Risk Factors Comparison 2024-03-04 to 2023-03-22 Form: 10-K

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We operate in a dynamic and rapidly changing business environment that involves risks and substantial uncertainty. The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below, some of which have manifested and any of which may occur in the future, and in other sections of this Annual Report on Form 10- K and in our subsequent filings with the **U. S. Securities and Exchange Commission, or** SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks, and you could lose all or part of your investment. Risks Related to the Discovery, Development and Commercialization of Our Product Candidates Our business is entirely dependent on the success of STAR- 0215 as a potential treatment for HAE **and STAR- 0310 as a potential treatment for AD** . Our business is entirely dependent on the success of STAR- 0215, a potential best- in- class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the potential treatment of **hereditary angioedema, or** HAE **, and STAR- 0310, a potential best- in- class monoclonal antibody OX40 antagonist that incorporates YTE half- life extension technology in preclinical development for the potential treatment of atopic dermatitis, or AD** . We ~~initiated~~ **presented results from** a Phase 1a clinical trial of STAR- 0215 in **healthy subjects** ~~August 2022 and announced the preliminary results from this trial~~ in December 2022 **,** ~~and additional initial results were presented in~~ February 2023 **, November 2023 and February 2024** . We initiated the Phase 1b / 2 ALPHA- STAR trial of STAR- 0215 in **patients with HAE in** February 2023 **. We expect to report initial proof- of- concept data in patients with HAE in the first quarter of 2024. If the results from ALPHA- STAR are positive, we expect to progress STAR- 0215 directly to a Phase 3 pivotal trial which we anticipate initiating in the first quarter of 2025. We also expect to submit an investigational new drug application, or IND, for STAR- 0310 by the end of 2024 and, if the IND is cleared, we anticipate initiating a Phase 1a clinical trial of STAR- 0310 in healthy subjects in the first quarter of 2025 and reporting initial results from the Phase 1a clinical trial in the third quarter of 2025, including PK and PD data and early signals on safety and tolerability. Assuming positive results from the Phase 1a clinical trial, we plan to initiate a Phase 1b clinical trial of STAR- 0310 in patients with AD in the second half of 2025 and would expect to report results from such trial in the second quarter of 2026** . We cannot give any assurance that we will generate **preclinical,** clinical or other data for STAR- 0215 **or STAR- 0310** sufficiently supportive to receive regulatory approval, which will be required before ~~it~~ **either** can be commercialized. We may, among other things, experience difficulties with patient recruitment, enrollment and retention, quality and provision of materials and supplies necessary to manufacture sufficient quantities of drug product to meet our **preclinical study and** clinical trial needs on a timely basis, **or** safety signals or pharmacodynamic, pharmacokinetic or efficacy data that does not align with our target profile for STAR- 0215 ~~,~~ **or** STAR- **0310. STAR-** 0215 **and STAR- 0310** will require significant preclinical, clinical and nonclinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity ~~for our product candidates~~ , and significant marketing efforts before we can generate any revenue from product sales. We ~~also~~ plan to ~~begin development~~ ---- **develop** ~~of~~ a drug device combination for STAR- 0215. There is no assurance that we will be successful in developing a drug device combination on a timely basis or at all, which could impede our development and commercialization strategy for STAR- 0215. The **U. S. Food and Drug Administration, or** FDA or other comparable foreign regulatory authorities could require nonclinical studies or clinical trials to support introduction of a drug device combination, which could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase our clinical trial costs, delay approval of STAR- 0215 and jeopardize our ability to commence product sales and generate revenue from STAR- 0215, if approved. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of STAR- 0215 **and STAR- 0310** , which may never occur. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize STAR- 0215 **or STAR- 0310** , we may not be able to generate sufficient revenue to continue our business and our business would be materially harmed. Interim topline **, initial proof- of- concept** and preliminary data from our clinical trials that we announce or publish from time to time may change as more study participant data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim topline **, initial proof- of- concept** or preliminary data from our clinical trials. Interim **data or preliminary** data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more data become available. **Interim or** ~~Preliminary~~ **preliminary data** ~~or topline results~~ also remain subject to audit and verification procedures that may result in the final data being materially different from the **interim or** preliminary data we previously published. As a result, interim **topline, initial proof- of- concept** and preliminary data should be viewed with caution until the final data are available. Adverse differences between **interim or** preliminary ~~or interim~~ data and final data could significantly harm our reputation and business prospects. Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials **, and results of later stage clinical trials may not enable marketing approval** . The outcome of preclinical studies and early clinical trials **, along with interim results from clinical trials,** may not be predictive of the success of later clinical trials ~~,~~ and ~~interim results~~ **may not be supportive** of **moving into later** clinical trials ~~do not necessarily predict success in future clinical trials~~ . Many companies in the pharmaceutical and biotechnology industries ~~,~~ have suffered significant **clinical**

and regulatory delays or setbacks in late- stage clinical trials after achieving positive **interim or final** results in preclinical studies or early development, and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support **advancing into later clinical trials or** approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We ~~have limited experience in designing clinical trials and~~ may be unable to design and execute a clinical trial or trials to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their product candidates. Even if we, or any future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities **, as the case may be,** may disagree and ~~may~~ not grant marketing approval of our product candidates. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, differences in study design, changes in and adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to receive positive results in preclinical studies or clinical trials of STAR-0215 **, STAR- 0310** or any other future product candidate, the development timeline and regulatory approval and commercialization prospects for such product candidate, and, correspondingly, our business and financial prospects would be negatively impacted. Clinical drug development involves a lengthy and expensive process with an uncertain outcome. If clinical trials of a product candidate fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulators, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates. We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining approval from the FDA of a **biologics license application, or** BLA, which would be required for approval of STAR- 0215 **and STAR-0310, or a new drug application** , or NDA. Comparable foreign regulatory authorities, such as the **European Medicines Agency, or** EMA, require similar approvals. We, and any future collaborators, may never receive such approvals. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy in humans of any product candidate that we may choose to develop before we, or they, will be able to obtain these approvals. ~~29Clinical~~ **35Clinical** testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials we initiate will be conducted as planned or completed on schedule, or at all. In addition, in the case of STAR- 0215, for which we have designed our clinical ~~studies~~ **trials** , and plan to design future ~~studies~~ **trials** , with the goal of demonstrating that it can be dosed in HAE patients every three months or potentially less frequently, clinical trials will necessarily be longer given the length of time between doses in the trials. **We also expect that later stage clinical trials we conduct for STAR- 0310 will be larger and more expensive when compared to those we are conducting for STAR- 0215 because AD, the indication for which we are developing STAR- 0310, is not a rare disease.** Further, the clinical development of product candidates is susceptible to the risk of failure or significant delays at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, failure to utilize clinically appropriate efficacy or safety targets or measurements in a clinical trial for the disease or patient population being studied **, failure to have a sufficient number of patients in a clinical trial to establish sufficient safety or efficacy to enable moving into a later stage clinical trial (such as a Phase 3 trial) or regulatory approval** , the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, failure to enroll a sufficient number of patients on a timely basis or at all, failure to retain a sufficient number of patients to complete any of our trials, determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable, or the need to conduct additional studies or add cohorts to a trial before advancing into the next stage of development. Certain of these risks are heightened in the context of drug development for treatments for rare diseases, in which non- traditional study designs, and often smaller trials are utilized, to demonstrate efficacy and safety, including open- label studies, single arm studies, non- inferiority studies, studies utilizing active comparators or studies utilizing natural history data, biomarkers or other forms of surrogate endpoints, may be utilized due to the challenges inherent in designing and conducting clinical trials for severe diseases with small patient populations. In addition, we may amend the clinical trial protocol to address any issues that we observe as a trial is progressing, including in response to factors impacting safety and the data collected or to adapt the study design to include more clinically appropriate safety or efficacy targets or measurements, or we may be required to make certain changes to clinical trial protocols in response to issues raised by the FDA, **the institutional review board, or** IRB, other regulatory authorities, investigators or clinical sites. Protocol amendments are subject to IRB and regulatory approval before we implement material changes, can result in additional costs, require additional data or participants, and could delay, interrupt, or limit the conduct of the clinical trial. If we terminate or experience delays in the completion of any clinical trials, the commercial prospects for our product candidates may be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval. It is possible that even if a product candidate that we choose to develop has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in any clinical trials we conduct, we may fail to detect toxicity of or intolerability caused by a product candidate, or mistakenly believe that a product candidate is toxic or not well tolerated when that is not in fact the case. We have not previously submitted an NDA or BLA to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product

