

Risk Factors Comparison 2024-02-21 to 2023-02-28 Form: 10-K

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You should consider carefully the following risk factors, together with all the other information in this report, including our Consolidated Financial Statements and notes thereto, and in our other public filings with the SEC. The occurrence of any of the following risks could harm our business, financial condition, results of operations and / or growth prospects or cause our actual results to differ materially from those contained in forward- looking statements we have made in this report and those we may make from time to time. You should consider all of the risk factors described when evaluating our business. Risks Related to our Limited Operating History, Financial Position and Capital Requirements We have a history of operating losses, have never generated any revenue from product sales and anticipate that we will continue to incur significant losses for the foreseeable future. We are a pre- commercial immuno- oncology company with a limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. All of our investigational products are in development, and none have been approved for commercial sale nor have we ever generated any revenue from product sales. Our revenues to date have been primarily from upfront and milestone payments, research and development support and clinical materials reimbursement from our strategic partners. For the years ended December 31, **2023 and 2022** and ~~2021~~ we had net losses of \$ **307 million and \$** 267 million ~~and net income of \$ 53 million~~, respectively. As of December 31, **2022-2023**, we had an accumulated deficit of \$ **542-849** million. We expect that it will be several years, if ever, before we have an investigational product ready for commercialization. While we may receive income from year to year under the Gilead Agreement and Taiho Agreement, we generally expect to incur substantial and increasing levels of operating losses over the next several years and for the foreseeable future as we advance our investigational products. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' equity and working capital. To become and remain profitable on a sustained basis, we must develop and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of our investigational products, obtaining marketing approval for these investigational products, manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post- marketing requirements. We may never succeed in these activities and, even if we succeed in commercializing one or more of our investigational products, we may never generate revenues that are significant or large enough to achieve sustained profitability. In addition, ~~as a young business,~~ we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. If we do achieve profitability from product sales, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional investigational products. Our failure to become and remain profitable on a sustained basis would decrease the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment. We may need to obtain additional funding ~~to finance our operations and complete the development and any commercialization of our investigational products~~. If we do not receive ~~substantial opt- in, milestone or royalty payments from our existing collaboration agreements~~, or are unable to raise additional capital when needed, we may be forced to restrict our operations or delay, reduce or eliminate our product development programs. The development of biopharmaceutical investigational products is capital intensive. Since our inception, we have used substantial amounts of cash to fund our operations and expect our expenses to increase substantially during the next few years as our investigational products enter and advance into and through large late- stage or registrational clinical trials and we expand our clinical, regulatory, quality and manufacturing capabilities. In addition, if we obtain marketing approval for any of our investigational products, we expect to incur significant commercialization expenses related to marketing, sales, manufacturing and distribution. As of December 31, **2022-2023**, we had \$ **866 +.14 billion million** of cash, cash equivalents and marketable securities. ~~While~~ **Together with the \$ 320 million we received from Gilead for their equity investment on January 29, 2024, our cash, cash equivalents and marketable securities were \$ 1.2 billion, which we believe that our cash position** will be sufficient to fund our anticipated level of operations into ~~2026-2027~~. **We cannot guarantee that we will be able to obtain additional capital in sufficient amounts our- or on terms acceptable to us, if at all. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate some or all of our research and development programs or future commercialization efforts. In addition, if we are able to raise additional capital, raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our intellectual property or investigational products. Our future capital requirements will depend on many factors related to the cost and timing of developing our investigational products**, including: • the number, scope, rate of progress and costs of clinical programs and investigational products as well as drug discovery, preclinical development activities, and laboratory testing; • the scope ~~and costs of manufacturing development and commercial manufacturing activities~~; • ~~the scope~~ of any cost sharing arrangements with our strategic partners; • the timing and amount of milestone payments and option fees we receive under the Gilead Collaboration Agreement and Taiho Agreement; • ~~the extent to which we acquire or in- license other investigational products and technologies~~; • ~~the cost, timing and outcome of regulatory review of our investigational products~~; • ~~the cost and timing of establishing sales and marketing capabilities, if any of our investigational products receive marketing approval~~; • ~~the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property- related claims~~; • ~~the costs associated with being a public company~~; and • ~~the cost associated with~~

commercializing our investigational products, if they receive marketing approval. ~~We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. 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 investigational products. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts. In addition, if we are able to raise additional capital, raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or investigational products.~~ Risks Related to the Discovery and Development of our Investigational Products If we are unable to obtain regulatory approval for our investigational products, or experience significant delays in doing so, our business will be materially harmed. We have no products approved for sale and our investigational products must be approved by the ~~Food and Drug Administration (FDA)~~ in the United States and similar regulatory authorities outside the United States, such as the EMA, prior to commercialization. The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes many years, if approval is obtained at all, and can vary substantially based upon a variety of factors. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the investigational product's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities, among other requirements. Our investigational products may not be effective, may be only moderately effective, may not have an acceptable durability of response, may not have an acceptable risk-benefit profile or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval or limit their commercial use. Our investigational products may not be approved even if they achieve their primary endpoints in any Phase 3 clinical trials or registrational trials we or our collaborators conduct. The FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for any of our investigational products. Regulatory authorities may refuse to accept any application or may decide that our data are 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 an investigational product. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may also cause delays in or prevent the approval of an application. For example, since a key element of our strategy is the development of intra-portfolio combinations, regulatory authorities may disagree that we have sufficiently demonstrated the contribution of each investigational product or other agent in our combination trials and require further studies. Even if we are able to obtain marketing approvals for any of our investigational products, those approvals may be for indications that are not as broad as desired or may contain other limitations that would adversely affect our ability to generate revenue from sales of those products. Moreover, if we are not able to differentiate our product against other approved products within the same class of drugs, or if any of the other circumstances described above occur, our business would be materially harmed and our ability to generate revenue from that class of drugs would be severely impaired. If we experience delays in obtaining approval or if we fail to obtain approval of our investigational products, the commercial prospects for our investigational products may be harmed and our ability to generate revenues will be materially impaired. Clinical drug development is a lengthy, expensive and uncertain process. **If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our investigational products, if approved, may be delayed and the credibility of our management team may be adversely affected and, as a result, our stock price may decline.** The research and development of drugs and biological products is an extremely risky industry. Only a small percentage of investigational products that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any investigational product, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our investigational products in humans. Clinical testing is expensive, can take many years to complete and its outcome is uncertain. **Further, from time to time, we may provide guidance regarding the expected timing or costs of various scientific, clinical, regulatory and other product development goals; including goals regarding the commencement or completion of, or the availability of data from, scientific studies and clinical trials and the submission of regulatory filings. Any such guidance will be based on a variety of assumptions. The actual timing or cost of these goals can vary dramatically compared to our guidance, in some cases for reasons beyond our control. If we do not meet such guidance the commercialization of our products may be delayed and the credibility of our management team may be adversely affected and, as a result, our stock price may decline.** The results of preclinical studies and early clinical trials are not always predictive of future results. The results of preclinical and early clinical trials of our investigational products and other products with the same mechanism of action may not be predictive of the results of later-stage clinical trials. Clinical trial failure may result from a multitude of factors including flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. A number of companies in the biopharmaceutical industry have suffered setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval. In particular, results from uncontrolled trials, meaning trials in which there is no control group such as a placebo group, are inherently difficult to interpret. This difficulty is compounded in clinical trials such as ours, in which two or more investigational products that have not yet been approved are being evaluated. Accordingly, the preliminary data from clinical trials of certain of our investigational products may not be predictive of future clinical trial

