Risk Factors Comparison 2024-03-07 to 2023-03-02 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Annual Report. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations. Risks Related to the Development of our Product Candidates ~~Our~~ **We develop our mRNA- based** product candidates **by leveraging** ~~are based on~~ our ~~ImmTOR~~ **proprietary technology and our manufacturing** platform **, RNA Armory ®** , which is an unproven approach ~~designed~~ to **the treatment of** ~~induce antigen- specific immune~~ **autoimmune disease** ~~tolerance to biologic drugs~~ . We are ~~very~~ early in most of our clinical development efforts and may not be successful in our efforts to ~~use our ImmTOR platform to~~ build a pipeline of product candidates and develop marketable drugs. ~~All of our~~ **Our mRNA approach to develop** product candidates **for the treatment of autoimmune diseases** ~~are derived from our ImmTOR platform, which~~ is an unproven approach ~~to induce antigen~~ **. Our most advanced product candidate, Descartes** - **08 is** ~~specific immune tolerance and to mitigate the immunogenicity of biologic therapies currently being implemented to treat patients. We are developing our ImmTOR platform to restore self- tolerance to autoantigens and potentially treat autoimmune diseases, to be co- administered with AAV gene therapies to potentially enable redosing of said gene therapies and improve and enable activity~~ in ~~biologics (including therapeutic enzymes and other immunogenic drugs). While we have completed our early development clinical trials and a~~ Phase 2 clinical **development. We** ~~trial for SEL- 212, we~~ have not ~~completed a clinical trial for any other product candidate, nor have we~~ demonstrated ~~our~~ **the** ability to successfully complete any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial product, or arrange for a third party to do so on our behalf, or conduct other sales and marketing activities necessary for successful product commercialization. We may have problems identifying new product candidates and applying our technologies to ~~these~~ other areas. Even if we are successful in identifying new product candidates, they may not be suitable for clinical development, including as a result of **manufacturing difficulties,** harmful side effects, limited efficacy or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. The success of our product candidates will depend on several factors, including the following: • design, initiation and completion of preclinical studies and clinical trials with positive results; • reliance on third parties, including but not limited to collaborators, licensees, clinical research organizations and contract manufacturing organizations; • receipt of marketing approvals from applicable regulatory authorities; • obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates and not infringing or violating patents or other intellectual property of third parties; • **manufacturability, manufacturing, logistics, and stability of our cell therapies, including autologous cell therapies; • growing our internal cGMP manufacturing capabilities to support commercial manufacturing or** making arrangements with third- party manufacturers ~~for, or establishing, commercial manufacturing capabilities, or establishing such capabilities ourselves~~ ; • launching commercial sales of our products, if and when approved, whether alone or in collaboration with others; • acceptance of our products, if and when approved, by patients and the medical community; • effectively competing with other therapies; • obtaining and maintaining coverage and adequate reimbursement by third- party payors, including government payors, for our products, if approved; • maintaining an acceptable safety profile of our products following approval; and • maintaining and growing an organization of scientists and **businesspeople** ~~business people~~ who can develop and commercialize our product candidates and technology. ~~The occurrence~~ **Our failure to successfully execute on** of any of the foregoing **for any reason** would effectively prevent or delay approval of our lead and other product candidates. ~~The ongoing COVID- 19 pandemic may continue to adversely impact our business, including our preclinical studies and clinical trials. We are applying our ImmTOR platform to antigen- specific immune tolerance for gene therapy involving gene augmentation, replacement or editing. Regulatory authorities in the United States and European Union have limited experience in reviewing and approving gene therapy products, which could affect the time and data required to obtain marketing authorization of any of our product candidates. Our future success depends in part on our successful development of viable gene therapy product candidates utilizing our ImmTOR platform. The regulatory approval process for gene therapy product candidates can be more lengthy, rigorous and expensive than the process for other better known or more extensively studied product candidates and technologies. Since we are developing novel treatments for diseases in which there is little clinical experience with new endpoints and methodologies, there is heightened risk that the FDA, the European Medicines Agency, or the EMA, or comparable regulatory bodies may not consider the clinical trial endpoints to provide clinically meaningful results, and the resulting clinical data and results may be more difficult to analyze. This may be a particularly significant risk for many of the genetically defined diseases for which we may develop product candidates alone or with collaborators due to small patient populations for those diseases, and designing and executing a rigorous clinical trial with appropriate statistical power is more difficult than with diseases that have larger patient populations. Regulatory agencies administering existing or future regulations or legislation may not allow production and marketing of products utilizing genome editing technology in a timely manner or under technically or commercially feasible conditions. Even if our product candidates obtain required regulatory approvals, such approvals may later be withdrawn as a result of changes in regulations or the interpretation of regulations by applicable regulatory agencies. Changes in applicable regulatory guidelines may lengthen the regulatory review process for our product candidates, require additional studies or trials, increase development costs, lead to changes in regulatory positions and~~

~~interpretations, delay or prevent approval and commercialization of such product candidates, or lead to significant post- approval limitations or restrictions. Additionally, adverse developments in clinical trials conducted by others of gene therapy products or products created using genome editing technology, or adverse public perception of the field of genome editing, may cause the FDA, the EMA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. Furthermore, regulatory action or private litigation could result in expenses, delays or other impediments to our research programs or the development or commercialization of current or future product candidates. Even if we comply with applicable laws, rules, and regulations, and even if we maintain close coordination with the applicable regulatory authorities with oversight over our product candidates, our development programs may fail to succeed. Regulatory authorities have substantial discretion in the approval process and may refuse to accept a marketing application as deficient or may decide that our data is insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Additionally, adverse developments in clinical trials conducted by others of gene therapy products or products created using genome editing technology, or adverse public perception of the field of genome editing, may cause the FDA and other regulatory bodies to revise the requirements for approval of any product candidates we may develop or limit the use of products utilizing genome editing technologies, either of which could materially harm our business. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product to market would materially and adversely affect our business, financial condition, results of operations and prospects.~~ Clinical drug development **is inherently risky and** involves a lengthy and expensive process **which is subject to a number of factors** , ~~with an uncertain outcome~~ **many of which are outside of our control** . We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. **Clinical** ~~Except for SEL- 212 and SEL- 302, our product candidates are in preclinical~~ development **is expensive, time consuming and involves significant risk** . It is impossible to predict when or if any of our product candidates will prove effective and safe in humans or will receive regulatory approval, and the risk of failure through the development process is high. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete **manufacturing and** preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. **Manufacturing cell therapies, particularly those modified with mRNA, is a new field.** Preclinical development is costly and inherently uncertain. Early preclinical results may not be predictive of future results, however, if our technology proves to be ineffective or unsafe as a result of, among other things, adverse side effects ~~, pre- existing anti- drug antibodies that can neutralize the viral vector and block gene transfer, or cellular immune response to the transduced cells~~ , we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the clinical development and commercialization of our product candidates. Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its outcome is inherently uncertain. A failed clinical trial can occur at any stage of testing. Moreover, the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. ~~For example, the topline clinical trial results we reported from our Phase 2 head- to- head COMPARE study of SEL- 212 and the top- line data from our SEL- 399 program may not be predictive of future results.~~ Moreover, we may not be able to complete, or may be required to deviate from the current clinical trial protocol for a variety of reasons. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in clinical trials after achieving positive results in preclinical development or early- stage clinical trials, and we cannot be certain that we will not face similar setbacks. **Serious adverse events, or** SAEs **,** caused by, or other unexpected properties of, any product candidates that we may choose to develop could cause us, an institutional review board or regulatory authority to interrupt, delay or halt clinical trials of one or more of such product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable non- U. S. regulatory authorities. If any product candidate that we may choose to develop is associated with SAEs or other unexpected properties, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which those undesirable characteristics would be expected to be less prevalent, less severe or more tolerable from a risk- benefit perspective ~~. In the SEL- 212 Phase 1 / 2 clinical program, we have observed multiple SAEs, and future SAEs may occur causing us to incur additional costs or experience delays in completing, or causing us to ultimately be unable to complete, the development and commercialization of our product candidates, and delay or prevent our ability to obtain FDA approval~~ . Moreover, preclinical and clinical data is often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or other regulatory authority approval. If we fail to produce positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects, would be negatively impacted. In addition, we cannot be certain as to what type and how many clinical trials the FDA will require us to conduct before we may gain regulatory approval to market any of our product candidates in the United States or other countries, if any. Prior to approving a new therapeutic product, the FDA generally requires that safety and efficacy be demonstrated in two adequate and well- controlled clinical trials. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval for, or commercialize, our product candidates, including: • clinical trials of our product candidates may produce unfavorable, incomplete or inconclusive results; • **we may be unable to manufacture our product candidates, which in some cases such as mRNA CAR- T, are manufactured on a patient- by- patient basis; •** regulators or institutional review boards may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site

or may place a clinical hold on existing clinical trials; • we may experience delays in reaching, or fail to reach, agreement on acceptable terms with contract research organizations, or CROs, or clinical trial sites; • we may be unable to recruit suitable patients to participate in a clinical trial, the number of patients required for clinical trials of our product candidates may be larger than we expect, enrollment in these clinical trials may be slower than we expect or participants may drop out of these clinical trials at a higher rate than we expect, or enrollment could be affected by the ongoing ~~COVID- 19 pandemic or the ongoing conflict~~ **conflicts** in Ukraine **and the Middle East** ; • the number of clinical trial sites required for clinical trials of our product candidates may be larger than we expect; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we may have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks; • investigators, regulators, data safety monitoring boards or institutional review boards may require that we or our investigators suspend or terminate clinical research, or we may decide to do so ourselves; • investigators may deviate from the trial protocol, fail to conduct the trial in accordance with regulatory requirements or misreport study data; • the cost of clinical trials of our product candidates may be greater than we expect or we may have insufficient resources to pursue or complete certain aspects of our clinical trial programs or to do so within the timeframe we planned; • the supply or quality of raw materials or manufactured product candidates (whether provided by us or third parties) or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or in a timely manner, or we may experience interruptions in supply; • **laboratories that we rely upon to perform certain quality control tests may become unavailable, or their services could be delayed; •** regulators may revise the requirements for approving our product candidates, or such requirements may not be as we expect; • the FDA or comparable foreign regulatory authorities may disagree with our clinical trial design or our interpretation of data from preclinical studies and clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design of our clinical trials; • regarding trials managed by our existing or any future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us; and • geopolitical events may affect international and overseas trial sites in ways beyond our control. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, or if we are forced to delay or abandon certain clinical trials or other testing in order to conserve capital resources, we may: • be delayed in obtaining marketing approval for our product candidates, if at all ~~; • lose the support of collaborators, requiring us to bear more of the burden of research and development~~ ; • obtain marketing approval in some countries and not in others; • obtain approval for indications or patient populations that are not as broad as intended or desired; • obtain approval with labeling that includes significant use or distribution restrictions or safety warnings; • be subject to additional post- marketing testing requirements; or • have a product removed from the market after obtaining marketing approval. We could also encounter delays if a clinical trial is suspended or terminated. Authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to **institutional review boards, or** IRBs **,** for reexamination, which may impact the costs, timing or successful completion of a clinical trial ~~. We filed an IND to conduct a Phase 1 / 2 clinical trial of our SEL- 302 product candidate in pediatric patients with methylmalonic acidemia in the third quarter of 2021. ImmTOR manufacturing continues to proceed in accordance with our expectations, and we have not observed any impact to any of our ImmTOR programs~~ . Our product development costs will increase if we experience delays in clinical testing or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant preclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary regulatory approvals could be delayed or prevented. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In addition, from time to time our competitors have ongoing clinical trials for product candidates that treat the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates ~~. The safety of our patients and investigators continues to be our utmost priority~~ . Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which could cause the value of our common stock to decline and limit our ability to obtain additional financing. We may conduct clinical trials for product candidates at sites outside the United States, and the FDA may not accept data from trials conducted in such locations or the complexity of regulatory burdens may otherwise adversely impact us. Opening trial sites outside the United States may involve additional regulatory, administrative and financial burdens, including compliance with foreign and local requirements relating to regulatory submission and clinical trial practices. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified

investigators in accordance with good clinical practices, or GCPs, and the FDA must be able to validate the data from the trial through an onsite inspection, if necessary. Generally, the patient population for any clinical trials conducted outside the United States must be representative of the population for which we intend to seek approval in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U. S. laws and regulations. Nonetheless, there can be no assurance that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional clinical trials, which would be costly and time- consuming and delay or permanently halt our development of any applicable product candidates. Additional risks inherent in conducting international clinical trials include: • foreign regulatory requirements that could burden or limit our ability to conduct our clinical trials; • increased costs and heightened supply constraints associated with the acquisition of standard of care drugs and / or combination or comparator agents for which we may bear responsibility in certain jurisdictions; • administrative burdens of conducting clinical trials under multiple foreign regulatory schema; • foreign exchange fluctuations; • more burdensome manufacturing, customs, shipment and storage requirements; • cultural differences in medical practice and clinical research; • lack of consistency in standard of care from country to country; • diminished protection of intellectual property in some countries; ~~and~~ • changes in country or regional regulatory requirements; and • geopolitical instability or wars in regions outside of the United States where we conduct clinical trials may impact ongoing clinical trials. We may not be able to qualify for or obtain various designations from regulators that would have the potential to expedite the review process of one or more of our product candidates and even if we do receive one or more such designations there is no guarantee that they will ultimately expedite the process, or aid in our obtaining marketing approval or provide market exclusivity. There exist several designations that we can apply for from the FDA and other regulators that would provide us with various combinations of the potential for expedited regulatory review, certain financial incentives as well as the potential for post- approval exclusivity for a period of time. These designations include but are not limited to orphan drug designation, breakthrough therapy designation, accelerated approval, fast track status and priority review for our product candidates. For example, ~~we and AskBio received~~ **Descartes- 08 has been granted** orphan drug designation **by the FDA** for **the treatment of MG** ~~SEL- 302 in November 2020~~ . We expect to seek one or more of these designations for our **other** current and future product candidates. There can be no assurance that any of our other product candidates will qualify for any of these designations. There can also be no assurance that any of our product candidates that do qualify for these designations will be granted such designations or that the FDA will not revoke a designation it grants at a later date **, or that Congress will not change the law about a designation** . Further, there can be no assurance that any of our product candidates that are granted such designations **, including Descartes- 08,** will ever benefit from such designations or that the FDA would not withdraw such designations once granted. Were we to receive a designation that promised a period of market exclusivity, such as orphan drug exclusivity, such exclusivity may not effectively protect the product from competition because different drugs can be approved for the same condition **. In particular, the scope of exclusivity afforded for mRNA- modified cell therapy products may not be well defined** . Further with respect to orphan drug status, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior if it is shown to be safer, more effective or makes a major contribution to patient care. Interim, top- line and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, top- line or preliminary data from our clinical studies, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a full analyses of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top- line 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. Preliminary or top- line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. 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. Interim, top- line or preliminary data may not be representative of final data. If final data is not as positive as earlier interim, top- line or preliminary we have released, our business prospects would be significantly harmed. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. As a result, preliminary and top- line data should not be relied upon in making an investment decision in our securities. ~~Negative public opinion and increased regulatory scrutiny of gene therapy and genetic research may damage public perception of our product candidates or compromise our ability to conduct our business or obtain regulatory approvals for our product candidates. Gene therapy remains a novel technology. Public perception may be influenced by claims that gene therapy is unsafe, and gene therapy may not gain the acceptance of the public or the medical community. In particular, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target and prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. More restrictive government regulations or negative public opinion 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 any products we may develop.~~ Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial

profile of an approved label, or result in significant negative consequences following marketing approval, if any. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials, could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign authorities and could result in decreased market acceptance of any of our product candidates, if approved ~~. Further, therapies such as those we are developing involve unique side effects that could be more significant than side effects from other types of therapies with singular components~~ . Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials 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 our product candidates for any or all targeted indications. **In November 2023, the FDA issued a statement that it is investigating serious risk of T- cell malignancy following BCMA- directed or CD19- directed autologous CAR- T cell immunotherapies. While the FDA noted that it currently believes that the overall benefits of these products continue to outweigh their potential risks for their approved uses, the FDA stated that it is investigating the identified risk of T- cell malignancy with serious outcomes, including hospitalization and death, and is evaluating the need for regulatory action.** Further, **in January 2024,** the ~~clinical development of SEL~~ **FDA announced it would require a so** ~~- 212 over~~ **called " boxed warning " be added to the prescribing information for all six then- currently approved CAR- T therapies. A boxed warning is the strongest safety labeling the FDA** ~~many -~~ **may** ~~years has required -~~ **require** ~~multiple clinical trials and resulted~~ **. However, because all currently approved CAR T- cell immunotherapies are** in **oncology indications,** ~~the~~ **there** ~~use of different formulations of ImmTOR~~ **can be no assurance that FDA will reach the same risk- benefit analysis in other indications** . While we ~~do~~ **believe our mRNA- based CAR- T product candidates may have a differentiated toxicity profile than currently approved DNA- based CAR- T therapies, there can be no assurance that the FDA would** not ~~believe~~ **treat Descartes- 08 or any of our other product candidates similar to approved DNA- based CAR- T therapies. The FDA' s investigation may impact the FDA' s review of product candidates** that ~~such differences~~ **we are developing, or that we may seek to develop** in ~~formulation will affect~~ **the future, which may, among** ~~the~~ **other** ~~safety~~ **things, result in additional regulatory scrutiny of** ~~or~~ **our product candidates, delay** the ~~efficacy of SEL~~ **timing for receiving any regulatory approvals or impose additional post** ~~- 212, we cannot guarantee~~ **approval requirements on any of our product candidates** that **receive regulatory approval** ~~any such formulation changes will not negatively impact the results of any clinical trials related to SEL- 212, or result in a significant difference in the safety and efficacy of SEL- 212~~ . ~~The~~ **Any** drug- related side effects observed in our clinical trials could also affect patient enrollment in our clinical trials or the ability of any enrolled patients to complete such trials or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw approvals of such product; • regulatory authorities may require the addition of labeling statements, such as a ~~" black box~~ **boxed** ~~"~~ warning or a contraindication; • regulatory authorities may impose additional restrictions on the marketing of, or the manufacturing processes for, the particular product; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; • we could be sued and held liable for harm caused to patients, or become subject to fines, injunctions or the imposition of civil or criminal penalties; • our reputation may suffer; and • we could be required to develop a **risk evaluation and mitigation strategies, or** REMS **,** plan to prevent, monitor and / or manage a specific serious risk by informing, educating and / or reinforcing actions to reduce the frequency and / or severity of the event. Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. Risks Related to **Manufacturing and** our Dependence on Third Parties ~~and Manufacturing~~ We ~~rely on 3SBio in China as our primary supplier of pegadricase and on other third parties for the manufacture of our product candidates for preclinical and clinical testing, and~~ expect to continue to **grow** ~~do so for the foreseeable future. Our reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or~~ **our** ~~that such quantities may not be available at an acceptable cost, or in compliance with regulatory requirements, which could delay, prevent or impair our development or commercialization efforts. We obtain the biologic pegadricase, a component of SEL- 212, primarily from 3SBio in China. Under the 3SBio License, we have limited rights to manufacture~~ **manufacturing** ~~pegadricase~~ **capabilities** and **resources** ~~while we have entered into a contract with a back- up supplier located outside of China, we expect to continue to rely on 3SBio as the primary supplier of pegadricase for the foreseeable future. Any disruption in production or inability of 3SBio in China to produce adequate quantities of pegadricase to meet our needs could impair our ability to operate our business on a day- to- day basis~~ and ~~to continue our research and development of our future product candidates. Furthermore, since 3SBio is located in China,~~ we **must incur significant** ~~are exposed to the possibility of product supply disruption and increased~~ costs ~~in the event of changes in the policies, laws, rules and regulations of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, trade tensions between the United States and China have been escalating in recent years. Most notably, several rounds of U. S. tariffs have been placed on Chinese goods being exported~~ to ~~the United States. Each of these U. S. tariff impositions against Chinese exports were followed by a round of retaliatory Chinese tariffs on U. S. exports to China. Pegadricase is subject to, and any other components we purchase from China may be subject to, these tariffs, which could increase our manufacturing costs and could make our products, if successfully developed~~ -- **develop this expertise** ~~and approved, less competitive than those of our competitors whose inputs are not subject to these tariffs. Moreover, as a result of the COVID- 19 pandemic, certain of our suppliers and CMOs in the United States, China and other countries may be affected, which could disrupt their activities. We could face difficulty sourcing key components necessary to produce supply of SEL- 212, which may negatively affect our clinical development activities and our agreement with Sobi. If COVID- 19 continues to impact U. S. business operations, including those of our CMOs and suppliers, we could face additional disruptions to our supply~~