candidates. Moreover, ~~we have limited experience~~ developing biologics **is highly complex** and ~~this lack of experience~~ **any delay or problems in such development, including with third party contract manufacturers that we use to make and develop the drug substance and drug substance for our product candidates,** may impede our ability to successfully complete clinical development of STAR- 0215 **, and successfully initiate and complete clinical development of STAR- 0310** or any future biologic product candidates we pursue and obtain FDA approval in a timely manner, if at all. Any inability to complete clinical development successfully could result in additional costs to us, or any future collaborators, and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if (1) we, or any future collaborators, are required to modify our trial designs, such as required modifications with respect to patient populations, endpoints, comparators or trial duration, (2) we, or any future collaborators, are required to conduct additional clinical trials or other testing of a product candidate beyond the trials and testing that we, or they contemplate, (3) we, or any future collaborators, are unable to successfully commence on a timely basis or complete clinical trials of a product candidate or other testing, (4) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (5) there are unacceptable safety concerns associated with a product candidate, we, or any future collaborators, may: ● be delayed in obtaining marketing approval for such product candidate; ● not obtain marketing approval at all; ● obtain marketing approval for indications or patient populations that are not as broad as intended or desired; **36** ● obtain marketing approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings ~~;~~ **:** ● be subject to additional post- marketing testing or other requirements, such as a **Risk Evaluation and Mitigation Strategy, or** REMS **,** program; or ● be required to remove the product from the market after obtaining marketing approval. ~~30Given~~ -- **Given** our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. Our failure to successfully complete clinical trials of a product candidate and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any product candidate would significantly harm our business. Adverse events or undesirable side effects caused by, or other unexpected properties of, a product candidate may be identified during development that could delay or prevent their marketing approval or limit their use. Adverse events or undesirable side effects caused by, or other unexpected properties of, a product candidate could cause us, any future collaborators, an IRB or regulatory authorities to interrupt, delay or halt clinical trials of one or more of such product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory authorities. If any such product candidate is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any future collaborators, may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. Many ~~compounds~~ **product candidates** that initially showed promise in clinical or earlier stage testing have later been found to cause **adverse events or** undesirable or unexpected side effects that prevented further development of the ~~compound~~ **product candidates** . If we, or any future collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of a product candidate, potential marketing approval or commercialization of such product candidate could be delayed or prevented. We, or any future collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval or commercialization of a product candidate, including: ● clinical trials may produce unfavorable ~~or~~ **,** inconclusive **or insufficient** results; ● we, or any future collaborators, may decide, or regulators may require us or them, to conduct additional **clinical trials, expand** clinical trials or abandon product development programs; ● the number of patients required for clinical trials may be larger than we, or any future collaborators, anticipate, ~~patient enrollment in these clinical trials may be slower than we, or any future collaborators, anticipate,~~ particularly with respect to STAR- ~~0215~~ **0310** , which is being developed as a potential treatment for **AD which, unlike** HAE **, is not a rare disease; ● patient enrollment in these clinical trials may be slower than we, or any future collaborators, anticipate, particularly with respect to STAR- 0215, which is being developed as a potential treatment for HAE, a rare disease** , which has a significant number of approved products and products in clinical development, or participants may drop out of these clinical trials at a higher rate than we, or any future collaborators, anticipate or the duration of these clinical trials may be longer than we anticipate; ● the cost of planned clinical trials may be greater than we anticipate; ● our third- party contractors or those of any future collaborators, including those manufacturing such product candidate or components or ingredients thereof, including a suitable presentation of a product candidate, such as a pre- filled syringe, or any drug device combination for a product candidate, or conducting clinical trials on our behalf or on behalf of any future collaborators, may fail to comply with regulatory requirements, program timelines or meet their contractual obligations to us or any future collaborators in a timely manner or at all; **37** ● regulators or IRBs may not authorize us, any future collaborators or our or their investigators to commence, conduct or continue a clinical trial at a prospective trial site or may not approve a protocol amendment to an ongoing clinical trial; ● we, or any future collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites; ● patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial' s duration; ● we, or any future collaborators, may have to delay, suspend or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected ~~31characteristics~~ -- **characteristics** of the product candidate, or ~~travel bans or other~~ restrictions imposed by applicable governmental authorities due to ~~the COVID- 19 pandemic or other epidemics or~~ public health ~~outbreaks~~ **crises, pandemics or epidemics** ; ● regulators or IRBs may require that we, or any future collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of

undesirable effects caused by a chemically or mechanistically similar drug or drug candidate; ● the FDA or comparable foreign regulatory authorities may disagree or subsequently find fault with our, or any future collaborators', clinical trial designs, including the size of the trials or inclusion or exclusion criteria, or our or their interpretation of data from preclinical studies and clinical trials or may require us to conduct a comparator trial in lieu of a placebo- controlled trial; ● ~~The~~ **the** FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third- party manufacturers with which we, or any future collaborators, enter into agreements for clinical, commercial supplies or drug device combinations for our product candidates; ● we are unable to develop or obtain a supplier for a suitable drug device combination for **STAR- 0215,** ~~our~~ **or any other** product ~~candidates~~ **candidate for which we seek to develop a drug device combination,** that meets the requirements of the FDA or comparable foreign regulatory authorities; ● adequacy of or changes in our manufacturing process or the product formulation or method of delivery; ● the supply or quality of drug ~~production~~ **product** or drug substance, raw materials or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; ● changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; and ● the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval. In addition, we may amend clinical trial protocols to address any issues that we observe as a trial is progressing, including in response to factors impacting safety and the data collected or to adapt the study design to include more clinically appropriate safety or efficacy targets or measurements, or we may be required to make certain changes in response to issues raised by the FDA, IRB, other regulatory authorities, investigators or clinical sites. Protocol amendments are subject to IRB and regulatory approval before we implement material changes, can result in additional costs, require additional data or participants, and could delay, interrupt, or limit the conduct of the clinical trial. If we terminate or experience delays in the completion of any clinical trials, the commercial prospects for our product candidates may be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval. ~~We~~ **38We** are planning to conduct clinical trials outside of the United States, which are subject to the risks set forth above, and certain additional risks, such as unforeseen global instability, including political instability or geopolitical events, including civil or political unrest (such as the war between Russia and Ukraine **and the conflict in the Middle East**), terrorist activity, unstable governments and legal systems, natural disasters or instability from ~~an outbreak of~~ **public health crises,** ~~pandemic~~ **pandemics and epidemics** ~~or contagious disease, such as the COVID- 19 pandemic~~ , in or around any countries in which we conduct clinical trials. Such additional risks could affect our ability to enroll patients in clinical trials in these countries, prevent patients already enrolled from completing such clinical trials, and / or cause other trial delays or otherwise adversely impact such clinical trials. ~~32Product~~ **Product** development costs for us, or any future collaborators, will increase if we, or they, experience delays in testing or pursuing marketing approvals and we, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of any future product candidate. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical **development** or clinical trial delays also could shorten any periods during which we, or any future collaborators, may have the exclusive right to commercialize product candidates or allow our competitors, or the competitors of any future collaborators, to bring products to market before we, or any future collaborators, do or closer in proximity to the launches of our products or those of our collaborators, and impair our ability, or the ability of any future collaborators, to successfully commercialize product candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any future product candidates. If we, or any future collaborators, experience delays or difficulties in the enrollment of patients in clinical trials, our or their receipt of necessary regulatory approvals could be delayed or prevented. We, or any future collaborators, may not be able to initiate or continue clinical trials for STAR- 0215 **, STAR- 0310** or any other future product candidate if we, or they, are unable to locate and enroll, and maintain the enrollment of, a sufficient number of eligible patients to participate in clinical trials as required by the FDA or comparable foreign regulatory authorities, such as the EMA. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including: ● the size and nature of the patient population; ● the severity of the disease under investigation; ● the proximity of patients to clinical sites; ● the eligibility criteria for the trial; ● the design of the clinical trial; ● efforts to facilitate timely enrollment; ● competing clinical trials; and ● clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any existing or newly approved drugs that may be approved for the indications we are investigating. Our ability to successfully **initiate and** complete any clinical trial for STAR- 0215 as a potential treatment for HAE, including our ~~recently initiated~~ **planned Phase 3 pivotal trial, assuming favorable results from the** Phase 1b / 2 ALPHA- STAR trial **, for STAR- 0310 as a potential treatment for AD, including the Phase 1a clinical trial we plan to begin in 2025 (assuming we successfully and timely submit an IND by the end of 2024)** , or for any other future product candidate for the potential treatment of any rare disease or any other indication will be dependent upon our ability to enroll, and maintain the enrollment of, a sufficient number of patients with such disease, which will be subject to a number of risks and uncertainties. For example, rare diseases, including HAE, have small patient populations and often have only a limited number of specialist physicians that regularly treat such patients. Further, these specialized sites typically treat a range of diseases and, at any point in time, may have constrained resources and capacity to handle clinical trials. In addition, ~~in the case of HAE, the indication on which we are currently focused,~~ approved products are available for the ~~rare disease~~ **treatment of HAE** , and additional products may become commercially available during the clinical development of ~~STAR~~ **39STAR** - 0215, and therefore patients and their healthcare providers may feel satisfied with their treatments. As a result, patients may not feel the need to participate in a clinical trial for another product candidate for the same disease or the criteria for the trial may not allow patients on such other therapies to enroll in the trial.