results for these or other investigational products when studied in a randomized environment or larger patient populations. ~~we do and adversely affect our commercial prospects and cause our stock price to decline.~~ Preliminary and interim data from our clinical studies that we announce or publish from time to time are subject to audit and verification procedures that could result in material changes in the final data and may change as more patient data become available. From time to time, we publish preliminary or interim data from our clinical studies. Preliminary data remain subject to audit confirmation and verification procedures that may result in the final data being materially different from the preliminary data we previously published. Interim data are also 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. As a result, **preliminary topline results that we report may differ from future results of the same studies** and interim data should be viewed with caution until the final data are available. Material adverse changes in the final data could significantly harm our **business prospects**. Most of our clinical trials are open-label studies and may be susceptible to bias. Most of our clinical trials, including our Phase 3 trials, are open-label studies in which both the patient and investigator know whether the patient is receiving the investigational products or either an existing approved drug or placebo. Open-label clinical trials are susceptible to bias that may exaggerate any therapeutic effect or overestimate the risk associated with the investigational product. Patients may perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. Investigators may interpret the information of the treated group more favorably given their awareness of the treatment regimen or may attribute safety risks to the investigational product. Enrollment and retention of subjects in clinical trials is expensive and time consuming, can be made more difficult or rendered impossible by competing treatments, clinical trials of competing investigational products, **geopolitical instability** and public health epidemics, each of which could result in significant delays and additional costs in our product development activities, or in the failure of such activities. We may encounter delays in enrolling, or be unable to enroll and maintain, a sufficient number of subjects to complete any of our clinical trials. Patient enrollment and retention in clinical trials is a significant factor in the timing **and cost** of clinical trials and depends on many factors, including the size of the patient population required for analysis of the trial's primary endpoints, the nature of the trial protocol, our ability to recruit clinical trial investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the investigational product **(including data that we report in our other clinical trials using the same investigational products) or with respect to other investigational products with the same mechanism of action as our investigational products**, the number and nature of competing products or investigational products and ongoing clinical trials of competing investigational products for the same indication, the proximity of subjects to clinical trial sites, the eligibility criteria for the clinical trial and our ability to obtain and maintain subject consents. For example, enrollment of oncology subjects in our clinical trials evaluating zimberelimab may be hampered by nivolumab from Bristol-Myers Squibb and pembrolizumab from Merck, both of which are approved and on the market. Subjects may opt to be treated with an approved product rather than our anti-PD-1 antibody investigational product. In addition, Roche / Genentech, Merck and ~~Beigene~~ **BeiGene** have initiated numerous Phase 3 trials with their respective anti-TIGIT antibodies, which could reduce the number of clinical sites and subjects available for our registrational program for domvanalimab (our anti-TIGIT antibody), including ~~ARC-10 and STAR-121~~ **and STAR-221**, each Phase 3 trials in lung cancer and ~~STAR-221, our Phase 3 trial in upper gastrointestinal tract cancer~~, **respectively**. **Geopolitical instability and Public-public** health outbreaks, such as the COVID-19 pandemic, may also have an adverse impact **on** our clinical trial operations. ~~Regulatory authorities and ethics committees may divert resources, prolonging the time for review of new studies and any protocol or other amendments for ongoing studies. For example, our investigational sites may intermittently divert resources in order to respond to an ongoing health crisis, which could cause delays and limit their ability to initiate new studies. The limited resources at investigational sites would further hinder their ability to screen and enroll subjects, conduct and report all patient assessments and collect all patients samples, thereby impacting our ability to assess the activity of our investigational products in a timely manner. Furthermore, supply chain challenges have made it more difficult to procure standard-of-care chemotherapy drugs utilized in our trials and timely ship materials to investigational sites, which has and may continue to delay or limit their screening and enrollment of patients. In addition, recruiting and retaining subjects in our clinical trials may be adversely impacted by negative results that we report in our other clinical trials using the same investigational products or by negative results reported by others using investigational products with the same mechanism of action as our investigational products.~~ Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our investigational products. Failures in planned subject enrollment or retention may result in increased costs or program delays and could render further development impossible. **If we do not achieve our product..... could significantly harm our business prospects.** Serious adverse events, undesirable side effects or other unexpected properties of our investigational products may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our investigational products or limitations on the use of our investigational products or, if discovered following marketing approval, revocation of marketing authorizations or subsequent limitations on the use of our investigational products. As we continue ~~our to development~~ **develop our** of these investigational products and initiate clinical trials of ~~our~~ additional investigational products, serious adverse events, undesirable side effects or unexpected characteristics may emerge causing us to abandon these investigational products or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Even if our investigational products initially show promise in **these** early clinical trials, the side effects of drugs are frequently only detectable after they are tested in large, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the investigational product or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious

adverse or unexpected side effects are identified during development and are determined to be attributed to our investigational product, we may be required to develop a Risk Evaluation and Mitigation Strategy (REMS) to mitigate those serious safety risks, which could impose significant distribution and use restrictions on our products. ~~Drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business prospects significantly. In addition, if one or more of our investigational products 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 additional warnings on the label; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients; • regulatory authorities may impose subsequent limitations on the use of the product; • we could be sued and held liable for harm caused to patients; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the particular investigational product, if approved, and could significantly harm our business, results of operations and prospects.~~ Adverse findings from clinical trials conducted by third parties investigating the same investigational products as us in different territories **or different investigational products directed to the same target as one of our programs** could adversely affect our development program. Lack of efficacy, adverse events, undesirable side effects or other adverse findings may emerge in clinical trials conducted by third parties investigating the same investigational products as us in different territories **or different investigational products directed to the same target as one of our programs**. For example, we and Gloria Biosciences, each licensed our rights to the same anti- PD- 1 antibody (which we refer to as zimberelimab) from WuXi Biologics (Cayman) Inc. (WuXi Biologics). Gloria Biosciences refers to this antibody as GLS- 010 and is conducting clinical trials with GLS- 010 in China. We have no control over their clinical trials or development program, and adverse findings from the results or their conduct of clinical trials could adversely affect our development of zimberelimab or even the viability of zimberelimab as an investigational product. We may be required to report Gloria Biosciences' adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of zimberelimab. We may face similar risks from any independent development conducted with our investigational products by Gilead and Taiho, following any exercise of their respective options to our programs. **Further, we have no control over the clinical trials or development programs of third parties developing investigational products directed to the same target as one of our programs. Adverse findings or results from any of their clinical trials could adversely affect the commercial prospects of our investigational products and cause our stock price to fluctuate or decline.** A key element of our strategy is the development of intra- portfolio combinations. If we are not successful in discovering, developing and commercializing investigational products that take advantage of different mechanisms of action to achieve superior outcomes relative to the use of single agents or other combination therapies, our ability to achieve our strategic objectives would be impaired. A key element of our strategy is to build a broad portfolio of investigational products that will allow for the development of intra- portfolio combinations. We believe that by developing or licensing these investigational products, we can control the combinations we pursue and, if and when approved, maximize the commercial potential of these combinations. However, these combinations have not been tested before and may fail to demonstrate synergistic activity against immunological targets, may fail to achieve superior outcomes relative to the use of single agents or other combination therapies, may exacerbate adverse events associated with one of the investigational products when used as monotherapy, or may fail to demonstrate sufficient safety or efficacy traits in clinical trials to enable us to complete those clinical trials or obtain marketing approval for the combination therapy. In addition, our early clinical trials may test more than one investigational product in uncontrolled studies, and it may be difficult to interpret the results of those uncontrolled trials or evaluate the contribution of each investigational agent in such combination. Even if we are successful in developing combination therapies, competition from other investigational products in the same class which are either already approved or further along in development than ours may prevent us from realizing the commercial potential of our combination therapies and prevent us from achieving our strategic objectives. Development of combination therapies may present more or different challenges than development of single agent therapies. Many of our investigational products are being pursued in combination with one or more additional products or investigational products. The development of combination therapies may be more complex than the development of single agent therapies and generally requires that sponsors demonstrate the contribution of each investigational product to the claimed effect and the safety and efficacy of the combination as a whole. This requirement may make the design and conduct of clinical trials more complex, requiring more clinical trial subjects. We also may not be able to meet the FDA's current or future approval standards required for combination therapies or combination products, if we decided to administer or package a combination therapy as a single drug product. For example, under the "combination rule", the FDA may not file or approve a fixed- dose combination product unless each component of a proposed drug product is shown to make a contribution to the claimed effects and the dosage of each component (amount, frequency, duration) is safe and effective for the intended population. To satisfy these requirements, the FDA typically requires a clinical factorial study, designed to assess the effects attributable to each drug in the combination product. This is particularly true when the ingredients are directed at the same sign or symptom of the disease or condition. The FDA has accepted a variety of approaches to satisfy the combination rule but the FDA has stated that factorial studies may be unethical (e. g., omitting a drug known to improve survival) or impractical (there may be too many components to conduct a factorial study, meaning the trial cannot be conducted). The FDA has also stated that it may be possible to use other types of clinical and nonclinical data and mechanistic information available to demonstrate the contributions of the individual active ingredients to the effect of the combination. Moreover, the applicable requirements for approval of a combination therapy may differ from country to country. In the event that one of our investigational products were to fail to demonstrate sufficient safety and efficacy or establish its contribution to the claimed effects of a combination therapies, we would need to identify alternatives. For example, we expect that our anti- PD- 1 antibody, zimberelimab, will form the backbone of many of the