chain that could affect the supply of drug product for our preclinical studies and clinical trials. Any of these matters could materially and adversely affect our business and results of operations. Any issues related to the manufacturing lots or similar action regarding pegadricase used in preclinical studies or clinical trials could delay the studies or trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply or maintain compliance with regulatory requirements by 3SBio could significantly delay our clinical development of potential products and reduce third- party or clinical researcher interest and support of our proposed trials. These interruptions or failures could also impede commercialization of our future product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. These factors and increasing wage rates due to increased demand for skilled laborers and the declining availability of skilled labor in China could cause our labor costs to rise. We rely, and expect to continue to rely, in addition to 3SBio, on other third parties for the manufacture of our product candidates for supply in preclinical studies and clinical trials, as well as for commercial manufacture if any of our product candidates receive marketing approval. Our reliance on such third parties increases the risk that we will not have sufficient quantities of our product candidates on a timely basis or at all, or that such quantities will be available at an **and /** acceptable cost or quality, which could delay, prevent or impair our **or** development or commercialization efforts. For example, we rely on third parties **to manufacture our products. We have growing manufacturing capabilities, and in order to continue to develop our current product candidates, apply** for the **regulatory approvals and, if approved, commercialize future products, we will need to continue to develop, contract for, or otherwise arrange for any necessary external manufacturing capabilities. We** manufacture of our **product candidates internally** gene therapy preclinical materials. Gene therapy is a relatively new area for commercial biopharmaceutical development and there **There** are a limited number of CMOs with **risks inherent in biological manufacturing and we may not meet our delivery time requirements or provide** adequate facilities **amounts of material to meet our needs,** and expertise **we may make errors** in this area. As a **manufacturing, any of which could delay our clinical trials and** result **in additional expense** , we may be unable to **us. Our autologous cell** successfully manufacture our gene therapy preclinical materials through a third party or scale up the manufacture of our gene therapy product candidates for clinical testing or commercialization , if at all **including Descartes- 08, are made on a patient- by- patient basis, rendering their manufacture less predictable and requiring more demanding logistics** . We **rely on one or more** may be unable to establish any agreements with third- party **laboratories to perform certain quality control tests. These laboratories could become unavailable, or provision of their services could be delayed. Additionally, as we scale up our manufacturing, we may encounter further challenges. Furthermore, competition for supply from our** manufacturers **from other companies, a breach or violation by such manufacturers of their contractual or regulatory obligations or a dispute with such manufacturers would cause delays in our discovery and development efforts, as well as additional expense to us. In developing manufacturing capabilities by building our own manufacturing facilities, we have incurred substantial expenditures, and expect to incur significant additional expenditures in the future. Also, we have had to, and will likely need to continue to recruit, hire, and train qualified employees to staff our facilities. If we are unable to manufacture sufficient quantities of material or if we encounter problems with our facilities in the future, we may also need to secure alternative suppliers, and such alternative suppliers may not be available, or we may be unable to enter into agreements with them** on acceptable **reasonable** terms **and in a timely manner. In addition, to the extent we or** or **our partners** at all, and even if we do rely on **contract** third- party manufacturers **manufacturing organizations** entails additional risks , **or CMOs** including the: • inability , **to supply our product candidates, any delays or disruptions in supply could have a material adverse impact on the research and development activities and potential commercialization of our or our partners' product candidates. The manufacturing process for any products that we may develop is subject to the FDA and foreign regulatory authority approval process and we will need to meet, or will need to contract with CMOs who can meet, all applicable FDA and foreign regulatory authority requirements on an ongoing basis. Our** failure or unwillingness **the failure** of **any CMO** third- party manufacturers to comply with **meet required** regulatory **authority** requirements **could result in** , maintain quality assurance, meet our needs, specifications or schedules or continue to supply products to us; • reduced control we have over product development, including with respect to our lead product candidate, due to our reliance on such third- party manufacturers, • breach of manufacturing agreements by the **delayed submission** third- party manufacturers; • misappropriation or disclosure of our proprietary information, including our trade secrets and know- how; • relationships that the third- party manufacturer may have with others, some of which may be our competitors, and, if it does not successfully carry out its contractual duties, does not meet expectations, experiences work stoppages, or needs to be replaced, we may need to enter into alternative arrangements, which may not be available, desirable or cost- effective; and • termination or nonrenewal of agreements by third- party manufacturers at times that are costly or inconvenient for us. Additionally, if our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory **applications** requirements of the FDA or others , they will not be able to secure and / or maintain **delays in receiving** regulatory approval for **any of** their manufacturing facilities. If the FDA or **our** a comparable foreign regulatory authority does not approve these facilities for **or our current** the manufacture of our **or future collaborators'** 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 . **To** Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocations, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, there -- **the extent** are a limited number of manufacturers that operate under cGMP regulations that might be capable of manufacturing our products. Therefore, our product candidates and any future

products that we **have** may develop may compete with other products for access to manufacturing facilities. Any failure to gain access to these limited manufacturing facilities could severely impact the clinical development, marketing approval and commercialization of our product candidates. Any performance failure on the part of our existing **,** or future manufacturers could delay clinical development or marketing approval. We do not currently have arrangements in place for - **or** redundant supply or a second source for required raw materials used in the manufacture of our product candidates or for the manufacture of finished product. Moreover, we often rely on one CMO to produce multiple product components. For instance, one of our CMOs produces several polymers used in our ImmTOR platform. If our current CMOs cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and expected future dependence upon others for the manufacture of our product candidates or products could delay, prevent or impair our development and commercialization efforts. If we are unable to maintain any of our existing collaborations, or if these arrangements are not successful, or we are unable to enter into future licenses , **manufacturing arrangements** our business could be adversely affected. We have entered into collaborations with other **third** parties, **we depend** including pharmaceutical and biotechnology companies and universities , to develop products based **and will depend in the future,** on our ImmTOR platform, and such collaborations and licensing arrangements currently represent a significant portion of our product pipeline and are expected to represent a larger portion of our pipeline in the future. Certain of our collaborations have provided us with important funding for some of our development programs and we expect to receive additional funding under collaborations in the future although not all of our collaborations may result in funding to us, and certain collaborations, licenses and agreements may result in increased expenditures by us. Our existing collaborations, and any future collaborations, may pose a number of risks, including the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to these **third parties to** collaborations; • collaborators may not perform their obligations **in a timely manner and consistent with contractual and regulatory requirements, including those related to quality control and quality assurance. The failure of any CMO to perform its obligations** as expected **;, or, to the extent we manufacture all or a portion of our product candidates ourselves, our failure to execute on our manufacturing requirements, could adversely affect our business in a number of ways, including:** • **we or our current or future** collaborators may not pursue development and commercialization **be able to initiate or continue clinical trials** of any product candidates that **are under** achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on preclinical or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities ; • **we or our current or future** collaborators may **be** delay **delayed** clinical trials **in submitting regulatory applications** , provide insufficient funding **or receiving regulatory approvals,** for a clinical trial program, 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; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates, which may cause collaborators to cease to devote resources to the commercialization of our product candidates; • a **we may lose the cooperation of our** collaborator **collaborators** with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products ; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or **our facilities and** the **those** preferred course of development **our CMOs** , might cause **and our products could be the subject of inspections by regulatory authorities that could have a negative outcome and result in** delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in **supply** litigation or arbitration, any of which would be time- consuming and expensive ; • collaborators **we may be required to cease distribution or recall some or all batches of our products or take action to recover clinical trial material from clinical trial sites; and • ultimately, we** may not properly maintain **be able to meet the clinical and commercial demands** or **for** defend our intellectual property rights or **our products. If we are unable** may use our proprietary information in such a way as to invite litigation that **enter into future collaborations and licensing arrangements, our business** could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • collaborations may be terminated and we would potentially lose the right to pursue further development or commercialization of the applicable product candidates as well as have difficulty entering into a similar collaboration where the potential collaborator is aware of the prior termination; • collaborators may learn about our technology and use this knowledge to compete with us in the future; • there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others; and • the number and type of our collaborations could adversely affect **affected** our attractiveness to future collaborators or acquirers . We are actively **intend to** exploring **explore** licenses and other strategic collaborations with additional pharmaceutical and biotechnology companies for development and potential commercialization of therapeutic products. However, we face significant competition in seeking appropriate collaborators . If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may not be able to access specific antigens that would be suitable to development with our technology, have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all . If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop our product candidates or bring them to market or continue to develop our programs, and our business may be materially and adversely

affected. We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including by failing to meet deadlines for the completion of such trials. We rely, and expect to continue to rely, on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct and manage our clinical trials, including our ongoing Phase ~~3 DISSOLVE~~ **1 / 2** clinical ~~program for SEL~~ **trial of Descartes** - **08** ~~212, consisting of the DISSOLVE I and DISSOLVE II trials, which we have agreed to continue to run on behalf of Sobi, and for our other product candidates~~ . We also expect to rely on other third parties to store and distribute drug supplies for our clinical trials. While we rely on these third parties for research and development activities, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP regulations, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, safety and welfare of trial participants are protected. Other countries' regulatory agencies also have requirements for clinical trials. If we or any of our CROs or third- party contractors fail to comply with applicable GCPs, the data generated in our 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. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government- sponsored database, www. ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, do not comply with confidentiality obligations, do not meet expected deadlines, experience work stoppages, terminate their agreements with us or need to be replaced, or do not conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we may need to enter into new arrangements with alternative third parties, which could be difficult, costly or impossible, and our clinical trials may be extended, delayed or terminated, or may need to be repeated. If any of the foregoing occur, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates or in commercializing our product candidates. ~~We have no experience manufacturing our product candidates for commercial use, and if we decide to establish our own commercial manufacturing facility, we cannot assure you that we can manufacture our product candidates in compliance with regulations at a cost or in quantities necessary to make them commercially viable. We have a pilot manufacturing facility at our Watertown, Massachusetts location where we conduct process development, scale- up activities and the manufacture of ImmTOR product candidates for preclinical use. We do not currently have any of our own manufacturing facilities that meet the FDA's cGMP requirements for the production of any product candidates used in humans, and rely on our CMOs for clinical production. We currently have no plans to establish our own commercial manufacturing facilities and we will continue to rely on our partnership with CMOs who are currently producing ImmTOR at the commercial scale for SEL- 212 using our proprietary process and equipment.~~ Risks Related to Commercialization of our Product Candidates and Legal Compliance Matters Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on several factors, including: • the efficacy, safety and potential advantages compared to alternative treatments; • our ability to **manufacture and distribute cell therapies in a timely and secure manner; • our ability to** offer our products for sale at competitive prices; • the convenience and ease of administration compared to alternative treatments; • product labeling or product insert requirements of the FDA or foreign regulatory authorities, including any limitations or warnings contained in a product' s approved labeling, including any black box warning or REMS; • the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments; • our ability to hire and retain a sales force ~~in the United States~~ ; • the strength of marketing and distribution support; • the availability of third- party coverage and adequate reimbursement for our product candidates, once approved; • the prevalence and severity of any side effects; and • any restrictions on the use of our products together with other medications. We currently have no sales organization ~~and expect to rely on Sobi for the marketing and sale of SEL- 212, if approved~~ . If we are unable to establish effective sales, marketing and distribution capabilities, or enter into agreements with third parties with such capabilities, we may not be successful in commercializing our product candidates if and when they are approved. We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product candidate for which we obtain marketing approval, we will need to establish a sales and marketing organization or make arrangements with third parties to perform sales and marketing functions and we may not be successful in doing so. We expect to ~~rely on Sobi for the marketing and sale of SEL- 212, if approved. For our other product candidates, we expect to~~ build a focused sales and marketing infrastructure to market or co- promote our product candidates in the United States and potentially elsewhere, if and when they are approved. There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time- consuming and could delay any product launch. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. We face substantial competition, including from biosimilars, which may result in others discovering, developing or commercializing competing products before or more successfully than we do. The development and commercialization of new drug and biologic products and technologies is highly competitive and is characterized by rapid and substantial technological development and product innovations. We are aware that pharmaceutical and biotechnology companies, offer or are pursuing the development of