Additionally, in the case of HAE, diagnosis is often delayed from onset of symptoms and patients that might be eligible for enrollment in our trials may not have been diagnosed and therefore are unaware of such eligibility. Finally, other companies are and will be conducting clinical trials in HAE or may have announced plans for future clinical trials for HAE that are seeking, or are likely to seek, to enroll patients with the disease and patients are generally only able to enroll in a single trial at a time. The small population of patients, competition for these patients and the limited trial sites and their constrained resources may make it difficult for us to enroll enough patients **in our clinical trials in HAE** , and to maintain the enrollment of enough patients, to complete **such** clinical trials ~~for any such future product candidate~~ . ~~33The~~ -- **The** clinical trials that we may conduct may also have inclusion and exclusion criteria that further limit the population of patients that we are able to enroll. In the case of HAE trials, the inclusion criteria may require that participants have had a certain number of attacks that occur within a defined period of time prior to being able to participate in the trial, which may impact or slow enrollment in the trial. For example, in the case of our **planned Phase 3 pivotal trial for STAR- 0215, we expect that, similarly to the** Phase 1b / 2 ALPHA- STAR trial, the inclusion criteria **will** require ~~that~~ participants **to** have had a certain number of attacks that occur within a defined period of time prior to being able to participate in the trial, which may impact or slow enrollment in the trial. These inclusion or exclusion criteria could limit the available patient pool and present challenges to clinical trial enrollment. Our inability, or the inability of any future collaborators, to enroll a sufficient number of patients for any clinical trials, including clinical trials for STAR- 0215 as a potential treatment for HAE **and clinical trials for STAR- 0310 as a potential treatment for AD** , that we or they may determine to pursue could result in significant delays or may require us or them to abandon one or more clinical trials altogether. Enrollment delays in any such clinical trials may result in increased development costs for the applicable product candidates, delay or halt the development of and approval processes for any future product candidates and jeopardize our, or any future collaborators', ability to commence sales of and generate revenues from any product candidates, which could cause the value of our company to decline **. We have conducted and intend to conduct certain of our clinical trials globally. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans may be delayed, which could materially harm our business. We have conducted and intend to continue conducting certain of our clinical trials globally. The acceptance by the FDA or other regulatory authorities of data from clinical trials conducted outside their jurisdiction may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U. S. population and U. S. medical practice, (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations and (iii) the data may be considered valid without the need for an on- site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. In addition, even where foreign clinical trial data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for marketing approval unless the clinical trial is well- designed and well- conducted in accordance with GCP requirements and the FDA is able to validate the data from the trial through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it could result in the need for additional trials, which could be costly and time- consuming, and which may result in current or future product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction. Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with: ● additional foreign regulatory requirements; ● foreign exchange fluctuations; 40 ● compliance with foreign manufacturing, customs, shipment and storage requirements; ● cultural differences in medical practice and clinical research; ● diminished protection of intellectual property in some countries; and ● interruptions or delays in our trials resulting from geopolitical events, such as war or terrorism** . Changes in product candidate manufacturing or formulation may result in additional costs or delay. As product candidates are developed through preclinical studies to later stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause a product candidate to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and / or jeopardize our ability to commence product sales and generate revenue. We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively. The development and commercialization of new drug products is highly competitive. **If** ~~We expect that~~ we **successfully develop and commercialize any of our product candidates** , **we** and any future collaborators ~~,~~ will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide **.** ~~with respect to any~~ **Many of the entities developing and marketing potentially competing products have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and commercialization. Even if we are able to successfully develop and commercialize a** product ~~candidates~~ **, our commercial opportunity will be reduced or eliminated if our competitors develop and commercialize products** that ~~we~~ **are more effective , have fewer side effects, are more convenient or are less expensive than** ~~or our product they, may seek to develop or commercialize in the future~~ . We are

developing STAR- 0215 for the potential treatment of HAE. The key competitive factors affecting the success of STAR- 0215, if approved, are likely to be its efficacy, safety, dosing frequency, method of administration, convenience, price and the availability of coverage and reimbursement from government and other third- party payors. In the United States, the FDA has approved four therapies for on- demand treatment of HAE: BERINERT, FIRAZYR, KALBITOR and RUCONEST. For long- term preventative treatment of HAE, the FDA has also approved four therapies: CINRYZE, HAEGARDA, TAKHZYRO and ORLADEYO. There are four main manufacturers of therapies for HAE: CSL Behring (BERINERT and HAEGARDA), Takeda (FIRAZYR, KALBITOR, CINRYZE and TAKHZYRO), Pharming (RUCONEST) and BioCryst (ORLADEYO). With the exception of KALBITOR, these therapies are also approved and commercially available outside of the United States (HAEGARDA is marketed as BERINERT SC outside of the United States). Historically, androgens and antifibrinolytic treatments have also been used as preventative treatment for HAE, however their use is declining with the availability of more- tolerable, HAE- specific therapies. On- demand and preventative HAE therapies target one of three primary mechanisms. BERINERT ~~and~~ **,** HAEGARDA, RUCONEST and CINRYZE are C1- INH replacement therapies. FIRAZYR is a ~~Bradykinin~~ **bradykinin** ~~2~~ receptor, or B2R, antagonist, and KALBITOR, TAKHZYRO and ORLADEYO target plasma kallikrein. TAKHZYRO is a monoclonal antibody and KALBITOR and ORLADEYO are small molecule inhibitors. On- demand therapies are taken as needed; BERINERT and RUCONEST are IV infusions approved for adult and pediatric patients, FIRAZYR is ~~a~~ **an** SC injection, approved for adults 18 and older, and KALBITOR is a series of ~~3~~ **three** SC injections, approved for patients 12 years and older. KALBITOR must be administered by a healthcare professional to monitor for the risk of anaphylactic reactions. ~~34Preventative~~ **41Preventative** therapies are taken chronically. CINRYZE is an IV infusion and HAEGARDA is an SC injection; both are administered twice a week and are approved for adult and pediatric patients 6 years and older. TAKHZYRO is an SC injection generally administered every two weeks; however, dosing every four weeks may be considered in some patients. TAKHZYRO is approved for patients 2 years and older. ORLADEYO is an oral capsule taken once daily with food for patients 12 years and older. Given that TAKHZYRO is an approved monoclonal antibody inhibitor of plasma kallikrein, if STAR- 0215 is approved, we expect that it will compete most directly with TAKHZYRO. We are aware of additional programs in development for HAE, which are focused largely on preventative approaches. For example, CSL Behring' s garadacimab (CSL312), a factor XIIa- inhibitory monoclonal antibody, or FXIIa mAb, has completed Phase 3 development for preventative treatment **and submitted regulatory applications for marketing approval in the United States and the European Union** . Ionis Pharmaceuticals, Inc.' s donidalorsen (IONIS- PKK- LRx), an antisense inhibitor of prekallikrein synthesis ~~is currently in~~ **has also completed** Phase 3 development for preventative treatment. Pharvaris is developing two oral treatments, **both of which** ~~PHVS416, in Phase 2 for on- demand treatment, and PHVS719, in Phase 1 for preventative treatment, that~~ are small molecule inhibitors of B2R **: PHVS416, which has completed Phase 2 development for on- demand treatment and for preventative treatment, and PHVS719, which is in Phase 1 development for preventative treatment** . KalVista Pharmaceuticals, Inc. has an oral small molecule plasma kallikrein inhibitor sebetralstat (KVD900) for on- demand treatment of HAE ~~in~~ **that has completed** Phase 2 development (the Phase 2 trial for KVD824 for preventative treatment was terminated). Intellia Therapeutics ~~has begun~~ **is in** Phase 1 / 2 trials for NTLA- 2002, a CRISPR knockout of the prekallikrein gene KLKB1. BioMarin Pharmaceutical Inc. ~~has begun~~ **is in** Phase 1 / 2 trials for BMN 331, a C1- INH gene therapy. ADARx Pharmaceuticals, Inc. has begun a Phase ~~1~~ **1b** clinical trial for ADX- 324, a prekallikrein siRNA inhibitor. Preclinical development programs for preventative treatment include KalVista' s oral FXIIa inhibitor and **Kyowa Kirin** ~~Orchard Therapeutics plc~~ and Pharming' s ex vivo hematopoietic stem cell gene therapy (OTL- 105). **We are developing STAR- 0310 for the treatment of moderate- to- severe AD. The key competitive factors affecting the success of STAR- 0310, if approved, are likely to be its safety and tolerability, efficacy, frequency of dosing, method of administration, convenience, price, and the availability of coverage and reimbursement from government and other third- party payors. In the United States, the FDA has approved two oral JAK inhibitors for the treatment of AD: RINVOQ and CIBINQO, and in the European Union OLUMIANT is also approved for the treatment of AD. Additionally, the FDA has approved two biologics for the treatment of AD: DUPIXENT and ADBRY. Standard of care also includes systemic steroids and topical medications which can treat symptoms but do not address underlying disease. Moderate- to- severe patients who do not respond to topical prescription therapies typically turn to biologics as their next option, and, subsequently, to JAK inhibitors. Both DUPIXENT and ADBRY are administered subcutaneously every two weeks, and work by targeting the Th2 inflammatory pathway (IL- 4 / 13, and IL- 13, respectively). RINVOQ and CIBINQO require daily oral administration and are only available to patients who do not sufficiently respond to systemic therapies including biologics. While these JAK inhibitors tend to have better efficacy than the two approved biologics, there are significant safety concerns including a boxed warning associated with JAK inhibitors. We are aware of additional programs in development for AD, which are focused largely on biologic approaches. Late- stage programs include Galderma' s nemolizumab, an IL- 31 antibody, and Eli Lilly' s lebrikizumab, an IL- 13 antibody, which are under regulatory review for approval by the FDA. Lebrikizumab has been approved in the European Union as EBGLYSS. There are other companies that have product candidates in early- stage development for moderate- to- severe AD, including Anaptys Bio (ANB032), RAPT Therapeutics (RPT193), Nektar Therapeutics (rezpegaldesleukin), Aslan Pharmaceuticals (eblasakimab), Pfizer (etrasimod, PF- 07275315 and PF- 07264660), LEO Pharma (LEO 138559 and 152020), Akesobio (AK120), Connect Biopharma (rademikibart), Biosion (BSI- 045B), Janssen (JNJ- 67484703), Bayer (zabedosertib), Sanofi (rilzabrutinib), Apogee Therapeutics (APG777), InnoCare Pharma (ICP- 332), Kymera Therapeutics (KTK- 474), Q32 Bio (bempikibart) and GSK (GSK1070806). Additionally, a new class of biologics is in clinical development targeting OX40, the same target as for STAR- 0310. Amlitelimab (Sanofi) is an anti- OX40 ligand (OX40L) antibody that has started a Phase 3 trial. Rocatinlimab (Amgen) is an afucosylated OX40 receptor (OX40R) antibody currently in Phase 3 trials in AD. IMG- 007 (Inmagene) is an OX40 receptor (OX40R) antibody in a proof- of- concept trial in AD.**