combination therapies we are pursuing. If we are unable to demonstrate the contribution of zimberelimab to the claimed effects of a combination therapy, we would need to identify an anti- PD- 1 antibody for use in such combination therapy. In the event we are unable to do so or are unable to do so on commercially reasonable terms, our business and prospects would be materially harmed. Certain of our investigational products may require companion diagnostics in certain indications. Failure to successfully develop, validate and obtain regulatory clearance or approval for such tests could harm our product development strategy or prevent us from realizing the full commercial potential of our investigational products. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as a medical device and may require separate regulatory authorization prior to commercialization. Certain clinical trials that we are conducting, such as our **STAR Phase 2 ARC- 7- 221 trial and our Phase 3 ARC- 10 trial**, **use a diagnostic test to measure** which are each being conducted in patients with **PD- L1 levels in tumor samples provided by enrolled $\geq 50\%$ NSCLC**, include the use of a diagnostic test to help identify eligible patients. Our future trials may also use a diagnostic test to help identify eligible patients. In addition, we have significant efforts directed to identifying changes in various cells and proteins to understand their relationship, if any, to the clinical activity observed in our clinical trials and to assess if such cells and / or proteins could be used as predictive biomarkers to select for patients more likely to respond to our investigational products. However, we cannot be certain that we will be able to identify any such biomarkers, that such biomarkers will result in us identifying the appropriate patients for our investigational products or that we or any third- party collaborators will be able to validate any diagnostic tests incorporating any predictive biomarkers we may identify. We currently do not have any plans to develop diagnostic tests internally. We are therefore dependent on the sustained cooperation and effort of third- party collaborators in developing and, if our investigational products are approved for use only with an approved companion diagnostic test, obtaining approval and commercializing these tests. If these parties are unable to successfully develop companion diagnostics for these investigational products, or experience delays in doing so, the development of our investigational products may be adversely affected and we may not be able to obtain marketing authorization for these investigational products. Furthermore, our ability to market and sell, as well as the commercial success, of any of our investigational products that require a companion diagnostic will be tied to, and dependent upon, the receipt of required regulatory authorization and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies. Any failure to develop, validate, obtain and maintain marketing authorization and supply for a companion diagnostic we need will harm our business prospects. The design or our execution of our ongoing and future clinical trials may not support marketing approval. The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. In some instances, there can be significant variability in safety or efficacy results between different trials with the same investigational product due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence to the dosing regimen or other protocol requirements and the rate of dropout among clinical trial participants. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from preclinical studies or clinical trials. Even if we adhere to guidance or advice given by the FDA or comparable foreign regulatory authorities, such adherence does not guarantee that the FDA will agree with our trial designs or data interpretations or prevent the FDA from changing the requirements for the approval of any investigational product. We have conducted, and continue to conduct, portions of our clinical trials outside the United States, and the FDA may not accept data from trials conducted in foreign locations. We have conducted, and we expect to continue to conduct, portions of our clinical trials outside the United States. 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 ethical principles. The trial population must also adequately represent the U. S. population, and the data must be applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside the United States must be representative of the population for which we intend to label the product 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. We cannot assure you that the FDA will accept data from trials conducted outside the United States. If the FDA does not accept the data from such clinical trials, we would likely need to conduct additional trials, which would be costly and time- consuming and delay or permanently halt our development of our investigational products.

Risks Related to Reliance on Third Parties, Manufacturing and Commercialization We expect to depend on our collaboration with Gilead for the research, development, manufacture and commercialization of our investigational products. If this collaboration is not successful, our business could be adversely affected. Our strategy for fully developing and commercializing our investigational products is dependent upon maintaining our current arrangements with Gilead and our other strategic partners. Our ability to leverage these arrangements to produce commercial success will depend, among other things, on our collaborators' cooperation and ability to successfully meet their responsibilities with regards to a clinical program. We cannot predict the success of any collaboration that we enter into. Our partnership with Gilead poses a number of risks **that could materially impact our operations and financial condition** including, but not limited to, the following:

- conflicts may arise between us and Gilead, such as conflicts regarding the combinations or indications to pursue or concerning the interpretation of clinical data, the commercial potential of any optioned investigational products, the interpretation of financial provisions or the ownership of intellectual property developed during the collaboration - **Any such conflicts could slow or prevent the development or commercialization of our investigational products;**
- if our joint development program does not result in the successful development and commercialization of products or if Gilead terminates the collaboration agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration - **If we do not receive the funding we expect under these agreements, our development of our investigational products could be delayed and we may need additional resources to develop our investigational products;**
- we