pharmaceutical products or technologies that may address one or more indications that our product candidates target, as well as smaller, early- stage companies, that offer or are pursuing the development of pharmaceutical products or technologies that may address one or more indications that our product candidates target. We face competition with respect to our current product candidates ~~,~~ and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources, established presence in the market and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and reimbursement for product candidates and in marketing approved products than we do. These third parties compete with us in recruiting and retaining qualified scientific, sales and marketing and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market, especially for any competitor developing a ~~competing immunomodulating therapeutic~~ **cell therapy product** that will likely share our same regulatory approval requirements. In addition, our ability to compete may be affected in many cases by insurers or other third- party payors seeking to encourage the use of generic or biosimilar products. We expect the product candidates we develop will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated. The **Biologics Price Competition and Innovation Act of 2009, or the** BPCIA **,** was enacted as part of the Affordable Care Act to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as " interchangeable " based on its similarity to an approved biologic. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the reference product was approved under a **biologics license application, or** BLA. The law is still being interpreted and implemented by the FDA, and as a result, its ultimate impact, implementation, and meaning are subject to uncertainty. However, any such processes could have a material adverse effect on the future commercial prospects for our biological products. We believe that any product candidate approved in the United States as a biological product under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider the subject product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. Even if we are able to commercialize any **of our** product candidates, the products may become subject to unfavorable pricing regulations or third- party coverage or reimbursement policies, any of which would have a material adverse effect on our business. Significant uncertainty exists as to the coverage and reimbursement status of any product candidates for which we obtain regulatory approval, especially novel products like our ~~gene~~ **cell** therapy product candidates, and may be particularly difficult because of the higher prices associated with **such** ~~gene therapy~~ product candidates. Our ability to commercialize any product candidates successfully will depend, in part, on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Obtaining and maintaining adequate reimbursement for our products may be difficult. We cannot be certain if we will obtain an adequate level of reimbursement for our products by third- party payors. Even if we do obtain adequate levels of reimbursement, third- party payors, such as government or private healthcare insurers, carefully review and question the coverage of, and challenge the prices charged for, products. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Third- party payors often require that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. Some third- party payors may require pre- approval of coverage for new and innovative therapies, such as our product candidates, before they will provide reimbursement. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or similar regulatory authorities outside of the United States. Moreover, eligibility for reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of products from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and adequate reimbursement rates from both government- funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our

ability to raise capital needed to commercialize products and our overall financial condition. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control, including possible price reductions, even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain marketing approval. There can be no assurance that our product candidates, if they are approved for sale in the United States or in other countries, will be considered medically necessary for a specific indication or cost- effective, or that coverage or an adequate level of reimbursement will be available. Moreover, there is heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. There can be no assurance that our product candidates, will not be subject to heightened governmental scrutiny, unfavorable regulatory inquiry or action, or Congressional inquiry. Product liability lawsuits against us could cause us to incur substantial liabilities and limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions; • decreased demand for any product candidates or products that we may develop; • injury to our reputation and significant negative media attention; • loss of clinical trial participants or increased difficulty in enrolling future participants; • significant costs to defend the related litigation or to reach a settlement; • substantial payments to trial participants or patients; • loss of revenue; • reduced resources of our management to pursue our business strategy; • the inability to commercialize any products that we may develop; • distraction of management' s attention from our primary business; and • substantial monetary awards to patients or other claimants ~~;~~ **.** We maintain general liability, product liability and umbrella liability insurance. Our existing insurance coverage may not fully cover potential liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. A product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business, including preventing or limiting the commercialization of any product candidates we develop. Our relationships with healthcare providers, customers and third-party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings. Arrangements with physicians, others who may be in a position to generate business for us, and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following: • the federal Anti- Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; • the federal False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government claims for payment that are false or fraudulent. Private individuals (e. g., whistleblowers) can bring these actions on behalf of the government; in addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act; • **the Health Insurance Portability and Accountability Act of 1996, or** HIPAA **,** which imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation; • HIPAA, as amended by HITECH and ~~its~~ **their respective** implementing regulations, which also ~~imposes~~ **impose** obligations, including mandatory contractual terms, on certain types of people and entities with respect to safeguarding the privacy, security and transmission of individually identifiable health information; • the federal Physician Payments **Sunshine Act, or the** Sunshine Act, which requires applicable manufacturers of certain products for which payment is available under a federal healthcare program to report annually to the government information related to certain payments or other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members; • analogous state laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third- party payors, including private insurers;

and requirements to comply with federal and pharmaceutical industry compliance guidelines; • state data privacy and price transparency laws, many of which differ from each other in significant ways and often are broader than and not preempted by HIPAA or the Sunshine Act, thus complicating compliance efforts; by way of example, the California Consumer Privacy Act, or CCPA, which went into effect January 1, 2020, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for " protected health information " maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context; and ~~•~~ similar healthcare laws and regulations in the **EU** ~~European Union~~ and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of certain protected information, such as the General Data Protection Regulation, or GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the **EU** ~~European Union~~ (including health data); in addition, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the **EU** ~~E. U.~~ will be regulated. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom' s departure from the EU **.** Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, including our relationships with physicians and other healthcare providers, some of whom may recommend, purchase and / or prescribe our product candidates, if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and affect the prices we may obtain. In the United States and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. For example, the **Patient Protection and Affordable Care Act of 2010, or the** ACA, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy reforms. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us. We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our products. 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 or approve new products can 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 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 agency have fluctuated in recent years as a result. 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 slow the time necessary for new drugs and biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. If a prolonged government shutdown occurs, or if global health concerns ~~continue~~ **were** to **again** prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can have a material adverse effect on our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations administered by the U. S. Commerce Department' s Bureau of Industry and Security, U. S. customs regulations, various economic and trade sanctions regulations including those administered or enforced by relevant

government authorities, such as by the U. S. Treasury Department' s Office of Foreign Assets Control or the U. S. Department of State, the U. S. Foreign Corrupt Practices Act of 1977, as amended, or **the** FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the ~~USA~~ **Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism, or** PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. U. S. sanctions laws and regulations may govern or restrict our business and activities in certain countries and with certain persons. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other partners 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 for clinical trials outside of the United States, to sell our product candidates abroad once we enter a commercialization phase, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other partners, even if we do not explicitly authorize or have actual knowledge of such activities. Our 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. If we or ~~our contract manufacturers or other~~ third parties **we rely upon** fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business. We and our contract manufacturers and other third parties with whom we do business are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, including biological materials and chemicals. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. The failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Risks Related to our Financial Position and Need for Additional Capital We are a development- stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability. Except for the year ended December 31, 2022, we have incurred significant operating losses since our inception. ~~Our~~ **We incurred a net loss of $ 219. 7 million, had** net income ~~was~~ **of** $ 35. 4 million ~~for the year ended December 31~~, ~~2022,~~ and **incurred a** net ~~losses~~ -- **loss** ~~were~~ **of** $ 25. 7 million ~~and $ 68. 9 million~~ for ~~each of~~ the years ended December 31, **2023, 2022, and** 2021 ~~and 2020~~, respectively. As of December 31, ~~2022~~ **2023**, we had an accumulated deficit of $ ~~394~~ **614**. ~~9~~ **6** million. To date, we have financed our operations primarily through public offerings and private placements of our securities, funding received from collaboration and license arrangements and ~~our~~ **a** credit facility. We currently have no source of product revenue, and we do not expect to generate product revenue for the foreseeable future. ~~We have~~ **Historically we** devoted substantially all of our financial resources and efforts to developing our ImmTOR platform **and following the closing of the Merger, or the Closing, we expect to devote substantially all of our financial resources and efforts to developing our mRNA- based therapies for the treatment of autoimmune diseases**, identifying potential product candidates and conducting preclinical studies and our clinical trials. We are in the early stages of **clinical** development of most of our product candidates ~~, and we have not completed development of any ImmTOR- enabled therapies~~. We expect to continue to incur significant expenses and operating losses for the foreseeable future. We expect that our expenses will increase substantially as we: • continue the research and development of our product candidates; • **increase** ~~seek to enhance~~ and ~~evolve~~ **develop** our **manufacturing** ~~ImmTOR platform~~ and **distribution capacities; •** discover and develop additional product candidates; • seek to maintain and enter into collaboration, licensing and other agreements, including, but not limited to research and development, and / or commercialization agreements; • seek regulatory approvals for any product candidates that successfully complete clinical trials; • potentially establish a sales, marketing and distribution infrastructure and scale up ~~external~~ **internal** manufacturing capabilities to commercialize any products for which we may obtain regulatory approval; • maintain, expand and protect our intellectual property portfolio, including through licensing arrangements; • add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts; • experience any delays or encounter any issues with any of the above, including, but not limited to, failed studies, complex results, safety issues or other regulatory, manufacturing or scale- up challenges; and • are exposed to broad macroeconomic conditions including inflation and supply chain tightness which could result in us paying more, or being unable, to access goods and services. To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates, discovering additional product candidates, obtaining regulatory approval and securing reimbursement for these product candidates, manufacturing, marketing and selling any products for which we may obtain regulatory approval, and establishing and managing our collaborations at various stages of a product candidate' s development.