The enrollment and retention of patients in clinical trials for STAR- 0215 **or STAR- 0310** may be disrupted or delayed as a result of clinicians' and patients' perceptions as to the potential advantages of STAR- 0215 **or STAR- 0310** in relation to commercially available therapies and other programs in development, including approved products as well as any other new products that may be approved in the future **,** for the treatment of HAE **or AD** . ~~35Our~~ **42Our** competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable side effects, have more convenient dosing regimens, including the potential for biannual or annual dosing regimens, or are less costly than any product candidates that we may develop, which could render any future product candidates obsolete and noncompetitive. 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, or any future collaborators, may develop. Our competitors also may obtain FDA or other marketing approval for their products before we, or any future collaborators, are able to obtain approval for ours, which could result in our competitors establishing a strong market position before we, or any future collaborators, are able to enter the market. Our potential future competitors may have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and ~~marketing~~ **commercializing** approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early **-** stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, or as a result of the development of drug products that have more convenient dosing regimens. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. We have limited financial and managerial resources and are focused on the ~~preclinical and~~ clinical development of STAR- 0215 as a potential treatment for HAE, a rare disease with unmet medical need **, and the preclinical and clinical development of STAR- 0310 as a potential treatment for AD** . We would expect that development of any other future product candidate would also be for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on STAR- 0215 **, STAR- 0310** and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate. ~~36Preclinical~~ -- **Preclinical** development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials and we may be unsuccessful in identifying any new product candidates. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support ~~our planned~~ **the submission of an** IND in the United States, or similar applications in other jurisdictions, including **clinical trial application, or** CTA **,** submissions in the ~~EU~~ **European Union** . Such studies are complex and may be subject to delays or increased costs due to our dependence upon third parties to assist us with such studies and the ability to source raw materials and the appropriate animals, including non- human primates, so that we can conduct such testing. There is currently a global shortage of non- human primates available for drug development. If the shortage continues, this could increase the cost of conducting our preclinical development and could also result in delays to our development timelines. In the event that the FDA or comparable foreign regulatory authorities require us to complete additional preclinical studies or we are required to satisfy other FDA requests or other requests of comparable foreign regulatory authorities prior to commencing clinical trials, the start of our clinical trials may be delayed or take longer to complete. Even after we receive and incorporate guidance from the FDA or comparable foreign regulatory authorities, such authorities may not agree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or comparable foreign regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that ~~we~~ **43we** will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications, including CTA submissions in the ~~EU~~ **European Union** , will result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin or that we can meet the requirements imposed by such authorities for beginning such trials on a timely basis or at all. In addition, any future research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds **or biologics** for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price. We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any future product candidate we may seek to develop. We have never obtained marketing approval for a product candidate. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for any of our product candidates in a Phase 3 clinical trial or in obtaining marketing approval thereafter. If we are able to

advance STAR- 0215 **, STAR- 0310** or any other future product candidate into late- stage development, it is possible that the FDA, EMA or other applicable foreign regulatory authority may refuse to accept for substantive review any applications that we submit for marketing approval of such product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of such product candidate. If the FDA, EMA or other applicable foreign regulatory authority does not accept or approve any applications that we submit for marketing approval, they may require that we conduct additional clinical or nonclinical studies, or conduct manufacturing validation studies, and submit that data before they will reconsider our applications. Depending on the extent of these or any other required studies, approval of any application that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA, EMA or other applicable foreign regulatory authority. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing STAR- 0215 **, STAR- 0310** or any future product candidate, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for STAR- 0215 **, STAR- 0310** or any future product candidates, which could significantly harm our business. ~~37If~~ **If** STAR- 0215 **, STAR- 0310** or any other future product candidate receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any future collaborators, to market the drug could be compromised. Clinical trials of product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that clinical trials for STAR- 0215 **, STAR- 0310** and any other future product candidate, or those of any future collaborator, may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur ~~:~~ **.** ● regulatory authorities may withdraw their approval of the drug or seize the drug; ● we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials; ● additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug; ● we may be subject to fines, injunctions or the imposition of civil or criminal penalties; ● regulatory authorities may require the addition of labeling statements, such as a " black box " warning or a contraindication; **44** ● we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients; ● we, or any future collaborators, could be sued and held liable for harm caused to patients; ● we may become the subject of government investigations, which would be expensive to manage and potentially result in the imposition of fines, injunctions or the imposition of civil or criminal penalties; ● the drug may become less competitive; and ● our reputation may suffer. Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price. Even if STAR- 0215 **, STAR- 0310** or any other future product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success and the market opportunity for the product candidate may be smaller than we estimate. Even if STAR- 0215 **, STAR- 0310** or any other future product candidate is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors and others in the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies. ~~38Efforts~~ -- **Efforts** to educate the medical community and third- party payors on the benefits of future product candidates may require significant resources and may not be successful. If STAR- 0215 **, STAR- 0310** or any other future product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of STAR- 0215 **, STAR- 0310** or any other future product candidates, if approved for commercial sale, will depend on a number of factors, including: ● the efficacy and safety of the product; ● the potential advantages of the product compared to existing approved treatments or alternative treatments, including the convenience and ease of administration compared to alternative treatments; ● the prevalence and severity of any side effects; ● the clinical indications for which the product is approved; ● whether the product is designated under physician treatment guidelines as a first- line therapy or as a second- or third- line therapy and whether there is an existing standard of care; ● limitations or warnings, including distribution or use restrictions, contained in the product' s approved labeling; ● our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices; ● the product' s convenience and ease of administration compared to alternative treatments; ● the willingness of the target patient population to try, and of physicians to prescribe, the product; ● the strength of sales, marketing, market access and distribution support; **45** ● the approval of other new products for the same indications; ● changes in the standard of care for the targeted indications for the product; ● the timing of market introduction of our approved products in relation to competitive products; ● availability and amount of reimbursement from government payors, managed care plans and other third- party payors **, along with any protocols implemented by such entities that require the use of competitive products prior to providing reimbursement for any of our product candidates, if approved** ; ● adverse publicity about the product or favorable publicity about competitive products; and ● potential product liability claims. The potential market opportunities for product candidates are difficult to estimate precisely. Any estimates we make as to the potential market opportunities for STAR- 0215 **, STAR- 0310** or any other future product candidates will be predicated on many assumptions, including industry knowledge and publications, third- party research reports and other surveys. These assumptions will involve the exercise of significant judgment on the part of our management, will be inherently uncertain and the reasonableness of these assumptions may not have been assessed by an independent source. If any such assumptions prove to be