will be heavily dependent on Gilead for its further development and commercialization of the investigational products from the programs that it opts ~~into in to~~; • we may not be successful in this collaboration due to various other factors, including our ability to demonstrate proof of concept in one or more clinical studies so that Gilead will exercise its option to these programs; • we have appointed ~~two three~~ individuals ~~that were~~ designated by Gilead to our board of directors pursuant to the terms of the ~~investor Investor~~ rights ~~Rights~~ agreement ~~Agreement~~, and Gilead owns approximately ~~18-33~~ **9-1** % of our outstanding common stock and ~~has will have~~ the right (but not the obligation) to acquire additional shares from us up to an amount resulting in Gilead owning a total of 35 % of our outstanding common stock and, as a result, may be able to exert significant influence over our company; • Gilead could independently develop, or develop with third parties, products that compete directly or indirectly with our investigational products if Gilead believes that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; and • because Gilead has an option to all of our programs, it will be difficult for us to enter into new collaborations. ~~Given~~ We rely on third parties to conduct..... Such changes carry the risk that they ~~the breadth of will not achieve these~~ ~~the~~ intended objectives. Any of these changes....., we, whether alone or in collaboration with Gilead ~~for programs that we commercialize together,.....~~ Given ~~the breadth of the collaboration~~, our ability to form new collaborations in the future will be limited. If Gilead declines to exercise its option to a program, we may need to enter into new collaborations for such programs with companies that have more resources and experience than us. We may not be successful in these efforts because third parties may not view our investigational products as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of an investigational product, we can expect to relinquish some or all of the control over the future success of that investigational product to the third party. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We ~~do not have the ability to conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we~~ are and expect to remain dependent on third parties, ~~such as Contract Research Organizations ("CROs"), clinical investigators and consultants,~~ to conduct our ongoing clinical trials and any future clinical ~~trials of our investigational products. These~~ **The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. There is no guarantee that any CROs, investigators or other third parties that help conduct or participate in our clinical trials will devote adequate time and resources to such trials or perform as contractually required. For example, many of these third parties have and continue to suffer from personnel constraints resulting from COVID- 19 and other economic factors which may other economic factors which may impact their ability to perform their contractual obligations. If any of these third parties fail fails to meet expected deadlines, fails to adhere to our clinical protocols or, fails to meet regulatory requirements or guidelines (including any GCP enforced by the FDA or comparable foreign regulatory authorities) , or otherwise performs in a substandard manner, or our ability to terminate its engagement with us use , data generated from our clinical trials may be jeopardized** the timelines for our development programs **clinical trials** may be extended or delayed , or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such ~~our ongoing~~ clinical trials unless we are able to transfer those subjects to another qualified clinical trial site , ~~which may be difficult or impossible.~~ In addition, ~~principal clinical trial~~ investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive ~~cash or equity~~ compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the ~~utility~~ **FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of certain data from the clinical trial , the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any NDA or BLA we submit to the FDA, or equivalent marketing application to we submit by the other FDA or any comparable foreign regulatory authority authorities outside the U.S.** Any such delay or rejection could prevent us from commercializing our investigational products. **Supply by** Furthermore, these third parties ~~of~~ may also have relationships with other ~~the~~ entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our investigational products and will not be able to, or may be delayed in our efforts to, successfully commercialize our products. We contract with third parties for the manufacturing and supply of investigational products for use in preclinical testing and clinical trials and for the supply of standard- of- care drugs or comparator agents ~~used~~ in our clinical trials , ~~which supply may become limited or interrupted~~ **which could delay, prevent or impair or our development efforts** may not be of satisfactory quality and quantity. We do not have any manufacturing **Manufacturing biologics, especially** facilities. We produce in ~~large~~ our laboratory relatively small quantities, **is often complex and may require the use of innovative technologies to handle living cells** compounds for evaluation in our research programs. We rely, and expect to continue to rely, on third parties for the manufacture and supply of our investigational products for preclinical and clinical testing, as well as for commercial manufacture if any of our investigational products are approved. ~~We~~ **If any of these third- parties fail to perform these activities for us, nonclinical or clinical development of our investigational products could be delayed, which could have an adverse effect on our business, financial condition, results of operations, and / or growth prospects. Further, we** currently have limited manufacturing arrangements for our investigational products and expect that each of our investigational products will only be covered by single source suppliers for the foreseeable

future. In particular, we have an exclusive relationship with WuXi Biologics, located in China, for the manufacture of zimerelimab drug substance. Our **contract reliance on limited manufacturers manufacturing** are subject to import arrangements increases the risk that we will not have and export rules and restrictions may not be able to obtain sufficient quantities of our investigational products for use in our clinical trials, which could delay, prevent or impair our development efforts. Any supply chain challenges may impact their affect our ability to acquire supply clinical sites with our investigational products and any standard- of- care drugs and comparator agents that we use in our clinical trials. These supply chain challenges can include longer lead times for the manufacturers of our investigational products to obtain raw materials, longer timeframes to procure or lack of supply for standard- of- care drugs or comparator agents used in our clinical trials, and transit delays at each point in the manufacturing, supply or distribution chain. For example, we use various standard- of- care chemotherapies, including 5- fluorouracil and oxaliplatin in our STAR- 221 clinical trial, and carboplatin in certain of our clinical trials. However, certain of the countries where we conduct the these following, intended objectives. Any of the these changes could cause technical skills or technology required to manufacture our investigational products may be unique or proprietary to perform differently the original manufacturer and we may have difficulty transferring such skills affect the results of planned clinical trials or technology to another-- other future clinical trials conducted third party and a feasible alternative may not exist. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our investigational products and with all applicable regulations jeopardize our ability to commercialize our investigational products and guidelines generate revenue. Our employees, clinical trial investigators, CROs, consultants, vendors, collaboration partners and any potential commercial partners may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors, collaboration partners and any potential commercial partners. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. Even if we receive marketing approval, we may not be successful in commercializing our investigational products. We have no sales, marketing or distribution capabilities or experience. If any of our investigational products ultimately obtains regulatory approval, we, whether alone or in collaboration with: • the design or results imposition by regulatory authorities of significant restrictions on a product's indicated uses, marketing or distribution; • the imposition by regulatory authorities of costly and time- consuming post- approval studies, post- market surveillance or additional clinical trials; • our failure to establish sales and marketing capabilities; • the likelihood failure of our products to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success; • unfavorable pricing regulations or third- party coverage and reimbursement policies; and • inaccuracies in our estimates of the addressable patient population resulting in a smaller market opportunity than we believed. Even if we receive marketing approval approval for one or more of our investigational products, our commercial success is dependent on obtaining coverage and reimbursement approval for a product from a government or other third- party payor, which coverage may be delayed or may not be sufficient to cover our costs. Our commercial success is dependent on obtaining coverage and reimbursement approval for a product from a government or other third- party payor, which is a time- consuming and costly process that could require us and any collaborators to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility; • the potential market for coverage and 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, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Obtaining reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Additionally, our collaborators will be required to obtain coverage and reimbursement for any related companion diagnostics tests the they develop separate and apart from the coverage and reimbursement we seek for our investigational products, once approved. Reimbursement may also impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-

party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance and we expect to experience pricing pressures in connection with the sale of any of our investigational products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. Our ability to obtain coverage and reimbursement approval for any of our investigational products, if approved, could have a material adverse effect on the demand for that investigational product; • the costs and complexities of manufacturing and delivering such investigational product to patients; • the potential of competing products; • the existence of uncertainty with respect to our ownership of technology or our other rights, which can exist **business and our overall financial condition. Even if our** there is a challenge to such ownership without regard to the merits of the challenge; and • industry and market conditions generally. The collaborator may also consider alternative investigational products or technologies **are approved by the FDA, they may never be approved for or similar indications commercialized outside the United States, which would limit our ability to realize their full market potential. In order to market any products outside the United States, we or our collaborators must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that may regulatory approval will be obtained in** available to collaborate on and whether such a collaboration could be more attractive than the one with us for our investigational product. We may also be restricted under any **other country** license agreements by one or more negative covenants or otherwise. For example, **the approval of zimberelimab for the treatment of recurrent or refractory classical Hodgkin's Lymphoma in China by Gloria Biosciences does not improve the chances of FDA approval for any BLA that we may submit for zimberelimab in the United States in any indication. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking foreign regulatory approvals could result in significant delays, difficulties and costs for us or our collaborators and may require additional preclinical studies or clinical trials which would be restricted costly and time consuming. Regulatory requirements can vary widely from entering into agreements on certain terms country to country and could delay or prevent the introduction of or our products in those countries at all with potential collaborators. Satisfying these Collaborations are complex and other regulatory requirements is costly, time consuming to negotiate, uncertain and document subject to unanticipated delays**. In addition, there **our or our collaborators' failure to obtain regulatory approval in any country may delay or have negative effects** been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators and changes to the strategies of the combined company. As a result, we may not be able to negotiate collaborations on **the process** a timely basis, on acceptable terms, or **for regulatory approval in** at all. If we are unable to do so, we may have to curtail the development of such investigational product, reduce or delay one or more of our other **countries** development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such investigational product, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense and may be prevented from or limited in forming additional strategic collaborations. **We** If we elect to increase our expenditures to fund development, manufacturing or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have **any** sufficient funds, we may not be able to further develop our investigational products **approved or for sale in any jurisdiction**, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we or our collaborators fail to comply with regulatory requirements in international markets or fail to obtain and maintain required approvals, our ability to realize the full market potential of our products will be harmed. Any investigational products for which we intend to seek approval as biologic products may face competition sooner than anticipated. The **Biologics Price Competition and Innovation Act of 2009 (BPCIA)** created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until twelve years from the date on which the reference product was first licensed. During this twelve- year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency of its product. **The law is complex and is still being interpreted and implemented by the FDA. As a result, any such processes could have a material adverse effect on the future commercial prospects for our biological products. Zimberelimab and domvanalimab are biological products and we may develop additional biological products in the future. We believe that any of our current and future investigational products approved as a biological product under a BLA should qualify for the twelve- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider our investigational products to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products will depend on a number of marketplace and regulatory factors that are still developing. Risks Related to our In- Licenses and Other Strategic Agreements** We are currently party to several in- license agreements under which we