We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Because of the numerous risks and uncertainties associated with pharmaceutical and biological product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA or other regulatory authorities to perform studies in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates, our expenses could increase and product revenue could be further delayed. We may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to remain profitable would depress our value and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations. We will need substantial additional funding in order to complete development of our product candidates and commercialize our products, if approved. If we are unable to raise capital when needed and on terms favorable to us, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts. We expect our expenses to increase in connection with our ongoing activities, particularly as we continue ~~to develop our gene therapy pipeline, including our collaboration with AskBio, research and develop our autoimmune programs and advance the evolution of our ImmTOR platform in combination with IL- 2, and continue~~ research and development for other product candidates. Additionally, if we obtain regulatory approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Accordingly, we will need to obtain substantial additional funding to continue operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our clinical trials, our other research and development programs or any future commercialization efforts. We believe that our existing cash, cash equivalents and restricted cash as of December 31, ~~2022~~ **2023 , combined with net proceeds received subsequent to December 31, 2023 in connection with our November 2023 private placement,** will enable us to fund our ~~current planned operations~~ **operating expenses** ~~into mid- 2024, though we may realize additional cash resources upon the achievement of certain contingent collaboration milestones~~ and ~~we~~ **capital expenditure requirements for at least the next 12 months. We** may pursue additional cash resources through public or private equity or debt financings, by establishing collaborations with other companies or through the monetization of potential royalty and / or milestone payments pursuant to our existing collaboration and license arrangements. Management' s expectations with respect to our ability to fund current and long- term planned operations are based on estimates that are subject to risks and uncertainties. If actual results are different from management' s estimates, we may need to seek additional strategic or financing opportunities sooner than would otherwise be expected. However, there is no guarantee that any ~~collaboration milestones will be achieved or that any~~ of these strategic or financing opportunities will be executed on favorable terms, and some could be dilutive to existing stockholders. If we are unable to obtain additional funding on a timely basis, we may be forced to significantly curtail, delay, or discontinue one or more of our planned research or development programs or be unable to expand our operations, meet long- term obligations or otherwise capitalize on our commercialization of our product candidates. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including: • the **timing for stockholder approval of the conversion of our Series A Non- Voting Convertible Preferred Stock, par value $ 0. 0001 per share, or Series A Preferred Stock, into shares of our common stock and any redemptions of Series A Preferred Stock for cash; • the** scope, progress, results and costs of our clinical trials, preclinical development, ~~and~~ **manufacturing,** laboratory testing **and logistics** ; • the number of product candidates that we pursue and the speed with which we pursue development ~~; • our collaboration agreements remaining in effect, our entering into additional collaboration agreements and our ability to achieve milestones under these agreements~~ ; • our headcount growth and associated costs; • the costs, timing and outcome of regulatory review of our 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 revenue, if any, from commercial sales 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; • the effect of competing technological and market developments; and • the extent to which we acquire or invest in businesses, products and technologies, including entering into licensing or collaboration arrangements for product candidates. **The Certificate of Designation of Preferences, Rights and Limitations of the Series A Non- Voting Convertible Preferred Stock, or the Certificate of Designation, contains a provision granting each holder of the Series A Preferred Stock the option to require us to redeem any or all of such holder' s shares of Series A Preferred Stock beginning on the date that is 18 months following Closing; provided, however, that no holder will have the right to seek redemption of any shares of Series A Preferred Stock to the extent that such holder would otherwise be unable to convert such shares of Series A Preferred Stock due to the common stock beneficial ownership limitation contained in the Certificate of Designation. The per- share redemption price is the average closing trading price of the common stock for the ten preceding trading days ending on, and including, the trading day immediately prior to the date a notice of conversion is delivered to us. We could be required to use a significant amount of our cash resources on hand to satisfy this redemption obligation, particularly if holders of Series A Preferred Stock exercise their redemption right with respect to a significant number of shares of Series A Preferred Stock or at a time when the trading price of our common stock is elevated. Further, in the event that we do not have sufficient cash on hand to satisfy our redemption obligations, we may need to raise additional capital to satisfy these potential obligations. Any redemption payments could materially limit the amount of cash we have available to fund our operations.** Any additional fundraising efforts may divert our management from their day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Market volatility resulting from the

~~COVID- 19 pandemic, the~~ ongoing ~~conflict~~ **conflicts** in Ukraine **and the Middle East** and current global macroeconomic conditions or other factors could also adversely impact our ability to access capital as and when needed. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders, and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs, including our clinical trial programs, or the commercialization of any product candidates, or be unable to sustain or expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. ~~The terms of our credit facility place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business. On August 31, 2020, we entered into a term loan, or the 2020 Term Loan, of up to $ 35. 0 million, consisting of term loans in an aggregate amount of $ 25. 0 million, or the Term A Loan, and term loans in an aggregate amount of $ 10. 0 million, or the Term B Loan, governed by a loan and security agreement among us and Oxford Finance LLC, or Oxford, as collateral agent and a lender, and Silicon Valley Bank, or SVB, as a lender. The Term A Loan was funded in full on August 31, 2020, the proceeds of which were used to repay our previously existing 2017 term loan and for general corporate and working capital purposes, and the draw period relating to the Term B Loan expired on September 30, 2021. The 2020 Term Loan is secured by a lien on substantially all of our assets, other than intellectual property, provided that such lien includes any rights to payments and proceeds from the sale, licensing or disposition of intellectual property. We also granted Oxford a negative pledge with respect to our intellectual property. Failure to satisfy our current and future debt obligations, including covenants to take or avoid specific actions, under the 2020 Term Loan could result in an event of default, our lenders could accelerate all of the amounts due. If we raise any additional debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.~~ Our ability to use our net operating loss and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations. We have net operating loss carryforwards, or NOLs, for federal and state income tax purposes that may be available to offset our future taxable income, if any. In general, under Sections 382 and 383 of ~~the U. S. Internal Revenue Code of 1986, as amended, or~~ the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to use its pre- change NOLs to offset future taxable income. If the ~~U. S. Internal Revenue Service, or~~ IRS, challenges our analysis that existing NOLs will not expire before utilization due to previous ownership changes, or if we undergo an ownership change ~~in connection with or after a public offering~~, our ability to use our NOLs could be limited by Section 382 of the Code. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Sections 382 and 383 of the Code. Furthermore, our ability to use NOLs of companies that we may acquire in the future may be subject to limitations. As a result, we may not be able to use a material portion of the NOLs reflected on our balance sheet, even if we attain profitability. ~~The reduction of the corporate tax rate under the TCJA may cause a reduction in the economic benefit of our NOLs and other deferred tax assets available to us.~~ Under current law, NOLs that arose before January 1, 2018 ~~, will begin~~ **may be carried forward up** to **20 years** ~~expire in 2041~~ . NOLs that arose after 2017 may be used to offset at most 80 % of our taxable income to the extent not offset by pre- 2018 NOLs **and such NOLs can be carried forward indefinitely** . As a result, we may become required to pay federal income taxes in future years despite having generated losses for federal income tax purposes in prior years. Risks Related to our Intellectual Property If we or our licensors are unable to adequately protect our proprietary technology, or obtain and maintain issued patents that are sufficient to protect our product candidates, others could compete against us more directly, which would negatively impact our business. Our success depends in large part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. The patent prosecution process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. As we reach the statutory deadlines for deciding whether and where to initiate prosecution in specific foreign jurisdictions by filing national stage applications based on our Patent Cooperation Treaty, or PCT, applications, we will have to decide whether and where to pursue patent protection for the various inventions claimed in our patent portfolio, and we will only have the opportunity to obtain patents in those jurisdictions where we pursue protection. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, such as, with respect to proper priority claims, inventorship, claim scope or patent term adjustments. If there are material defects in the form or preparation of our patents or patent applications, such patents or applications may be invalid and unenforceable. Moreover, our competitors may independently develop equivalent knowledge, methods and know- how. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. We also cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete and thorough, nor can we be

certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents covering technology that we license from third parties. We may also require the cooperation of our licensors to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Moreover, we have obligations under our licenses, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license could have a material adverse impact on our business. **Some of our patent licenses are non- exclusive. In those cases, a competitor could obtain a license to the same or similar technology from the licensor. We have at least one exclusive patent license that is restricted to a particular field of use. A competitor could obtain a license to a similar technology outside of that field of use.** We cannot provide any assurances that the issued patents we currently own, or any future patents, include claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. Further, it is possible that a patent claim may provide coverage for some but not all parts of a product candidate or third- party product. These and other factors may provide opportunities for our competitors to design around our patents. Moreover, other parties may have developed technologies that may be related or competitive to our approach, and may have filed or may file patent applications, and may have received or may receive patents that may overlap or conflict with our patent applications, either by claiming similar methods or by claiming subject matter that could dominate our patent position. In addition, it may be some time before we understand how the patent office reacts to our patent claims and whether they identify prior art of relevance that we have not already considered. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in any owned patents or pending patent applications, or that we were the first to file for patent protection of such inventions, nor can we know whether those from whom we may license patents were the first to make the inventions claimed or were the first to file. For these and other reasons, the issuance, scope, validity, enforceability and commercial value of our patent rights are subject to a level of uncertainty. Our pending and future patent applications may not result in patents being issued that protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. We may be subject to a third- party preissuance submission of prior art to the U. S. Patent and Trademark Office, or USPTO **, or other patent office** , or become involved in opposition, derivation, reexamination, inter partes review, post- grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize product candidates without infringing third- party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Furthermore, an adverse decision in an interference proceeding can result in a third party receiving the patent right sought by us, which in turn could affect our ability to develop, market or otherwise commercialize our product candidates. The issuance, scope, validity, enforceability and commercial value of our patents are subject to a level of uncertainty. The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. Due to legal standards relating to patentability, validity, enforceability and claim scope of patents covering biotechnological and pharmaceutical inventions, our ability to obtain, maintain and enforce patents is uncertain and involves complex legal and factual questions. Even if issued, a patent' s validity, inventorship, ownership or enforceability is not conclusive. Accordingly, rights under any existing patent or any patents we might obtain or license may not cover our product candidates, or may not provide us with sufficient protection for our product candidates to afford a commercial advantage against competitive products or processes, including those from branded and generic pharmaceutical companies. In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how, information, or technology that is not covered by our patents. Although our agreements require all of our employees to assign their inventions to us, and we require all of our employees, consultants, advisors and any other third parties who have access to our trade secrets, proprietary know- how and other confidential information and technology to enter into appropriate confidentiality agreements, we cannot be certain that our trade secrets, proprietary know- how, and other confidential information and technology will not be subject to unauthorized disclosure or that our competitors will not otherwise gain access to or independently develop substantially equivalent trade secrets, proprietary know- how, and other information and technology. 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 globally. If we are unable to prevent unauthorized disclosure of our intellectual property related to our product candidates and technology to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could adversely affect our business and operations. Any litigation to enforce or defend our patent rights, even if we were to prevail, could be costly and time- consuming and would divert the attention of our management and key personnel from our business operations. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded if we were to prevail may not be commercially meaningful. Even if we are successful, domestic or foreign litigation, or USPTO or foreign patent office proceedings, may result in substantial costs and distraction to our management. We may not be able, alone or with our licensors or potential collaborators, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the