inaccurate, the actual markets for STAR- 0215 **, STAR- 0310** or any other future product candidate could be smaller than our estimates of the potential market opportunities. ~~39If~~ **If** we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution arrangements with third parties, we may not be successful in commercializing any future product candidates that we may develop if and when those product candidates are approved. We currently do not have a ~~formal~~ sales, marketing or distribution infrastructure. To achieve commercial success for any approved product, we would need to either develop a sales and marketing organization or outsource these functions to third parties. We expect to use a combination of focused in- house sales and marketing capabilities and third- party collaboration, licensing and distribution arrangements to sell any products that receive marketing approval. We generally expect that we would seek to retain full commercialization rights **in the United States** for products that we can commercialize with a specialized sales force and to retain co- promotion or similar rights when feasible in indications requiring a larger commercial infrastructure. The development of sales, marketing and distribution capabilities will require substantial resources, will be time- consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, at such time as we need to, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to a product, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently. We ~~may~~ **generally expect to** collaborate **or partner** with third parties for commercialization ~~of~~ **outside the United States and both inside the United States and outside the United States for** any products that require a large sales, marketing **, reimbursement** and product distribution infrastructure **, such as STAR- 0310 if approved for the treatment of moderate- to- severe AD** . We **would do so** ~~intend to potentially commercialize product candidates~~ through collaboration, licensing and distribution arrangements ~~with third parties~~ . As a result of entering into arrangements with third parties to perform sales, marketing **, reimbursement** and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates that receive marketing approval. **46STAR- 0215,** STAR- ~~0215~~ **0310** and any other future biologic product candidates will be regulated as biological products, or biologics, and therefore they may be subject to competition from biologic products that are biosimilar to or interchangeable with an FDA- licensed reference biologic product. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, **created** ~~was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, to establish~~ an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve **biological products that are** biosimilar **to or** ~~biologics, including the possible designation of a biosimilar as "~~ interchangeable with ~~"~~ **an FDA- licensed reference biologic. Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product** based on **the reference** ~~its similarity to an approved biologic~~ **biological product until four years after the date of first licensure of the reference product.** In addition,the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed.During this 12- year period of exclusivity,another company may still develop and receive approval ~~of~~ **for** a competing **version of** ~~biologic,so long as its BLA does not rely on~~ the reference product ~~,~~ **if the FDA approves a full BLA for the competing product containing** the sponsor' s **own preclinical** data ~~or submit~~ **and data from adequate and well- controlled clinical trials to demonstrate** the **safety,purity** ~~application as a biosimilar application.The law is complex~~ and **potency of** ~~is still being interpreted and implemented by the~~ **their product** ~~FDA.As a result,its ultimate impact,implementation,and meaning are subject to uncertainty~~ . In December 2022, Congress clarified through **the Food and Drug Omnibus Reform Act, or** FDORA **,** that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the **same** first day on which such a product is approved as interchangeable with the reference product **and the exclusivity period may be shared amongst multiple first interchangeable products** . **More recently, in October 2023, the FDA issued its first interchangeable exclusivity determination** ~~Under~~ **under** the BPCIA ~~, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product~~ . **We** In addition, the licensure of a..... prospects for our biological products. 40We believe that **our current** ~~STAR- 0215~~ and any of our future product candidates we develop as ~~a~~ biologic ~~product~~ **products** under a BLA should qualify for the 12- year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once ~~approved~~ **licensed** , will be substituted for any one of ~~the~~ **our** reference products in a way that is similar to traditional generic substitution for non- biological products **is not yet clear and** will depend on a number of marketplace and regulatory factors that are still developing. Nonetheless, the approval of ~~biosimilars~~ **biosimilar** ~~to~~ **products referencing any of** our product candidates would have a material adverse impact on our

business due to increased competition and pricing pressures. **Moreover, the ultimate impact, implementation and meaning of the BPCIA are subject to uncertainty, and any new regulations, guidance, policies or processes adopted by the FDA to implement the law could have a material adverse effect on the future commercial prospects for our biological products. For more information on biosimilars and regulatory exclusivity for biologic drugs in the United States, please see the section of this Annual Report on Form 10- K entitled " Business — Government Regulation and Product Approval — Biosimilars and Regulatory Exclusivity. "** If the FDA or comparable foreign regulatory authorities approve generic versions of any **of our** future products that receive marketing approval through the NDA pathway, or such authorities do not grant such **future** products appropriate periods of ~~data~~ **non- patent** exclusivity before approving generic versions of our products, our sales could be adversely affected. Once an NDA is approved, the product covered thereby becomes a " reference- listed drug " in the FDA' s publication, " Approved Drug Products with Therapeutic Equivalence Evaluations, " commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference- listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient (s), dosage form, strength, route of administration and conditions of use or labeling as the reference- listed drug and that the generic version is bioequivalent to the reference- listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference- listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference- listed drug is typically lost to the generic product. The FDA may not approve an ANDA for a generic product until any applicable period of non- patent exclusivity for the reference- listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non- patent exclusivity ~~for~~ **47for** a new drug containing a new chemical entity, or NCE **. For the purposes of this provision, an NCE is a drug that contains an active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance** . Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference- listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference- listed drug. **The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical trials, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application.** Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our ~~products~~ **product candidates** are approved, even if we still have patent protection for such ~~products~~ **product candidates** . Competition that any such ~~products~~ **product candidates** of ours may face from generic versions of such products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we ~~have~~ **may** ~~made~~ **make** in those product candidates. Business disruptions could delay completion of clinical trials, seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations, and those of third- party research institution collaborators, contract research organizations, or CROs, contract manufacturing operations, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, ~~medical~~ **public health crises, pandemics or** epidemics **,** such as the ~~ongoing~~ COVID- 19 ~~pandemic~~ **pandemics** , and other natural or man- made disasters or business interruptions, for which we may be partly uninsured, as well as impacts of geopolitical events, including civil or political unrest (such as the war between Russia and Ukraine **and the conflict in the Middle East**), terrorist activity and unstable governments and legal systems. In addition, we expect that we will rely on third- party research institution collaborators for conducting research and development of STAR- 0215 **, STAR- 0310** and any other future product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could delay completion of any clinical trials for such product candidates, seriously harm our operations and financial condition and increase our costs and expenses. ~~41We~~ **We** are subject to risks associated with public health crises **, pandemics** and epidemics ~~.~~ **. Public health crises,** pandemics **and epidemics** , such as the COVID- 19 pandemic ~~. Public health outbreaks, epidemics, pandemics of contagious or infectious diseases, such as COVID- 19~~ , may significantly disrupt our business. Such ~~outbreaks~~ **events** pose the risk that we or our employees, contractors, suppliers, or other partners may be prevented from conducting business activities for an indefinite period of time due to **the** spread of ~~the~~ disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facilities or the facilities of our contractors, suppliers, and other partners. The development of STAR- 0215 **, STAR- 0310** or any other future product candidates could be negatively impacted by public health crises, **pandemics or** epidemics ~~or pandemics, including a resurgence of the COVID- 19 pandemic,~~ for a variety of reasons, including delays of the initiation, recruitment and overall timing of clinical trials, delays at the FDA and other regulatory authorities ~~, who have been diverting resources to help address the pandemic since its inception and may continue to do so~~ , the disruption or delays of regulatory or manufacturing activities, including due to facility shut downs, capacity constraints at third party manufacturers ~~due to the focus on vaccines and other treatments to address the pandemic,~~ and increased costs or the inability to source key raw materials ~~that are being diverted for efforts related to the public health crisis~~ , or other adverse effects that negatively impact our business or operations. A pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on. Furthermore, delays and disruptions experienced by our collaborators or other third parties due to ~~the~~ **a** pandemic could adversely impact the ability of such parties to fulfill their obligations, which could affect the clinical development of our