acquired rights to use, develop, manufacture and / or commercialize certain of our investigational products. If we breach our obligations under these agreements, we may be required to pay damages, lose our rights to these investigational products or both, which would adversely affect our business and prospects. We rely, in part, on license and other strategic agreements, which subject us to various obligations, including diligence obligations with respect to development and commercialization activities, reporting and notification obligations, payment obligations for achievement of certain milestones and royalties on product sales, negative covenants and other material obligations. We may need to devote substantial time and attention to ensuring that we are compliant with our obligations under these agreements. If we fail to comply with the obligations under our license agreements or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and our licensors may have the right to terminate the license. If our license agreements are terminated, we may not be able to develop, manufacture, market or sell the products covered by our agreements and those being tested or approved in combination with such products. Such an occurrence could materially adversely affect the value of the investigational product being developed under any such agreement and any other investigational products being developed or tested in combination.

Domvanalimab For example, **which we in-licensed from Abmuno Therapeutics, and** zimberelimab, which we in-licensed from WuXi Biologics, **are intended to be used as the cornerstone of our combination strategy. Domvanalimab, which we in-licensed from Abmuno Therapeutics, is being evaluated in combination in four- our registration- two most advanced Phase 3 studies :ARC-10, PACIFIC-8 (in collaboration with AstraZeneca), STAR-121 (being operationalized by Gilead) and STAR-221.** In the event we breach our license agreement with **Abmuno Therapeutics and / or** WuXi Biologics **and / or Abmuno Therapeutics**, and our license agreements are terminated, we would **have be unable to cease these development activities pursue our intra-portfolio combination strategy**, or we would have to negotiate a new or reinstated agreement, which may not be available to us on equally favorable terms, or at all. In addition, the agreements under which we license intellectual property or technology to or from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our collaborations or other strategic partnerships on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected investigational products. We may not realize the benefits of any acquisitions, in- license or other collaborations or strategic alliances that we enter into. We have entered into in- license agreements with multiple licensors and option agreements to enable the development and commercialization of our investigational products worldwide. In the future, we may seek to enter into acquisitions or additional licensing arrangements with third parties to expand our pipeline or that we believe will complement or augment our development and commercialization efforts with respect to our investigational products and any future investigational products that we may develop. These transactions can entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management' s time and attention in order to manage a collaboration or develop acquired products, investigational products or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write- downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating **the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. As a result, if we enter into in- license, acquisition or collaboration agreements, or strategic partnerships, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them to market with our existing operations and generate product revenue company culture, which could delay our timelines or otherwise adversely affect our business.**

Risks Related to Intellectual Property
If we are unable to obtain and maintain sufficient intellectual property protection for our investigational products, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our investigational products and research programs. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business, however, we cannot predict: • if and when patents may issue based on our patent applications; • the scope of protection of any patent issuing based on our patent applications; • whether the claims of any patent issuing based on our patent applications will protect our investigational products and their intended uses or prevent others from commercializing competitive technologies or products; • whether or not third parties will find ways to invalidate or circumvent our patent rights; • whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and / or • whether we will need to initiate litigation or administrative proceedings to enforce and / or defend our patent rights which will be costly whether we win or lose. Obtaining and enforcing patents is expensive and time- consuming and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Even if we successfully file and prosecute a patent application, we may not be able to maintain and / or enforce the issued patent. We may determine that filing or maintaining such a patent or any action to enforce a patent may be too high or not in the best interest of our company or our stockholders. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, **CROs** contract research organizations, contract manufacturers, consultants, advisors and other

third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. We also cannot be certain that the claims in our pending patent applications directed to our investigational products and / or technologies will be considered patentable by the ~~U. S. Patent and Trademark Office (USPTO)~~ or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our investigational products is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our investigational products. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries. ~~In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated. From time to time we may be required to license technology from additional third parties to further develop or commercialize our investigational products. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our investigational products, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our investigational products could cause us to abandon any related efforts, which could seriously harm our business and operations.~~ We may become involved in lawsuits alleging that we have infringed the intellectual property rights of third parties or to protect or enforce our patents or other intellectual property, which litigation could be expensive, time consuming and adversely affect our ability to develop or commercialize our investigational products. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. For example, we are aware of certain patents ~~owned or licensed by Bristol-Myers Squibb having claims directed broadly to treating cancer with anti-PD-1 antibodies (the BMS Patents), which expire in 2023 and 2024. The BMS Patents have been and may in the future be the subject of litigation. In addition, we are aware of certain patents held by Genentech relating to methods of using an anti-PD-1 or anti-PD-L1 antibody in combination with an anti-TIGIT antibody for the treatment of cancer (the "Genentech Patents"), which expire in 2034, two of which were statutorily disclaimed. These~~ Merck has challenged the Genentech Patents ~~patents in are, or have been, the subject of post-grant~~ proceedings before at the USPTO ~~and other global patent offices~~. If the validity of the ~~BMS Patents and Genentech Patents are upheld following all challenges, and if we receive regulatory approval for zimmerelimab prior to expiration of the BMS Patents or domvanalimab or AB308 in combination with zimmerelimab in a territory with standing intellectual property rights~~ prior to expiration of the Genentech Patents, then we may need to delay commercialization or we may need to obtain a license, which license may not be available on commercially reasonable terms, or at all. If we were sued for patent infringement, we would need to demonstrate that our investigational products, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing investigational product or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing investigational product. However, we may not be able to obtain any required 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. 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 investigational products or force us to cease some of our business operations, which could materially harm our business. In addition, we may find that competitors are infringing our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have

asserted are invalid or unenforceable, or that the party against which we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to defend or pursue such litigation, which typically last for years before they are concluded. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor. While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our investigational products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition. We may not be able to protect our intellectual property rights outside of the U. S. Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our investigational products throughout the world would be prohibitively expensive. As such, 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. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. Further, we file patent applications in Russia and the Eurasian patent office, which is headquartered in Moscow. Sanctions against Russia may make it difficult to file and maintain patents in these countries, and Russia has begun taking actions against "unfriendly" countries, including the U. S., which may adversely affect the scope of and / or our ability to enforce our intellectual property rights. In any of these countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our investigational products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. However, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, ~~that~~ **which** have increased uncertainties as to the ability to obtain and enforce patent rights in the future. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries could increase the uncertainties and costs. For example, in September 2011 the Leahy-Smith America Invents Act (the "**A**merica Invents Act **A**") was signed into law and included a number of significant changes to U. S. patent law as then existed. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. After March 2013, under the America Invents Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. The U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U. S. Congress, the U. S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to

enforce our existing patents and patents that we might obtain in the future. We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technology and investigational products, we may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. Elements of our investigational product, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, third parties with which we share our facilities or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with which we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, **CROs** ~~contract research organizations~~, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. 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. 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. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed. We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, collaborators or other third parties have an interest in our patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our investigational products or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and / or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Patent terms may be inadequate to protect our competitive position on our investigational products for an adequate amount of time. Patent rights are of limited duration. Given the amount of time required for the development, testing and regulatory review of new investigational products, patents protecting such candidates might expire before or shortly after such investigational products are commercialized. Even if patents covering our investigational products are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain 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 and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

