January 1, 2021. The TCA includes specific provisions concerning pharmaceuticals, including the mutual recognition of cGMP inspections of manufacturing facilities for medicinal products and cGMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations. Because a significant proportion of the regulatory framework in the UK applicable to our business and our product candidates is derived from EU directives and regulations, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval, and commercialization of our product candidates in the UK. In general, the EU laws that have been transposed into UK law through secondary legislation remain applicable in Great Britain. However, these rules may have diverged or may in the future diverge from the EU rules, and general uncertainty regarding the future of the relationship between the UK and EU, as well as the laws and rules in each such jurisdiction, remains. As of January 1, 2021, the Medicines and Healthcare Products Regulatory Agency (MHRA) is the UK' s standalone medicines and medical devices regulator. As a result of the Northern Ireland protocol, different rules apply in Northern Ireland than in Great Britain; broadly, Northern Ireland continues to follow the EU regulatory regime, but its national competent authority remains the MHRA. However, on February 27, 2023, the UK Government and the European Commission reached political consensus on the " Windsor Framework, " which will revise the Northern Ireland protocol in order to address some of the perceived shortcomings. Under the proposed changes, Northern Ireland would be reintegrated under the regulatory authority of the MHRA with respect to medicinal products. The implementation of the Windsor Framework will occur in various stages, with new arrangements relating to the supply of medicines into Northern Ireland due to take effect in 2025. There could be additional uncertainty and risk around what these changes will mean for any of our business operations in the UK. Following the Transition Period, the UK is no longer covered by the centralized procedures for obtaining EU- wide**

marketing authorization from the EMA and companies established in the UK must follow one of the UK national authorization procedures or one of the remaining post- Brexit international cooperation procedures to obtain marketing authorization to commercialize a product in the UK. The MHRA may rely on a decision taken by the European Commission with respect to the approval of a new (centralized procedure) marketing authorization when making a determination with respect to an application for a Great Britain marketing authorization, or use the MHRA' s decentralized or mutual recognition procedures, which enable marketing authorizations approved in EU member states (or Iceland, Liechtenstein, or Norway) to be granted in Great Britain. Any delay in obtaining, or an inability to obtain, any marketing approvals in the UK or EU, as a result of Brexit or otherwise, could prevent us from commercializing our product candidates in the UK or EU and restrict our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other requirements, some of which could be significant, in connection with the importation of our product candidates into the UK or EU, or we may incur expenses in establishing a manufacturing facility in the UK or EU in order to circumvent such requirements. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval for our product candidates in the UK or EU or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability. Any further changes in international trade, tariff, and import / export regulations, as a result of Brexit or otherwise, may impose unexpected duty costs or other non- tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the UK. 143