product candidates. **For example** ~~We continue to monitor our operations and applicable government recommendations , and we have made modifications to our normal operations because of~~ the COVID- 19 pandemic **adversely** ~~, including working from home. Remote working arrangements could impact~~ **impacted** ~~employees' productivity and morale, strain our technology resources and introduce operational risks. Additionally, the risk of cyber- attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks. The COVID- 19 pandemic has continued to impact~~ the global supply chain, primarily through constraints on raw materials ~~.~~ **, and** ~~These~~ **these** constraints on raw materials ~~are~~ also ~~impacting~~ **impacted** companies outside of our direct industry, which **resulted** ~~is resulting~~ in a competitive supply environment causing higher costs **for a period during and following the COVID- 19 pandemic** . ~~Measures~~ **48Measures** taken by governments, actions taken to protect employees and the broad impact ~~of the~~ **public health crises,** ~~pandemic~~ **pandemics or epidemics would have** on all business activities may materially and adversely affect our business, results of operations and financial condition. Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop. We face an inherent risk of product liability claims as a result of the clinical testing of product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we or any future collaborators commercially sell any product that we may or they may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of any future product candidates. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for any future product candidates or products that we may develop; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● significant costs to defend resulting litigation; ● substantial monetary awards to trial participants or patients; ~~42~~ ● loss of revenue; and ● the inability to commercialize any products that we may develop. Although we maintain general liability insurance ~~of $ 5. 0 million in the aggregate~~ and clinical trial liability insurance **that we believe is customary and adequate** ~~of $ 10. 0 million in the aggregate~~ , this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if and when we begin selling any product candidate that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of any future product candidates, which could adversely affect our business, financial condition, results of operations and prospects. ~~Risks~~ **49Risks** Related to Our Financial Position and Need for Additional CapitalWe will need substantial additional funding. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts. Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time- consuming, expensive and uncertain process that takes years to complete. We are continuing to conduct clinical trials, preclinical and nonclinical studies, including ~~the addition of two cohorts to our Phase 1a trial of STAR- 0215 and~~ our Phase 1b / 2 ALPHA- STAR trial, which we initiated in February 2023, **our ALPHA- SOLAR trial, a long- term open- label clinical trial assessing the long- term safety and efficacy of STAR- 0215, and preparatory work for our potential Phase 3 pivotal trial, assuming favorable results from the Phase 1b / 2 ALPHA- STAR trial, and preclinical and nonclinical studies to support the submission of an IND for STAR- 0310 by the end of 2024. Additionally, we** are ramping up manufacturing of clinical supplies for STAR- 0215 and plan to begin the development of drug device combinations for our potential Phase 3 ~~clinical~~ **pivotal** ~~trials~~ **trial** and commercialization of STAR- 0215 ~~, and~~ **. We** expect that our expenses will increase substantially as a result **of all of these activities. We will need to raise additional capital in order to fund activities for STAR- 0215 beyond our planned Phase 3 pivotal trial, and for STAR- 0310, for activities beyond our planned Phase 1a trial and for any development of STAR- 0310 outside of AD** . In addition, we may in the future initiate new research, preclinical and clinical development efforts, and seek marketing approval, for other product candidates, and would expect our expenses to increase in connection with each of these activities. If we obtain marketing approval for any of our product candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator, and these activities would require substantial additional funding. In addition, while we may seek one or more collaborators for future development of our product candidates, we may not be able to enter into a collaboration for any of our product candidates on suitable terms or at all. In any event, our existing cash, cash equivalents and short- term investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Furthermore, we have incurred and will continue to incur significant additional costs associated with operating as a public company. Accordingly, we will be required to obtain substantial additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds. Adequate additional funding may not be available to us on acceptable terms, on a timely basis or at all, impacting our ability to execute on our strategic plans. General economic conditions, both inside and outside the **United States** ~~U. S.~~ , including heightened inflation, capital market instability and volatility, interest rate and currency rate fluctuations, and economic slowdown or recession as well as ~~the COVID- 19 pandemic~~ **pandemics** , **epidemics** and geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia **and the conflict in the Middle East**), have resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital. In addition, market volatility, high

levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. Our failure to raise capital on acceptable terms as and when needed may force us to delay, reduce or eliminate our research and development programs or any future efforts to seek approval for and commercialize products, and would have a material adverse effect on our business, results of operations, financial condition and ability to pursue our business strategy. Based on our current operating plan, we expect that our existing cash, cash equivalents and short- term investments **will enable us to** ~~as of December 31, 2022 are sufficient~~ fund our operating expenses and capital expenditure requirements **into mid- 2027. Our current operating plan includes the development of STAR- 0215 and STAR- 0310, including (i) for STAR- 0215, support for all program activities** through **completion** ~~the first half~~ of **a planned Phase 3 pivotal trial, and (ii) for STAR- 0310, the anticipated submission of an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated milestone payments under a license agreement, or the License Agreement, that we entered into with Ichnos Sciences SA and Ichnos Sciences Inc., or collectively Ichnos, in October** ~~2025~~ **2023)** . Our estimate as to how long we expect our cash, cash equivalents and short- term investments to be able to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including: ● our ability to meet our overall timing expectations for STAR- 0215 **and STAR- 0310** ; ~~43~~ ● the progress, timing, costs and results of clinical trials of, and research, preclinical and clinical development, and manufacturing efforts for, STAR- 0215 **, STAR- 0310** and any other future product candidates, including potential future clinical trials and all activities necessary to initiate and conduct clinical trials; **50** ● our ability to enter into and the terms and timing of any additional collaborations, licensing or other arrangements that we may establish; ● the number and characteristics of future product candidates that we pursue and their development requirements; ● the outcome, timing and costs of seeking regulatory approvals; ● the costs of the evaluation, selection, testing and scale up activities related to developing a drug device combination for **STAR- 0215,** ~~our~~ **or any other** product ~~candidates~~ **candidate for which we seek to develop a drug device combination,** for late- stage clinical trials and commercialization to the extent such costs are not the responsibility of any future collaborators; ● the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, market access, distribution, supply chain and manufacturing capabilities, scaling up the manufacturing of drug substance and drug product to clinical and commercial scale, securing all raw materials necessary to conduct such scale- up and successfully completing all other activities related thereto; ● subject to receipt of marketing approval, revenue, if any, received from commercial sales of our product candidates; ● if we obtain marketing approval of any of our products, our ability to successfully compete against other approved products that are approved or used as treatments for the indications for which our products are approved, including with respect to STAR- 0215 in HAE **and with respect to STAR- 0310 in AD** ; ● our headcount growth and associated costs; ● the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and ● the costs of operating as a public company. Furthermore, we hold a portion of cash and cash equivalents that we use to meet our working capital and operations expense needs in deposit accounts at one financial institution. The balance in these accounts typically exceed the Federal Deposit Insurance Corporation standard deposit insurance limit of $ 250, 000. If a financial institution in which we hold such funds fails, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such ~~uninsured~~ **insured** funds. Any such loss or lack of access to these funds could adversely impact our short- term liquidity and ability to meet our operating expense obligations. We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability. Our losses from operations were $ ~~51~~ **83** . ~~8~~ **0** million and $ ~~194~~ **53** . ~~9~~ **5** million ~~(including $ 164. 6 million of in- process research and development expenses)~~ for the years ended December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~507~~ **580** . ~~6~~ **5** million. We have not generated any revenues from product sales, have not completed the development of any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through private placements of preferred stock before we became a public company and our private placement of preferred stock in February 2021, which we refer to as the February 2021 Financing, registered offerings of our common stock **and / or warrants** , and our at- the- market **offering** programs, and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. ~~44We~~ **51We** expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. ~~Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.~~ We anticipate that we will continue to incur significant expenses and operating losses and we may incur increased expenses if and to the extent we: ● initiate and continue research and preclinical and clinical development efforts for STAR- 0215 **, STAR- 0310** and any other future product candidates; ● seek to identify and develop any other future product candidates; ● seek regulatory and marketing approvals for STAR- 0215 **, STAR- 0310** and any other future product candidate that successfully completes clinical trials, in the United States and other markets; ● establish sales, marketing, market access, distribution, supply chain and other commercial infrastructure in the future to commercialize products for which we may obtain marketing approval, if any; ● require the manufacture of larger quantities of STAR- 0215 **, STAR- 0310** and any other future product candidates for clinical development and potentially commercialization; ● implement changes in product candidate manufacturing or formulation; ● develop drug device combinations for **STAR- 0215,** ~~our~~ **or any other** product ~~candidates~~ **candidate for which we seek to**