Risks Related to our Business Operations We expect to expand our business operations and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations. We expect to grow our business operations, including, if any of our investigational products receives marketing approval, adding employees in sales and marketing. To manage our anticipated future growth, we must:

- identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our investigational products; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our investigational products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement

the tasks necessary to further develop and commercialize our investigational products and, accordingly, may not achieve our research, development and commercialization goals. Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. We conduct our operations in the San Francisco Bay Area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel and rapidly increasing wages. Our industry also has experienced a high rate of turnover in recent years, ~~which has worsened during the COVID-19 pandemic~~. While we have expanded a number of our in-office roles to permit remote work arrangements, allowing us to seek talent from outside the San Francisco Bay Area, we still may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and / or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our investigational products and to grow our business and operations as currently contemplated. We are highly dependent on the services of our founders, Terry Rosen, Ph. D., who serves as our Chief Executive Officer, and Juan Jaen, Ph. D., who serves as our President. We are highly dependent on the services of our founders, Terry Rosen, Ph. D., who serves as our Chief Executive Officer, and Juan Jaen, Ph. D., who serves as our President. Although we have entered into employment agreements with them, they are not for a specific term and each of them may terminate their employment with us at any time, though we are not aware of any present intention of either of these individuals to leave us. Drs. Rosen and Jaen have significant experience identifying and developing biopharmaceuticals. We believe that their drug discovery and development experience, and overall biopharmaceutical company management experience, would be difficult to replace. However, the historical results, past performance and / or acquisitions of companies with which they were affiliated do not necessarily predict or guarantee similar results for our company. Further, Drs. Rosen and Jaen have certain other business and personal commitments outside of serving as the Chief Executive Officer and President of Arcus, including serving on the boards of other companies and foundations, which may result in diversion of their focus and attention on our company. We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their investigational products are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer, which is highly competitive with rapidly changing standards of care. As such, our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any products that we may develop or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain marketing 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. We are aware of several pharmaceutical companies developing products in the same class as our investigational products, some of which are further along in development than our corresponding assets. See "Item 1. Business — Competition" for additional information regarding our competitors. As more investigational products within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for investigational products in that class will likely need to show a risk benefit profile that is competitive with or more favorable than those products and investigational products in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or investigational products, or if the approval of other agents for an indication or patient population significantly alters the standard of care with which we tested our investigational products, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenue and financial condition would be materially and adversely affected. Our internal information technology systems, and those of our third-party CROs and other third parties upon which we rely, are subject to failure, security breaches and other disruptions, which could result in a material disruption of our investigational products' development programs, jeopardize sensitive information, prevent us from accessing critical information or result in a loss of our assets, and potentially expose us to notification obligations, loss, liability or reputational damage and otherwise adversely affect our business. We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information, including but not limited to intellectual property, proprietary business information and personal information **(collectively - It is critical that we do so in a secure manner to maintain the confidentiality. " Sensitive integrity and availability of such confidential information - Information ")**. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third-party contractors **and other parties** who have access to our **confidential sensitive information. Despite Our ability to monitor the these implementation of third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If the third parties we rely on experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if these third parties fail to satisfy their privacy- or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such an award. In addition, supply chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our**

supply chain or our third- party partners' supply chains have not been compromised. Despite the implementation of security measures, given ~~their--~~ **the** size and complexity and the increasing amounts of **confidential sensitive** information that they maintain, our internal information technology systems and those of our third- party CROs and other third parties upon which we rely are vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and / or other third parties, or from cyberattacks by malicious third parties (including the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information and other assets), which may compromise our system infrastructure, lead to data leakage, impair key business processes or other critical business operations, delay our development programs, or result in the loss of assets or other liability.

Our ~~We have monitoring systems in place and have detected at least one intrusion into our computer systems and attempts to exfiltrate our data. Although our investigation in each case indicates that it did not have a material adverse effect on our operations nor result in any compromise of our information, there can be no assurance of a similar result in the future. The COVID-19 pandemic and our~~ reliance on internet technology and the number of our employees who are working remotely has increased the opportunities for cybercriminals to exploit vulnerabilities. ~~Overall, there has been a significant increase in fraud schemes, including a successful social engineering attack against us through one of our employees.~~ We cannot assure you that our data protection efforts and our investment in information technology will prevent breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. Furthermore, as the cyber threat landscape evolves, these attacks are growing in frequency, sophistication and intensity, and becoming increasingly difficult to detect. There can be no assurance that we and our third- party CROs and other third parties upon which we rely will be successful in detecting, preventing or fully recovering systems or data from all breakdowns, service interruptions, attacks or breaches of systems that could adversely affect our business and operations and / or result in the loss or disclosure of critical or sensitive data or other assets, which could result in financial, legal, business or reputational harm to us. Ransomware attacks have risen dramatically and we may be forced to pay to unlock our data and information, re- access our systems and resume our ability to conduct business operations. **Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.** The loss of clinical trial data for our investigational products could significantly increase our costs to recover or reproduce the data and result in delays in our development programs, impair our ability to obtain marketing approval and reduce the commercial opportunity for our investigational products. **We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and / or software, including that of any third parties we rely), but we may not be able to detect and remediate all such vulnerabilities including on a timely basis. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident.** Moreover, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and / or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. In particular, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and / or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business. Although we maintain insurance coverage to insure against losses suffered as a result of malicious intrusions and cyberattacks, such coverage may be insufficient to fully compensate us for the loss or there may be disputes with our insurers about the availability of insurance coverage for our claims. Cyber insurance may become increasingly difficult to maintain and we may not be able to maintain coverage at a reasonable cost or in an amount adequate to compensate for any loss or satisfy any liability that may arise. **Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Our sensitive information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel' s, or the third parties' upon whom we rely use of generative artificial intelligence (AI) technologies. Any sensitive information (including confidential, competitive, proprietary, or personal data) that is inputted into a third- party generative AI platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI model.** Unfavorable global economic, political and trade conditions could adversely affect our business, financial condition or results of operations and may exacerbate the effects of the risks described herein. Current global economic conditions are highly volatile due to a number of reasons, including ~~the COVID-19 pandemic and~~ geopolitical instability arising from, such as the ongoing military conflict between Russia and Ukraine and the ~~imposition~~ **recent eruption of war between Israel** sanctions against Russia by the U. S. and **EU Hamas**, which has contributed to rising inflation that has increased our operating expenses and disruptions in the capital and credit markets that may reduce our ability to raise additional capital when needed on acceptable terms, if at all. While we do not have any clinical studies ongoing in Russia, Ukraine or Belarus, we do file patent applications in Russia and the Eurasian patent office, which is headquartered in Moseow. Sanctions may make it difficult to file and maintain patents in these countries, and Russia has begun taking actions against “unfriendly” countries, including the U. S., which may adversely affect the scope of and / or our ability to enforce our intellectual property rights. Emerging international trade relations **and new legislation** may