United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other proceedings, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings. In addition, during the course of this kind of litigation or proceedings, there could be public announcements of the results of hearings, motions or other interim proceedings or developments or public access to related documents. If investors perceive these results to be negative, the market price for our common stock could be adversely affected. If we are unable to protect the confidentiality of our trade secrets and know- how, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know- how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also seek to enter into confidentiality and invention or patent assignment agreements with our employees, advisors and consultants. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Our trade secrets may also be obtained by third parties by other means, such as breaches of our physical or computer security systems. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates. As is the case with other biotechnology companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biotechnology industry involves both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. In addition, recent patent reform legislation could further increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act America Invents Act, or the Leahy- Smith Act, included provisions that affect the way patent applications are prosecuted and may also affect patent litigation, including first- to- file provisions. A third party that files a patent application in the USPTO before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This requires us to be cognizant of the time from invention to filing of a patent application. Thus, for our U. S. patent applications containing a priority claim after March 16, 2013, the date such provisions became effective, there is a greater level of uncertainty in the patent law. Moreover, some of the patent applications in our portfolio will be subject to examination under the pre- Leahy- Smith Act law and regulations, while other patents applications in our portfolio will be subject to examination under the law and regulations, as amended by the Leahy- Smith Act. This introduces additional complexities into the prosecution and management of our portfolio. In addition, the Leahy- Smith Act limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. These provisions apply to all of our U. S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a federal court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims because it may be easier for them to do so relative to challenging the patent in a federal court action. It is not clear what, if any, impact the Leahy- Smith Act will have on the operation of our business. However, the Leahy- Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. In addition, recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. From time to time, the U. S. Supreme Court, other federal courts, the U. S. Congress or the USPTO may change the standards of patentability, and any such changes could have a negative impact on our business. Depending on these and other decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change or be interpreted in unpredictable ways that would weaken our ability to obtain new patents or to enforce any patents that may issue to us in the future. In addition, these events may adversely affect our ability to defend any patents that may issue in procedures in the USPTO or in courts. Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business. Our commercial success depends upon our ability, and the ability of our collaborators, to develop, manufacture, market and sell our product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. There is considerable intellectual property litigation in the biotechnology and pharmaceutical industries. While no such litigation has been brought against us and we have not been held by any court to have infringed a third party' s intellectual property rights, we cannot guarantee that our technology, product candidates or use of our product candidates do not infringe third- party patents. We are aware of numerous patents and pending applications owned by third parties, and we monitor patents and patent applications in the fields in which we are developing product candidates, both in the United States and elsewhere. However, we may have failed to identify relevant third- party patents or applications. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Moreover, it is difficult for industry participants, including us, to identify all third- party patent rights that may be relevant to our product candidates and technologies because patent searching is imperfect due to

differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We may fail to identify relevant patents or patent applications or may identify pending patent applications of potential interest but incorrectly predict the likelihood that such patent applications may issue with claims of relevance to our technology. In addition, we may be unaware of one or more issued patents that would be infringed by the manufacture, sale or use of a current or future product candidate, or we may incorrectly conclude that a third- party patent is invalid, unenforceable or not infringed by our activities. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidates or the use of our product candidates. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Other parties may allege that our product candidates or the use of our technologies infringes patent claims or other intellectual property rights held by them or that we are employing their proprietary technology without authorization. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our product candidates and technology, including interference or derivation proceedings before the USPTO and similar bodies in other countries. Third parties may assert infringement claims against us based on existing intellectual property rights and intellectual property rights that may be granted in the future. Patent and other types of intellectual property litigation can involve complex factual and legal questions, and their outcome is uncertain. If we are found, or believe there is a risk we may be found, to infringe a third party' s intellectual property rights, we could be required or may choose to obtain a license from such third party to continue developing and marketing our product candidates and technology. However, we may not be able to obtain any such license on commercially reasonable terms or 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. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Even if we are successful in such proceedings, we may incur substantial costs and divert management time and attention in pursuing these proceedings, which could have a material adverse effect on us. Patent litigation is costly and time- consuming. We may not have sufficient resources to bring these actions to a successful conclusion. There could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Any of these risks coming to fruition could have a material adverse impact on our business. We may become involved in lawsuits to protect or enforce our patents or other intellectual property, and our issued patents covering our product candidates could be found invalid or unenforceable or could be interpreted narrowly if challenged in court. Competitors may infringe our intellectual property, including our patents or the patents of our licensors. As a result, we may be required to file infringement claims to stop third- party infringement or unauthorized use. This can be expensive, particularly for a company of our size, and time- consuming. If we initiated legal proceedings against a third party to enforce a patent, if and when issued, covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement, or failure to claim patent-eligible subject matter. Grounds for unenforceability assertions include allegations that someone connected with the 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. Such mechanisms include re- examination, post- grant review, inter partes review, interference proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our product candidates or competitive products. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Moreover, even if not found invalid or unenforceable, the claims of our patents could be construed narrowly or in a manner that does not cover the allegedly infringing technology in question. Such a loss of patent protection would have a material adverse impact on our business. The lives of our patents may not be sufficient to effectively protect our products and business. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non- provisional filing date. Although various extensions may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, proprietary technologies and their uses are obtained, once the patent life has expired, we may be open to competition. In addition, although upon issuance in the United States a patent' s life can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. If we do not have sufficient patent life to protect our product candidates, proprietary technologies and their uses, our business and results of operations will be adversely affected. 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 noncompliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and, in some jurisdictions, during

the pendency of a patent application. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have an adverse effect on our business. ~~If we fail to comply with our obligations in our intellectual property licenses and funding arrangements with third parties, we could lose rights that are important to our business. We are party to multiple license agreements that impose, and we may enter into additional licensing and funding arrangements with third parties that may impose, diligence, development and commercialization timelines, milestone payment, royalty, insurance and other obligations on us. Under our existing licensing agreements, we are obligated to pay royalties on net product sales of product candidates or related technologies to the extent they are covered by the agreement. Our results of operations will be affected by the level of royalty payments that we are required to pay to third parties. We cannot precisely predict the amount, if any, of royalties that we will be required to pay to third parties in the future. Any disagreements with the counterparty over the amount of royalties owed could lead to litigation, which is costly. In addition, if we fail to comply with our obligations under current or future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market any product candidate that is covered by these agreements, or may face other penalties under the agreements. Such an occurrence could materially adversely affect the value of product candidates being developed using rights licensed to us under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements may result in our having to negotiate new or reinstated agreements with less favorable terms, or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. Furthermore, our counterparties may allege that we are operating outside the scope of the licenses granted and terminate our license or otherwise require us to alter development, manufacturing or marketing activities.~~ We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in- licenses. We currently have rights to certain intellectual property, through licenses from third parties and under patents and patent applications that we own, to develop our product candidates. Because we may find that our programs require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in- license or use these proprietary rights. We may be unable to acquire or in- license compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third- party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third- party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of that program and our business and financial condition could suffer. We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. We may also engage advisors and consultants who are concurrently employed at universities or other organizations or who perform services for other entities. Although we try to ensure that our employees, advisors and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, advisors or consultants have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such party' s former or current employer or in violation of an agreement with another party. Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims. In addition, while it is our policy to require our employees, consultants, advisors and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Similarly, we may be subject to claims that an employee, advisor or consultant performed work for us that conflicts with that person' s obligations to a third party, such as an employer, and thus, that the third party has an ownership interest in the intellectual property arising out of work performed for us. Litigation may be necessary to defend against these claims. ~~Although we have no knowledge of any such claims being alleged to date, if such claims were to arise, litigation may be necessary to defend against any such claims.~~ If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management. We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection. Filing, prosecuting and defending patents on product candidates in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States could be less extensive than in the United States, assuming that rights are obtained in the United States

and assuming that rights are pursued outside the United States. In this regard, in addition to the United States, we also seek to protect our intellectual property rights in other countries. The statutory deadlines for pursuing patent protection in individual foreign jurisdictions are based on the priority date of each of our patent applications. For all of the patent families in our portfolio, including the families that may provide coverage for our lead product candidate, the relevant statutory deadlines have not yet expired. Therefore, for each of the patent families that we believe provide coverage for our lead product candidate, we will need to decide whether and where to pursue additional protection outside the United States. In addition, the laws of some foreign countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, for our existing patent rights outside the United States and any foreign patent rights we may decide to pursue in the future, we may not be able to obtain relevant claims and / or we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our product candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing. If we do not obtain additional protection under the Hatch- Waxman Act and similar foreign legislation extending the terms of our patents for our product candidates, our business may be harmed. Depending upon the timing, duration and specifics of FDA regulatory approval for our product candidates, one or more of our U. S. patents may be eligible for limited patent term restoration under **the Drug Price Competition and Patent Term Restoration Act of 1984, or** the Hatch- Waxman Act. The Hatch- Waxman Act permits a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. Patent term restorations, however, are limited to a maximum of five years and cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA. The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. It takes at least six months to obtain approval of the application for patent term extension. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened, our competitors may obtain earlier approval of competing products and our ability to generate revenues could be materially adversely affected. Risks Related to our Operations Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel. We are highly dependent on Carsten Brunn, Ph. D., our President and Chief Executive Officer, as well as the other principal members of our management, scientific and clinical ~~team~~ **teams** . Although we have entered into employment agreements or offer letters with Dr. Brunn and other executive officers, each of them may terminate their employment with us at any time. We do not maintain " key person " insurance for any of our executives or other employees. Recruiting and retaining qualified scientific, clinical, manufacturing, technology and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize product candidates. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. We have incurred increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives and corporate governance practices. As a public company, we have incurred and expect to continue to incur significant legal, accounting and other expenses. If we are unable to maintain effective internal control over financial reporting, we may not have adequate, accurate or timely financial information, and we may be unable to meet our reporting obligations as a public company or comply with the requirements of the SEC or Section 404 **of the Sarbanes- Oxley Act of 2002** . This could result in a restatement of our financial statements, the imposition of sanctions, including the inability of registered broker dealers to make a market in our common stock, or investigation by regulatory authorities. Any such action or other negative results caused by our inability to meet our reporting requirements or comply with legal and regulatory requirements or by disclosure of an accounting, reporting or control issue could adversely affect the trading price of our securities and our business. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. **We have identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our consolidated financial statements or cause us to fail to meet our periodic reporting obligations. In connection with the audit of our consolidated financial statements as of and for the**