develop a drug device combination, for late- stage clinical trials and commercialization; ● maintain, expand and protect our intellectual property portfolio; and ● hire and retain additional personnel or add information systems, equipment or physical infrastructure to support our operations. To become and remain profitable, we or any potential future collaborators must develop and eventually commercialize at least one product candidate with significant market potential. This will require that we or our collaborators be successful in a range of challenging activities, including completing preclinical studies and clinical trials of one or more product candidates, obtaining marketing approval for one or more these product candidates, manufacturing, marketing and selling those products for which we or our collaborators may obtain marketing approval and satisfying any post- marketing requirements. We or our collaborators may never succeed in any or all of these activities and, even if we or our collaborators do succeed, we or our collaborators may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause investors to lose all or part of their investments in us. ~~45Raising~~ -- **Raising** additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates. We will need to raise additional capital to develop and commercialize STAR- 0215 **and STAR- 0310** or to acquire, develop and commercialize any other future product candidates or to pursue other strategic options. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, our existing stockholders' ownership interests may be substantially diluted, and the terms of these securities could include liquidation or other preferences and anti- dilution protections that could adversely affect your rights as a common stockholder. For example, in connection with ~~the~~ **our** acquisition of Quellis Biosciences, Inc. **,** or Quellis **,** in January 2021 and our February 2021 Financing, we issued an aggregate of 86, 077 shares of Series X, of which 53, 532 shares of Series X Preferred Stock automatically converted into 8, 921, 966 shares of our common stock upon the stockholder approval of the conversion of the Series X Preferred Stock into common stock in June 2021. Subsequently, an additional 1, ~~090~~ **438** shares ~~were~~ **have** converted into ~~181~~ **239** , **608** ~~698 shares of common stock. On January 3, 2023, an additional 348 shares have subsequently converted into 57, 910~~ shares of common stock. The remaining 31, 107 shares of Series X Preferred Stock are convertible into 5, 184, ~~479~~ **591** shares of common stock at the election of the holders thereof, subject to certain beneficial ownership limitations. In addition, our June 2018 ~~and~~ **,** February 2019 **and October 2023** registered offerings of common stock and common stock warrants and our **January 2020,** December 2022 and ~~January~~ **February** ~~2020~~ **2024** registered ~~offering~~ **offerings** of common stock were highly dilutive to existing stockholders' ownership ~~interests~~ **52interests** . Further, exercise of the common stock warrants sold in our June 2018 ~~and~~ **,** February 2019 **and October 2023** offerings could result in additional dilution upon exercise. Debt financing, if available, would result in periodic payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day- to- day activities, which may adversely affect our management' s ability to oversee the development of any future product candidate. If we raise additional funds through collaborations or marketing, distribution, licensing or royalty arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. Risks Related to Our Dependence on Third PartiesWe may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans. The development and commercialization of product candidates require substantial cash to fund expenses. We may seek one or more collaborators for the development and commercialization of STAR- 0215 **, STAR- 0310** or any other future product candidates. Likely collaborators may include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. Collaborations are complex and time- consuming to negotiate and document. Further, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. In addition, any collaboration agreements that we enter into in the future may contain, restrictions on our ability to enter into potential collaborations or to otherwise develop specified compounds **or biologics** . ~~46We~~ **We** face significant competition in seeking appropriate collaborators and strategic partners. Whether we reach a definitive agreement for a collaboration or strategic partnership will depend, among other things, upon our assessment of the other party' s resources and expertise, the terms and conditions of the proposed transaction and the proposed party' s evaluation of a number of factors. Those factors may include the potential differentiation of ours or a partner' s product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator or strategic partner may also be considering alternative transaction types and structures that may be more attractive than the one with us. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not

have sufficient funds, we may not be able to further develop the product candidate or bring it to market and generate product revenue. If we enter into collaborations with third parties for the development and commercialization of a product candidate, our prospects with respect to such product candidate will depend in significant part on the success of those collaborations. If we enter into collaborations for the development and commercialization of a product candidate, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of such product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon ~~research~~ **53research** or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. Collaborations involving product candidates pose a number of risks, including the following: ● collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; ● collaborators may not perform their obligations as expected; ● collaborators may not pursue development and commercialization of a product candidate or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the market or competitive landscape, changes in the collaborators' strategic focus or available funding or external factors, such as an acquisition, that divert resources or create competing priorities; ● collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; ● a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products; ● disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; ● collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; ~~47~~ ● collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and ● collaborations may be terminated and, if terminated, may result in negative publicity for our product candidate and the need for additional capital to pursue further development or commercialization of the applicable product candidates. In addition, all of the risks related to product development, regulatory approval and commercialization described in this " Risk Factors " section would apply to the activities of our collaborators. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination or a sale or other transaction involving our collaboration, it or the party with which it entered into a business combination, sale or other transaction could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us. ~~We~~ **54We** rely on third parties to conduct our **preclinical studies and** clinical trials. If they do not perform satisfactorily, our business could be significantly harmed. We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct **ongoing and planned preclinical studies and** clinical trials of STAR- 0215 **, STAR- 0310** or any other future product candidates. Any of these third parties could terminate its engagement with us under certain circumstances or encounter, for example, business challenges, such as a loss of business, **public health crises, pandemics or epidemics, such as** the COVID- 19 pandemic **,** or the impacts of geopolitical events, including civil or political unrest (such as the war between Russia and Ukraine **and the conflict in the Middle East**), or enter into transactions, such as business combinations, that temporarily or permanently impact the amount or type of resources that they are able or willing to devote to our engagement. We might not be able to enter into alternative arrangements or do so on commercially reasonable terms or on a timely basis. In addition, there is a natural transition period when a new CRO begins work. As a result, delays would likely occur, which could materially impact our ability to meet our expected **preclinical and** clinical development timelines and harm our business, financial condition and prospects. Further, our reliance on these third parties for **preclinical and** clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of a product candidate, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA and most other comparable regulatory authorities outside the United States require us to comply with standards, commonly referred to as current GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. The FDA and other comparable regulatory authorities outside the United States enforce these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or any of our third- party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or other comparable regulatory authorities outside the United States may require us to perform additional clinical trials before approving a product candidate, which would delay the marketing approval process. We cannot be certain that, upon inspection, the FDA or other comparable regulatory authorities outside the United States will determine that any of our clinical trials comply with GCPs. **Similar standards, known as Good Laboratory Practices, apply to preclinical studies and nonclinical trials and other studies.** We are also required to register clinical trials and post the results of completed clinical trials on a government- sponsored database, ClinicalTrials. gov, within certain timeframes. Other regions, including the ~~EU~~ **European Union** , have similar requirements. The failure to comply with these registration and posting requirements can result in fines, adverse publicity and civil and criminal sanctions. Furthermore, the third parties that conduct **preclinical studies and** clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we are not able to control whether or not they

devote sufficient time, skill and resources to our development programs. Any such contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our **preclinical and** clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our **preclinical studies or** clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for the applicable product candidates. If that occurs, we would not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be impaired. ~~48We~~ **We** also rely on other third parties to store and distribute drug supplies for any clinical trials we pursue. Any performance failure on the part of any such distributors or impacts from geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia **and the conflict in the Middle East**), terrorist activity and unstable governments and legal systems could delay clinical development or marketing approval of any future product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue. ~~The~~ **55The** manufacturing of pharmaceutical products and, in particular, biologics, is complex and we do not have our own ~~clinical~~ manufacturing capabilities. We rely on third parties to produce **preclinical,** clinical and commercial supplies of any **current and** future product candidates. We currently have no manufacturing facilities and rely on third- party contract manufacturers to manufacture all of our preclinical product candidate supplies and clinical trial product supplies and will need to rely on third- party contract manufacturers ~~for~~ to manufacture any **commercial supply or** drug device combination for a product candidate **. We are also using a contract manufacturer to build the master cell bank that will be necessary for the manufacture of STAR- 0310, which we in- licensed in October 2023** . We do not own, nor do we plan to own, any manufacturing facilities. There can be no assurance that our preclinical ~~and~~ **,** clinical **and commercial** development product supplies, including drug substance, drug product ~~or~~ **,** planned drug device combinations, ~~from~~ **or the master cell bank for STAR- 0310, that are being manufactured by** third parties will not be **delayed,** limited or interrupted, or be of satisfactory quality or continue to be available at acceptable prices. Additionally, the process of manufacturing pharmaceutical products and, in particular, biologics is complex, highly regulated, and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, difficulties in scaling the production process and use of excipients which may, among other things, impact shelf life and present concerns with process controls. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our third- party contract manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business. If the contract manufacturers we engage are unable to supply us with sufficient **preclinical or** clinical ~~grade~~ **quality and** quantities of our product candidates ~~or~~ **,** drug device combinations for our product candidates **, or to build the master cell bank for STAR- 0310** , and we are unable to timely establish an alternate supply from one or more third- party contract manufacturers, we will experience delays in our development efforts as we seek to locate and qualify new **or additional** manufacturers. In particular, any replacement of our third- party contract manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements. We ~~obtain~~ **currently rely on single source third- party manufacturers and suppliers for the antibodies used to make STAR- 0215, STAR- 0215** drug product and ~~drug substance from single third~~ **to label and pack STAR** ~~party contract manufacturers~~ **0215, and we expect to continue to do so to meet our nonclinical, clinical and commercial needs for STAR- 0215, STAR- 0310, and any other product candidate** , which exacerbates these and other related risks for us. Additionally, contract manufacturers may rely on single source suppliers for certain of the raw materials or drug components for our preclinical and clinical product supplies. We may be unable to obtain raw materials or drug components for an indeterminate period of time if any of **our** third- party suppliers and manufacturers were to cease or interrupt production or otherwise fail to supply these materials or components to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier or manufacturer, failure by the supplier or manufacturer to comply with **current good manufacturing practices, or** cGMPs, contaminations, business interruptions, or labor shortages or disputes **, or if we were to terminate our relationship with any of our third- party suppliers or manufacturers for any reason. For example, we are utilizing a Chinese contract development and manufacturing organization, or CDMO, for the process and product development for STAR- 0310 and proposed legislation has been introduced in Congress that could prohibit U. S. companies that receive U. S. government funding from contracting with certain Chinese companies, which given the political complexities could, even though we have not received government funding to date, cause us to reevaluate our relationship with our Chinese CDMO** . Suppliers may extend lead times, limit supplies or increase prices due to capacity constraints or other factors beyond our control. We cannot be sure that single source suppliers for our raw materials or drug components will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these raw materials or components for our intended purpose. If current or future suppliers are delayed or unable to supply sufficient raw materials or components to manufacture product for our preclinical studies and clinical trials, we may experience delays in our development efforts as materials are obtained or we locate and qualify new raw material manufacturers. The manufacturing process for a clinical candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with their standards, such as cGMPs. In the event that any of our manufacturers fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of