also adversely impact our operations and / or financial condition by limiting or preventing the activities of third parties that we engage or increasing the cost of our operations. For example, WuXi Biologics, located in China, is our sole manufacturer of our investigational biologics, including zimberelimab, domvanalimab and ~~AB308~~. In addition, if tariffs were to be imposed on the investigational products they manufacture for us, such tariffs would have an adverse impact on our operating results and financial condition. Furthermore, the current inflationary environment related to increased aggregate demand and supply chain constraints ~~have~~ ~~has~~ increased our operating expenses and may continue to affect our operating expenses. Economic conditions may also strain our suppliers, possibly resulting in supply disruptions that impact our ongoing clinical trials and other operations. A significant worsening of global economic conditions could materially increase these risks we face. Any new or prolonged downturn of global economic conditions could harm our business **operations** and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability may depend, in part, on our ability to commercialize our investigational products in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our investigational products before we receive marketing approval from the applicable regulatory authority in that foreign market, and we may never receive such marketing approval for any of our investigational products. To obtain marketing approval in many foreign countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our investigational products, and we cannot predict success in these jurisdictions. If we obtain approval of our investigational products and ultimately commercialize our investigational products in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our investigational products in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third- party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our investigational products could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. We or the third parties upon which we depend may be adversely affected by earthquakes, fires or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Our headquarters and main research facility are located in the San Francisco Bay Area, which in the past has experienced severe earthquakes and fires. In addition, fires and other natural disasters may increase in frequency and severity over time due to climate change. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third- party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history and our ability to generate profits in the future is uncertain. Unused net operating loss carryforwards ("**NOLs**") for the tax year ended December 31, 2017 and prior tax years will carry forward to offset future taxable income, if any, until such unused NOLs expire. Unused NOLs generated after December 31, 2017, under current tax law, will not expire. Our NOLs may be carried forward indefinitely. In addition, the future deductibility of such NOLs will be limited to 80 % of current year taxable income in any given year. Both our current and our future unused losses (and tax credit carryforwards) may be subject to further limitation under Sections 382 and 383 of the Internal Revenue Code (**IRC**) of 1986, as amended (**the "IRC"**), if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three- year period. We performed an analysis under IRC Section 382 and 383 through October 31, 2020 with respect to our net operating loss and credit carryforwards. We concluded that an ownership change, as defined under IRC Section 382, occurred in previous years but that such ownership change did not result in the expiration of our net operating loss or credit carryforwards prior to utilization. We may incur additional ownership changes in the future in connection with any equity issuance, including any additional issuances to Gilead. If we experience any such ownership change, we may be limited in our ability to use our net operating loss and credit carryforwards and be required to make material cash tax payments. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited. For example, while California recently enacted a franchise tax law restoring the usability of California state NOLs to offset taxable income for tax years beginning on January 1, 2022, previous law significantly limited the use of California state NOLs for taxable years 2020 and 2021. Similar laws in the future could accelerate or permanently increase state taxes owed. Therefore, even if we attain sustained profitability, we may be unable to use all or a material portion of our NOLs and other tax attributes, which could adversely affect our future cash flows. Changes in tax laws and regulations or exposure to additional tax liabilities could adversely affect our financial results. The rules dealing with U. S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue

Service, or IRS, and the U. S. Treasury Department. **We actively monitor legislative and regulatory developments that may affect our tax liability in order to identify and evaluate if such proposals would have a material impact, whether detrimental or beneficial, on our financial results.** Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the option to currently deduct research and development expenditures and requires taxpayers to capitalize and amortize U. S. based and non- U. S. based research and development expenditures over five and fifteen years, respectively, pursuant to IRC Section 174. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or issued, which could result in an increase in our or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law. Risks Related to Our Industry Product liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of any investigational products that we may develop. We face an inherent risk of product liability exposure related to the testing of our investigational products in human 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 investigational products or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in: • delay or termination of clinical trials; • decreased demand for any investigational products or products that we may develop; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial subjects; • initiation of investigations by regulators; • significant costs to defend the related litigation and diversion of management' s time and our resources; • substantial monetary awards to study subjects or patients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; and • the inability to commercialize any products that we may develop. Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as our investigational products advance through clinical trials and if we successfully commercialize any products. 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. Failure to comply with **health privacy and data protection laws and regulations, or other obligations** could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. We and **any potential collaborators third parties upon whom we rely** may be subject to federal, state, and foreign data protection, **privacy, and information security laws and regulations (i.e., laws guidance, industry standards, external and internal regulations that address privacy and data security) policies, contractual requirements, and other obligations**. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e. g., Section 5 of the FTC Act), that govern the collection, use, disclosure, and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under **federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (HITECH)**. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA. The legislative and regulatory landscape for privacy and data security continues to evolve, and we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy and data security in the United States, the EU and other jurisdictions. This increased focus on privacy and data security issues may negatively affect our operating results and our business. For example, the California Consumer Privacy Act of 2018, **as amended by the California Privacy Rights Act of 2020 (collectively, "CCPA") applies to personal information of consumers, business representatives which took effect on January 1, 2020, gives and employees who are California residents expanded, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used.** In addition, **the CCPA provides for administrative noncompliance that may carry fines of up to \$ 7, 500 per violation and the CCPA authorizes private lawsuits to recover statutory damages for certain data breaches. Similar laws are being considered in several** While it exempts some data regulated by HIPAA and certain clinical trials data, the CCPA may increase our compliance costs and potential liability with respect to other **states, as well as at personal information we collect about California residents. Some observers note that the federal and local levels, and we expect CCPA could mark the beginning of a trend toward more stringent privacy legislation states to pass similar laws in the U- future.** **Foreign S., which could increase our potential liability and adversely affect our business. International data protection laws also apply to health- related and other personal data obtained outside the United States. GDPR in the European Union. Regulation and Canada' s Personal Information Protection and Electronic Documents Act (EU " PIPEDA "), or the applicable provincial alternatives, 2016 / 679 (General Data Protection Regulation) took effect in May 2018 and imposes - impose - in some cases, stricter -- strict obligations than data protection laws in the United States on the use of health- related and other personal data. These requirements, include including the obligation to appoint data protection officers in certain circumstances, rights for individuals to be " forgotten " and to data portability, and the obligation to make public notification of significant data breaches. Under the GDPR General Data Protection Regulation, data protection authorities can also impose administrative temporary or definitive bans on data processing and other corrective actions or fines of up to 4 % of our total worldwide turnover or up to € 20 million under the EU GDPR / 17. 5 million pounds sterling under the UK GDPR (in either case, whichever is higher), or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests. In Canada, PIPEDA and various**

related provincial laws, as well as Canada's Anti-Spam Legislation ("CASL"), may apply to our operations. We also target customers in Asia and may be subject to new and emerging data privacy regimes, including China's Personal Information Protection Law ("PIPL"). We may also be subject to new laws governing the privacy of consumer health data. For example, Washington's My Health My Data Act ("MHMD") broadly defines consumer health data, places restrictions on processing such data (including imposing stringent requirements for consent), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws. In the ordinary course of business, we may transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the UK have significantly restricted the transfer of personal data to the United States and other to countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant organizations based in the United States who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. We publish privacy policies, notices and other statements regarding data privacy and security. If these policies, notices or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences. Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model. Our failure to comply with the General Data Protection Regulation only permits the transfer of personal data outside the European Economic Area (EEA) or that of the third parties upon whom we rely to countries that offer a level of data protection deemed adequate by the European Commission, unless an approved data transfer mechanism is in place. One such mechanism was invalidated by the European Court of Justice, adding to the complexity of transferring personal data outside the EEA. The General Data Protection Regulation increases our responsibility and liability in relation to personal data that we process, and we must put in place additional mechanisms to ensure compliance with the new EU data protection rules. Failure to comply with U.S. and international foreign data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we or the third parties upon whom we rely have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis; if viable, these claims carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. Our business operations expose us to broadly applicable fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Our operations are subject, either directly or indirectly through our customers and third-party payors, to various U.S. federal and state health care laws, including fraud and abuse,