year ended December 31, 2023, we identified a material weakness in our internal control over financial reporting and concluded that our internal control over financial reporting was not effective as of December 31, 2023. There are no material accounting errors or omissions within the consolidated financial statements as a result of this material weakness. We concluded that we did not design and implement effective internal controls specifically related to the documentation of the assumptions supporting the valuation of the in- process intangible assets in connection with the Old Cartesian material business combination and the initial and ongoing contingent value right obligation issued at the time to legacy Selecta stockholders. This includes a lack of sufficient documentation to provide evidence of the associated management review controls. In response to the identified material weakness above, we, with the oversight of the Audit Committee of the Board of Directors, or the Audit Committee, intend to take comprehensive actions to remediate the material weakness in internal control over financial reporting. We expect to re- evaluate the scope and level of precision for conducting and documenting the reviews over significant acquisitions and contingent value rights including the review of prospective financial information used in valuation reports produced by third- party specialists supporting the accounting for business combinations and contingent value rights. The remediation efforts are intended both to address the identified material weakness and to enhance our overall financial control environment. This material weakness and any other failure to maintain effective internal control over financial reporting could result in a loss of confidence in the reliability of our financial statements which could have a negative impact on the trading price of our common stock and harm our ability to raise additional capital on acceptable terms or at all. A variety of risks associated with maintaining our subsidiary in Russia or expanding operations internationally could adversely affect our business. In addition to our U. S. operations, we maintain a wholly owned subsidiary in Russia, Selecta (RUS). However, we are in the process of winding down ~~these~~ **all remaining** operations **of this subsidiary** . We may face risks associated with winding down the operations of our subsidiary in Russia, or with any international operations, including possible unfavorable regulatory, pricing and reimbursement, legal, political, tax and labor conditions, and risks associated with our compliance with evolving international sanctions, which could harm our business. We may also rely on collaborators to commercialize any approved product candidates outside of the United States. Doing business internationally involves a number of risks, including but not limited to: • multiple, conflicting and changing laws and regulations, such as privacy regulations, tax laws, export and import restrictions, employment laws, regulatory requirements and other governmental approvals, permits and licenses; • failure by us to obtain and maintain regulatory approvals for the use of our product candidates in various countries; • additional potentially relevant third- party patent rights; • complexities and difficulties in obtaining protection of and enforcing our intellectual property rights; • difficulties in staffing and managing foreign operations; • complexities associated with managing multiple- payor reimbursement regimes, government payors or patient self- pay systems; • limits on our ability to penetrate international markets; • financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our product candidates and exposure to foreign currency exchange rate fluctuations, which could result in increased operating expenses and reduced revenues; • natural disasters, political and economic instability, including wars, events of terrorism and political unrest, outbreak of disease, including the COVID- 19 pandemic, boycotts, curtailment of trade and other business restrictions, economic sanctions, and economic weakness, including inflation; • changes in diplomatic and trade relationships; • challenges in enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; • restriction on cross- border investment, including enhanced oversight by the Committee on Foreign Investment in the United States and substantial restrictions on investment from China; • certain expenses including, among others, expenses for travel, translation and insurance; • legal risks, including use of the legal system by the government to benefit itself or affiliated entities at our expense, including expropriation of property; • regulatory and compliance risks that relate to maintaining accurate information and control over sales and activities that may fall within the purview of the FCPA its books and records provisions, or its anti- bribery provisions; and • risks that we may suffer reputational harm as a result of our operations in Russia. Any of these factors could significantly harm our future international expansion and operations and, consequently, our results of operations. Our business and operations, including our development programs, could be materially disrupted in the event of system failures, security breaches, violations of data protection laws or data loss or damage by us or third parties on which we rely, including our CROs or other contractors or consultants. Our internal computer systems and those of third parties on which we rely, including our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could have a material adverse effect on our business operations, including a material disruption of our development programs. Unauthorized disclosure of sensitive or confidential patient or employee data, including personally identifiable information, whether through breach of computer systems, systems failure, employee negligence, fraud or misappropriation, or otherwise, or unauthorized access to or through our information systems and networks, whether by our employees or third parties, could result in negative publicity, legal liability and damage to our reputation. Unauthorized disclosure of personally identifiable information could also expose us to sanctions for violations of data privacy laws and regulations around the world. To the extent that any disruption or security breach resulted in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development of our product candidates could be delayed. For example, the loss of or damage to clinical trial data, such as from completed or ongoing clinical trials, for any of our product candidates would likely result in delays in our marketing approval efforts and significantly increased costs in an effort to recover or reproduce the data. We have previously been, and expect to remain, the target of cyber- attacks. As we become more dependent on information technologies to conduct our operations, cyber incidents, including deliberate attacks, such as ransomware attacks, and attempts to gain unauthorized access to computer systems and networks, may increase in frequency and sophistication. These incidents pose a risk to the security of our systems

and networks, the confidentiality and the availability and integrity of our data and these risks apply both to us, and to third parties on whose systems we rely for the conduct of our business. While we do not believe the effect of these incidents has historically been material to our results of operations, financial condition or prospects, cyber threats are persistent and constantly evolving. Such threats have increased in frequency, scope and potential impact in recent years, which increases the difficulty of detecting and successfully defending against them. As cyber threats continue to evolve, we may be required to incur additional expenses in order to enhance our protective measures or to remediate any information security vulnerability. There can be no assurance that we or our third- party providers will be successful in preventing cyber- attacks or mitigating their effects. Similarly, there can be no assurance that our collaborators, CROs, third- party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack or destruction or loss of data could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber- attacks or destruction or loss of data and may incur significant additional expense to implement further data protection measures. It is also possible that unauthorized access to data may be obtained through inadequate use of security controls by our suppliers or other vendors. Although we have general liability insurance coverage, our insurance may not cover all claims, continue to be available on reasonable terms or be sufficient in amount to cover one or more large claims. Additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition. Acquisitions or joint ventures could disrupt our business, cause dilution to our stockholders and otherwise harm our business. We may acquire other businesses, product candidates or technologies as well as pursue strategic alliances, joint ventures, technology licenses or investments in complementary businesses. We have not made any acquisitions to date, and our ability to do so successfully is unproven. Any of these transactions could be material to our financial condition and operating results and expose us to many risks, including: • disruption in our relationships with future customers or with current or future distributors or suppliers as a result of such a transaction; • unexpected liabilities related to acquired companies; • difficulties integrating acquired personnel, technologies and operations into our existing business; • diversion of management time and focus from operating our business to acquisition integration challenges; • increases in our expenses and reductions in our cash available for operations and other uses; • possible write- offs or impairment charges relating to acquired businesses; and • inability to develop a sales force for any additional product candidates. Foreign acquisitions involve unique risks in addition to those mentioned above, including those related to integration of operations across different cultures and languages, currency risks and the particular economic, political and regulatory risks associated with specific countries. Also, the expected benefit of any acquisition may not materialize. Future acquisitions or dispositions could result in potentially dilutive issuances of our equity securities, the incurrence of debt, contingent liabilities or amortization expenses or write- offs of goodwill, any of which could harm our financial condition. We cannot predict the number, timing or size of future joint ventures or acquisitions, or the effect that any such transactions might have on our operating results. Risks Related to our Common Stock The market price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. The trading price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control. The stock market in general and the market for smaller biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your common stock at or above the price at which you purchased. The market price for our common stock may be influenced by many factors, including: • the success of competitive products or technologies; • results or progress, or changes in approach or timelines, of clinical trials of our product candidates or those of our competitors; • failure or discontinuation of any of our development programs; • commencement of, termination of, or any development related to any collaboration or licensing arrangement; • regulatory or legal developments in the United States and other countries; • development of new product candidates that may address our markets and make our product candidates less attractive; • changes in physician, hospital or healthcare provider practices that may make our product candidates less useful; • announcements by us, our collaborators or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; • announcement or market expectation of additional financing efforts; • developments or disputes concerning patent applications, issued patents or other proprietary rights; • the recruitment or departure of key personnel; • the level of expenses related to any of our product candidates or clinical development programs; • failure to meet or exceed financial estimates, projections or development timelines of the investment community or that we provide to the public; • the results of our efforts to discover, develop, acquire or in- license additional product candidates or products; • actual or expected changes in estimates as to financial results, development timelines or recommendations by securities analysts; • variations in our financial results or those of companies that are perceived to be similar to us; • changes in the structure of healthcare payment systems; • sale of common stock by us or our stockholders in the future as well as the overall trading volume of our common stock; • changes in the composition of our stockholder base; • activity in the options market for shares of our common stock; • market conditions in the pharmaceutical and biotechnology sectors; • general economic, industry and market conditions; and • the other factors described in this " Risk Factors " section. Our executive officers, directors, and principal stockholders, if they choose to act together, will continue to have the ability to control or significantly influence all matters submitted to stockholders for approval. Our executive officers, directors and stockholders who own more than 5 % of our outstanding common stock and their respective affiliates, in the aggregate, hold shares representing approximately ~~38~~ **60** . ~~4~~ **1** % of our outstanding voting stock as of December 31, ~~2022~~ **2023 , and assuming the conversion of all shares of Series A Preferred Stock into common stock and reflecting the completion of the November 2023 private placement, which occurred subsequent to December 31, 2023** . As a result, if these stockholders choose to act together, they would be able to control or significantly influence all matters

submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would control or significantly influence the election of directors, the composition of our management and approval of any merger, consolidation or sale of all or substantially all of our assets. **Future** ~~Sales~~ **sales** of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. ~~Sales~~ **Concurrently and in connection with the execution** of **the Merger Agreement, certain Old Cartesian securityholders, as of immediately prior to the Merger, and certain of our directors and officers as of immediately prior to the Merger entered into lock- up agreements with us, pursuant to which each such stockholder is subject to** a ~~substantial number~~ **lockup on the sale or transfer** of shares of our common stock ~~in~~ **held by each such stockholder, including** ~~the~~ **those** ~~public market could occur at any time. These sales, or the perception in the market that the holders of a large number of~~ shares ~~intend to sell~~ **received by Old Cartesian securityholders in the Merger, for a period of 180 days from the Closing. Upon expiration of this 180- day lockup period, these** shares **will become** ~~, could reduce the market price of our common stock reduce. As of December 31, 2022, we had 153, 042, 435 shares of common stock outstanding. Also, as of December 31, 2022, 15, 844, 651 and 1, 705, 558 shares of common stock that are subject to outstanding options or restricted stock unit awards, respectively, under our outstanding equity plans are~~ eligible for sale in the public market ~~to the extent permitted by the provisions of various vesting schedules, and Rule 144 under the Securities Act~~. ~~Additionally~~ **On November 13** , ~~as of December 31, 2022~~ **2023** , ~~up to 31~~ **we also entered into a Registration Rights Agreement** , ~~228~~ **or the RRA** , ~~279 shares~~ **with holders** of common stock **and Series A Preferred Stock signatory thereto. Pursuant to the RRA, we** are ~~issuable upon exercise~~ **obligated to prepare and file a resale registration statement with the SEC by the Filing Deadline (as defined therein). We agreed to use our reasonable best efforts to cause this registration statement to be declared effective by the SEC within 45 calendar days** of ~~outstanding warrants~~ **the Filing Deadline (or within 90 calendar days of the Filing Deadline if the SEC reviews the registration statement). Once such registration statement is declared effective, the shares to which the registration statement relates will no longer constitute restricted securities and may be sold freely in the public markets, subject to lapse on any related contractual restrictions related thereto of any holder party thereto, and subject to any restrictions that may be applicable to any control securities** . If ~~these additional shares of common stock are sold~~ **our stockholders sell, indicate an intention to sell** , or it is perceived that they will ~~be sold,~~ **sell substantial amounts of our common stock** in the public market **after legal restrictions on resale lapse** , the trading price of our common stock could decline. **In addition** ~~We may not have the funds necessary to fulfill our obligation to repurchase certain warrants. Under certain circumstances~~ , ~~holders~~ **shares** of ~~certain warrants may require us to repurchase the remaining unexercised portion of such warrants for an amount of cash equal to the value of the warrant as determined in accordance with the Black- Scholes option pricing model and the terms of the warrants. Our ability to repurchase the warrants depends on~~ our **common stock** ~~ability to generate cash flow in the future. To some extent, this is subject to general economic, financial, competitive, legislative and regulatory factors and other factors~~ that are ~~beyond~~ **subject to** our **outstanding options** ~~control. We cannot be certain that we~~ will **become eligible** ~~maintain sufficient cash reserves or~~ **for sale in the public market** ~~that our business will generate cash flow from operations at levels sufficient~~ to **the extent** ~~permit~~ **permitted by** ~~us to repurchase~~ the ~~warrants. Provisions~~ **provisions** ~~in our restated certificate~~ of ~~incorporation~~ **various vesting agreements** and ~~restated bylaws~~ **Rules 144 and 701 under the Securities Act. Anti- takeover provisions in our charter documents** and under Delaware law **and the terms of some of our contracts** could make an acquisition of **us** ~~our company, which may be beneficial to our stockholders,~~ more difficult and may prevent attempts by our stockholders to replace or remove our ~~current~~ management. Provisions in our restated certificate of incorporation ~~and~~ **, as amended,** ~~our~~ **or the Charter, and amended and** restated **by-** ~~bylaws~~ -- **laws** may ~~discourage,~~ delay or prevent **an** ~~a merger,~~ acquisition or ~~other~~ **a** change in **management** ~~control of our company that stockholders may consider favorable, including transactions in which a stockholder might otherwise receive a premium for its shares~~ . These provisions ~~could also limit~~ **include a prohibition on actions by written consent of our stockholders and** the **ability of our board of directors,** ~~price that investors might be willing to pay in the future for~~ -- **or** ~~shares~~ **the Board** of ~~our common~~ **Directors, to issue preferred** stock **without stockholder approval** ~~, thereby depressing the market price of our common stock~~ . In addition, because **we are incorporated in Delaware, we are governed by the provisions of Section 203 of the DGCL, which prohibits stockholders owning in excess of 15 % of our outstanding voting stock from merging** ~~our~~ -- **or** ~~board of directors is responsible~~ **combining with us. Although we believe these provisions collectively will provide** for ~~appointing~~ **an opportunity to receive higher bids by requiring potential acquirers to negotiate with our Board of Directors,** ~~the~~ **they** ~~members of our management team~~ **would apply even if the offer may be considered beneficial by some stockholders. In addition** , these provisions may frustrate or prevent any attempts by our stockholders to replace or remove ~~our~~ **then** current management by making it more difficult for stockholders to replace members of ~~our~~ **the** ~~board~~ **Board** of ~~directors~~ **Directors** ~~. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware~~ , which **is responsible** ~~prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us~~ for **appointing** ~~a period of three~~ -- **the members** ~~years after the date~~ of **management** ~~the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner~~ . Furthermore, our **Charter** ~~restated certificate of incorporation~~ specifies that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for most legal actions involving claims brought against us by stockholders. We believe this provision benefits us by providing increased consistency in the application of Delaware law by chancellors particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi- forum litigation. However, the provision may have the effect of discouraging lawsuits against our directors, officers, employees and agents as it may limit any stockholder' s ability to bring a claim in a judicial forum that such stockholder finds favorable for disputes with us or our directors, officers, employees or

agents. **In addition, the Certificate of Designation relating to our Series A Preferred Stock may delay or prevent a change in control of our Company. At any time while at least 30 % of the originally issued Series A Preferred Stock remains issued and outstanding, we may not consummate a Fundamental Transaction (as defined in the Certificate of Designation) or any merger or consolidation of the Company with or into another entity or any stock sale to, or other business combination in which the stockholders of the Company immediately before such transaction do not hold at least a majority of the capital stock of the Company immediately after such transaction, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series A Preferred Stock. This provision of the Certificate of Designation may make it more difficult for us to enter into any of the aforementioned transactions.** We have been in the past and may in the future be subject to **stockholder litigation** ~~securities class action lawsuits~~ . In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. Involvement in such litigation, could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. On **February 21, 2024, Paul Wymer, a purported stockholder of our Company, filed an action against us and members of our Board of Directors in the U. S. District Court for the Southern District of New York, titled Wymer v. Cartesian Therapeutics, Inc., et al., No. 24- cv- 01288. The complaint alleges that the defendants violated Sections 14 (a) and 20 (a) of the Exchange Act by failing to disclose purportedly material information to our stockholders in our Preliminary and Definitive Proxy Statements filed on January 31, 2024, and February 14, 2024, respectively, in connection with the solicitation of stockholder approval of a proposal to convert our Series A Preferred Stock into our common stock, subject to certain beneficial ownership limitations, or the Conversion Proposal. The complaint seeks injunctive relief enjoining or rescinding the Merger, issuance of an amended proxy statement, and attorneys' fees and costs. Additional similar lawsuits may be filed. We believe this lawsuit is without merit and intend to vigorously defend against this plaintiff' s claims. On February 7, 2024, Justin Sloan, a purported stockholder of our Company, filed a putative class action on behalf of himself and similarly situated stockholders of the Company against our Company and members of our Board of Directors in the Court of Chancery of the State of Delaware, titled Sloan v. Barabe, et al., No. 2024- 0105. The complaint alleges that the individual defendants breached their fiduciary duties by failing to disclose purportedly material information to our Company' s stockholders in our Preliminary Proxy Statement filed on January 31, 2024 in connection with the solicitation of stockholder approval of the Conversion Proposal. The complaint seeks a temporary injunction against the stockholder vote on the Conversion Proposal, compensatory damages, pre- and post- judgment interest, and attorneys' fees and costs. At a telephonic hearing on February 28, 2024, the Court denied the Plaintiff' s motion to expedite the proceedings, rejecting Plaintiff' s argument that the lawsuit raised colorable disclosure claims warranting expedited treatment. Additional similar lawsuits may be filed. We believe this lawsuit is without merit and intend to vigorously defend against this plaintiff' s claims. On** August 3, 2020, a stockholder of Selecta filed a stockholder derivative action, purportedly on behalf of Selecta and against certain current and former members of the Company' s Board of Directors, as well as one affiliated company owned by a current board member, in the Court of Chancery of the State of Delaware, namely Franchi v. Barabe, et al. The complaint alleges that the individual defendants breached their fiduciary duties and committed corporate waste when they authorized a private placement transaction, announced on December 19, 2019, at a price allegedly below fair value. The complaint further alleges that the four defendant directors who participated in the private placement were unjustly enriched in connection with the transaction. On September 25, 2020, the defendants filed a motion to dismiss the lawsuit. On November 6, 2020, the plaintiff filed an amended complaint, and the defendants filed a second motion to dismiss on January 8, 2021. On December 31, 2020, we received a litigation demand letter from two other putative stockholders relating to the same private placement transaction. On April 12, 2021, the Court of Chancery in the State of Delaware granted a motion to stay the litigation pending a review by a Special Committee appointed by the Company' s Board of Directors. While the litigation was stayed, the parties reached an agreement in principle to settle the matter, and on March 18, 2022, they submitted a Stipulation and Agreement of Settlement and other documentation to the Court for its approval of the settlement. On July 21, 2022, the Court held a settlement hearing, at which the settlement was approved. On August 1, 2022, the Court entered an Order and Final Judgment which dismissed the action, and all claims contained therein, with prejudice. We could receive other demands or be subject to other litigation. **We** ~~While we~~ intend to vigorously defend against any demands which we believe to be without merit ~~,~~ **.** ~~there~~ **There** can be no assurance as to the outcome of any stockholder litigation. Unfavorable outcomes in ~~securities~~ class action litigation could require us to pay extensive damages, which could delay or prevent our ability to develop our product candidates and harm our operations. **Risks Related to the Merger There is no guarantee that the Merger will increase stockholder value. In November 2023 we merged with Old Cartesian. We cannot guarantee that implementing the Merger and related transactions will not impair stockholder value or otherwise adversely affect our business. The Merger poses significant integration challenges between our businesses and management teams which could result in management and business disruptions, any of which could harm our results of operation, business prospects, and impair the value of the Merger to our stockholders. Pursuant to the terms of the Merger Agreement, we are required to recommend that our stockholders approve the conversion of shares of our Series A Preferred Stock into shares of our common stock. We cannot guarantee that our stockholders will approve this matter, and if they fail to do so we may be required to settle such shares in cash and our operations may be materially harmed. Under the terms of the Merger Agreement, we agreed to call and hold a meeting of our stockholders to obtain the requisite approvals for the conversion of shares of Series A Preferred Stock into shares of our common stock, and, if such approval is not obtained at that meeting, to seek to obtain such approvals at an annual or special stockholders' meeting to be held at least every six months thereafter until such approval is obtained, which would be time- consuming and costly. Additionally, beginning on the date that is 18 months from the date of the Closing, the**

holders of our then- outstanding shares of Series A Preferred Stock will be entitled to elect to have such shares of Series A Preferred Stock redeemed for cash at a price per share equal to the ten- day trailing average closing trading price of the common stock at such time, as described in our Certificate of Designation relating to the Series A Preferred Stock. If we are forced to cash settle a significant amount of the Series A Preferred Stock, it could materially affect our results of operations. The failure to successfully integrate the businesses of Selecta and Old Cartesian in the expected timeframe would adversely affect our future results. Our ability to successfully integrate the operations of Selecta and Old Cartesian will depend, in part, on our ability to realize the anticipated benefits and cost savings from the Merger. If we are not able to achieve these objectives, the anticipated benefits and cost savings of the Merger may not be realized fully, or at all, or may take longer to realize than expected, and the value of our common stock may be adversely affected. In addition, the integration of Selecta' s and Old Cartesian' s respective businesses will be a time- consuming and expensive process. Proper planning and effective and timely implementation will be critical to avoid any significant disruption to our operations. It is possible that the integration process could result in the loss of key employees, the disruption of our business or the identification of inconsistencies in standards, controls, procedures and policies that adversely affect our ability to maintain relationships with customers, suppliers, distributors, creditors, lessors, clinical trial investigators or managers or to achieve the anticipated benefits of the Merger. Delays encountered in the integration process could have a material adverse effect on our operating results and financial condition, including the value of its common stock. We have incurred substantial expenses related to the integration of Old Cartesian. We have incurred substantial expenses in connection with the Merger and the subsequent integration of Old Cartesian with Selecta. There are a large number of processes, policies, procedures, operations, technologies and systems that must be integrated, including purchasing, accounting and finance, sales, billing, payroll, research and development, marketing and benefits. Both we and Old Cartesian have incurred significant transaction expenses in connection with the drafting and negotiation of the Merger Agreement and significant severance expenses as a result of the Merger. While we and Old Cartesian have assumed that a certain level of expenses will be incurred, there are many factors beyond our control that could affect the total amount or the timing of the integration expenses. Moreover, many of the expenses that have been and will be incurred are, by their nature, difficult to estimate accurately. These integration expenses have resulted in our taking significant charges against earnings following the completion of the Merger, and the amount and timing of such charges are uncertain at present.