transparency and other healthcare laws and regulations, and similar laws in other jurisdictions in which we conduct our business. These laws may impact, among other things, our research and proposed sales, marketing and education programs and constrain the business of financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. The laws that may affect our ability to operate include, but are not limited to the federal Anti-Kickback Statute; federal civil and criminal false claims laws, such as the ~~False Claims Act (FCA)~~; HIPAA; federal and state consumer protection and unfair competition laws; the federal transparency requirements under the ~~Physician Payments~~ Sunshine Act; state and foreign law equivalents of each of these federal laws; and state and foreign laws that require pharmaceutical companies to implement compliance programs. Many of these laws are discussed in detail ~~in above under~~ “Item 1. Business — Government Regulation — Other U. S. Healthcare Laws and Compliance Requirements” ~~for additional information~~. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have continued their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time- and resource- consuming and can divert management’s attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business. Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. We have entered into consulting and advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of our investigational products, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant civil, criminal and administrative penalties such as fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with which 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. Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict, and may have a significant adverse effect on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of investigational products, restrict or regulate post-approval activities, and affect the ability to profitably sell investigational products for which marketing approval is obtained. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, on August 16, 2022, President Biden signed into law the ~~Inflation Reduction Act of 2022 (IRA)~~, which, among other things, (1) directs the ~~HHS U. S. Department of Health and Human Services~~ to negotiate the price of certain single-source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025 and eliminates the “donut hole” under the Medicare Part D program by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. **These provisions take effect progressively starting in fiscal year 2023, although the Medicare drug price negotiation program is currently subject to legal challenges. The HHS has and will continue to issue and update guidance as these programs are implemented.** It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. We expect that other healthcare reform measures may be adopted in the future, and that any such health reform measures could have an adverse effect on our business and / or results of operation. ~~For additional detail regarding health care reform activities that may impact our business, see “Item 1. Business — Government Regulation — Healthcare Reform” for additional information.~~ We are subject to certain U. S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. U. S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations (collectively, “Trade Laws”) prohibit, among other things, companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U. S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. We, and the third parties with which we share our facilities, 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. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of 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. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with which we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of 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 and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to Owning our Common Stock The stock price of our common stock has been and may continue to be volatile or may decline regardless of our operating performance. The market price of our common stock has fluctuated and may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- overall performance of the equity markets;
- our operating performance and the performance of other similar companies;
- results from our ongoing clinical trials and future clinical trials with our current and future investigational products or of our competitors;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory, trade or legal developments in the United States and other countries, including changes in tariffs or other trade restrictions and the changes in the structure of healthcare payment systems;
- the level of expenses related to future investigational products or clinical development programs;
- our failure to achieve product development goals in the timeframe we announce;
- announcements of acquisitions, strategic alliances or significant agreements by us or by our competitors;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;
- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the size of our market float; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many immuno- oncology companies. Stock prices of many immuno- oncology companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business. The amount of our future losses is uncertain and our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our investigational products or competing investigational products, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- our progress towards the achievement of any product development goals or milestones we announce, including any delays or failures which lead to the suspension or termination of any clinical trial or development program;
- the timing and cost of, and level of investment in, research and development activities relating to our investigational products, which may change from time to time;
- option fees received by us in connection with option exercises by Gilead and / or Taiho pursuant to their respective option agreements and / or payments received by us from Gilead or Taiho in connection with the achievement of certain development and / or regulatory milestones;
- amounts payable by us in connection with the achievement of development, regulatory and commercial milestones under our in- license and other strategic agreements;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional investigational products;
- our ability to obtain marketing approval for our investigational products, and the timing and scope of any such approvals we may receive;
- the changing and volatile U. S. and global economic environments; and
- future accounting pronouncements or changes in our accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. The concentration of our stock ownership will likely limit our stockholders' ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval. Based upon shares outstanding as of ~~December 31, 2022~~ **January 31, 2024**, our executive officers, directors and the holders of more than 5 % of our outstanding common stock, in the aggregate, beneficially owned approximately ~~47.52. 6-0~~ **48.33. 9-1** % of our common stock. In particular, **as of January 31, 2024**, Gilead owns approximately ~~18.33. 9-1~~ **18.33. 9-1** % of our outstanding common stock **(and has the right to acquire additional shares of our common stock from us to enable it to own up to 35 % of our outstanding common stock)**, and we have appointed its ~~two~~ **three** designees to our board of directors pursuant to the terms of ~~our the investor- Investor rights Rights agreement Agreement~~ **our the investor- Investor rights Rights agreement Agreement**. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or

preventing a change of control of our company that other stockholders may view as beneficial. Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock. Our status as a Delaware corporation and the anti-takeover provisions of the Delaware General Corporation Law may discourage, delay or prevent a change in control by prohibiting us from engaging in a business combination with an interested stockholder for a period of three years after the person becomes an interested stockholder, even if a change of control would be beneficial to our existing stockholders. In addition, our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that may make the acquisition of our company more difficult, including the following:

- a classified board of directors with three-year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our board of directors;
- the ability of our board of directors to issue shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquirer;
- the exclusive right of our board of directors to elect a director to fill a vacancy created by the expansion of our board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by a majority vote of our entire board of directors, the chairman of our board of directors or our chief executive officer, which could delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors;
- the requirement for the affirmative vote of holders of at least 66 2/3 % of the voting power of all of the then-outstanding shares of the voting stock, voting together as a single class, to amend the provisions of our amended and restated certificate of incorporation relating to the management of our business or our amended and restated bylaws, which may inhibit the ability of an acquirer to effect such amendments to facilitate an unsolicited takeover attempt; and
- advance notice procedures with which stockholders must comply to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquirer from conducting a solicitation of proxies to elect the acquirer's own slate of directors or otherwise attempting to obtain control of us.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15 % or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision. These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for our stockholders to realize value in a corporate transaction. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation and our bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our certificate of incorporation or our bylaws or any action asserting a claim against us that is governed by the internal affairs doctrine. In addition, to prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our bylaws provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. While the Delaware courts have determined that these types of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of these provisions, which may require significant additional costs associated with resolving such action in other jurisdictions, and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

General Risk Factors Sales of substantial amounts of our ~~outstanding~~ shares may cause the price of our common stock to decline. The price of our common stock could decline if there are substantial sales of our common stock, **particularly including any sales by us, our directors, executive officers and, significant stockholders or the sales agents under the equity distribution agreement**, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. We have also registered shares of common stock that we have issued and may issue under our employee equity incentive plans. These shares can be sold freely in the public market upon issuance, subject to vesting conditions and, in the case of our affiliates, volume limitations under Rule 144 under the Securities Act of 1933, as amended. If we fail to maintain proper and effective internal controls, our ability to produce accurate and timely financial statements could be impaired, which could result in sanctions or other penalties that would harm our business. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the New York Stock Exchange. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal controls over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed

and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. Accordingly, we cannot assure you that we will not in the future identify one or more material weaknesses in our internal control over financial reporting, which may have a negative impact on our ability to timely and accurately produce financial statements, may result in a material misstatement of our Consolidated Financial Statements or may negatively impact the confidence level of our stockholders and other market participants with respect to our reported financial information. Ensuring that we have adequate internal controls over financial reporting is a costly and time-consuming effort that needs to be re-evaluated frequently. **Recent trends in Remote remote** work arrangements ~~as a result of the COVID-19 pandemic~~ have led to changes in work patterns that can make it more difficult to properly perform our controls and may create risks that result in deficiencies in the design of our controls. To the extent necessary, implementing any changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. 64