components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third- party, which we may not be able to do on reasonable terms or on a timely basis, if at all. The transfer of the manufacturing of biologic products to a new contract manufacturer and any additional process development that may be necessary can be lengthy and involve significant additional costs. If ~~we~~ **56we** 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 and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer would negatively affect our ability to develop product candidates in a timely manner or within budget. ~~49Further~~ -- **Further** , our reliance on third- party manufacturers exposes us to risks beyond our control, including the: ● inability to meet our drug specifications, quality requirements or drug device combination requirements consistently ~~; ● delays in process development~~ ; ● inability to initiate or continue preclinical studies or clinical trials of product candidates or drug device combinations under development; ● delay or inability to procure or expand sufficient manufacturing capacity; ● costs and validation of new equipment and facilities required for scale- up; ● inability of our third- party manufacturers to execute process development, manufacturing, technology transfers, manufacturing procedures and other logistical support requirements appropriately or on a timely basis; ● manufacturing and drug quality issues, including related to scale- up of manufacturing; ● failure to comply with ~~cGMP~~ **cGMPs** and similar foreign standards; ● reliance on a limited number of sources, and in some cases, potentially single sources for drug components and raw materials, such that if we are unable to secure a sufficient supply of these drug components and raw materials, we will be unable to manufacture and sell our future product candidate in a timely fashion, in sufficient quantities or under acceptable terms; ● price increases or decreased availability of drug components or raw materials; ● lack of qualified backup suppliers for those components and raw materials that are purchased from a sole or single source supplier; ● inability to negotiate development and manufacturing agreements with third parties under commercially reasonable terms, if at all; ● breach, termination or nonrenewal of development and manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; ● disruption of operations of our third- party manufacturers or suppliers by conditions unrelated to our business or operations, including supply chain issues, capacity constraints, transportation and labor disruptions, global competition for resources, the bankruptcy of the manufacturer or supplier, a business combination or strategic transaction involving the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter and / or general economic conditions, heightened inflation, interest rate and currency rate fluctuations, and economic slowdown or recession; ● disruptions of operations caused by geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia **and the conflict in the Middle East**), terrorist activity, insurrection or other wars or significant conflicts, unstable governments and legal systems man-made or natural disasters or public health **crises,** pandemics ~~or~~ **and** epidemics, including, for example, the COVID- 19 pandemic; ● carrier disruptions or increased costs that are beyond our control, including increases in material, labor or other manufacturing- related costs or higher supply chain logistics costs; ● failure to deliver our drugs under specified storage conditions and in a timely manner; ~~and~~ **and57** ● the possible misappropriation of our proprietary information, including our trade secrets and know- how. ~~50Some~~ -- **Some** of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production, any of which could result in a failure to begin our clinical trials or having to stop or delay ongoing clinical trials. In addition, our third- party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our **preclinical,** clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business. In addition, our contract manufacturers are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier' s or manufacturer' s facility, which could impact the contract supplier' s or manufacturer' s ability to manufacture for us. In addition, a material shortage, contamination, recall or restriction on the use of substances in the manufacture of our product candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our product candidates, could adversely impact or disrupt the commercial manufacture or the production of **preclinical or** clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects. Any of these events could lead to **preclinical study or** clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved. Risks Related to Our Intellectual PropertyIf we are unable to obtain and maintain sufficient patent protection for product candidates, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize such product candidates successfully 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 STAR- 0215 **, STAR- 0310** and any other future product candidates. If we do not adequately protect our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. **See the section " Business — Intellectual Property "** ~~To protect our proprietary position, we have filed an International, or~~ **for** ~~PCT,~~ **more details regarding our STAR- 0215 and STAR- 0310** patent **portfolio** ~~application directed to STAR- 0215 and a provisional dosing regimen patent application in the U. S., and intend to file patent applications in the United States and abroad related to STAR- 0215 and future novel product candidates and related technologies that are important to our business~~ . The patent application and approval process is expensive and time- consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Failure to protect or to obtain,

maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and product candidates. The enforcement, defense and maintenance of such patents and other intellectual property rights may be challenging and costly. We cannot be certain that any patent application directed to ~~STAR- 0215 or~~ **our** ~~any~~ **current or** future product ~~candidate~~ **candidates** will be issued in a form that provides us with adequate protection to prevent competitors from developing competing products. As a biopharmaceutical company, our patent position is uncertain because it involves complex legal and factual considerations. The standards applied by **the United States Patent and Trademark Office, or** USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from any applications that are currently pending or that we file in the future. As such, we do not know the degree of future protection that we will have for ~~STAR- 0215~~ **our product candidates** and ~~its~~ **their** use. The scope of patent protection that the USPTO and foreign patent offices will grant with respect to ~~STAR- 0215~~ **our product candidates** is uncertain. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. For example, it is possible that the USPTO and foreign patent offices will not allow broad antibody claims that specifically cover our STAR- 0215 **and STAR- 0310** product ~~candidate~~ **candidates** and antibodies closely related to ~~it~~ **them** . As a result, upon receipt of FDA approval, or regulatory approval in foreign jurisdictions, competitors may be free to market antibodies almost identical to ours, including biosimilar antibodies, thereby decreasing our market share. However, a competitor cannot submit to the FDA an application for a biosimilar product based on STAR- 0215 **, STAR- 0310** or any future biologic products until four years following the date of approval of our " reference product, " and the FDA may not ~~approve~~ **58approve** such a biosimilar product until 12 years from the date on which the reference product was approved. See the section ~~of this Annual Report on Form 10- K entitled~~ " Business — Government Regulation and Product Approval — Biosimilars and Regulatory Exclusivity " for more details regarding biosimilar regulatory exclusivities. ~~51Our~~ -- **Our owned and in- licensed** pending ~~International~~ patent ~~application~~ **applications** ~~, U. S. provisional dosing regimen patent application~~ and any future patent applications we file cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, patents are granted to the party who was the first to file a patent application. However, prior to March 16, 2013, in the United States, patents were granted to the party who was the first to invent the claimed subject matter. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the USPTO, or become involved in post- grant review procedures, oppositions, derivations, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing antibodies or compounds similar or identical to our product candidates, or limit the duration of the patent protection of our product candidates. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Patent applications may not result in patents being issued which protect any current and future product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation **of** ~~. If~~ the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does. Even if patent applications that we file issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with any of our future products. Alternatively, our competitors may seek to market biosimilar versions of any approved products by submitting an application for a biosimilar product under the BPCIA. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. If we do not obtain protection under the **Drug Price Competition and Patent Term Restoration Act of 1984, or the** Hatch- Waxman Act **,** and similar non- United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed. Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to

exclude others from commercializing products similar or identical to ours. ~~52Depending~~ **59Depending** upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents, if issued, may be eligible for limited patent term extension under the Hatch- Waxman Act, or under similar legislation in other countries. The Hatch- Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended. However, 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. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. As a result, our revenue from applicable products could be reduced, possibly materially. **We rely on in- licensed patent and other intellectual property rights for our STAR- 0310 program and we may need to obtain licenses from third parties to other intellectual property rights for the development and commercialization of our STAR- 0310 and STAR- 0215 programs; if we fail to comply with our existing or future obligations under these licenses, or if these licenses are terminated, we could lose license rights that are important to our business.** Our **ability to** ~~development ----~~ **develop** and ~~commercialization~~ **commercialize our STAR- 0310 program is heavily dependent on an in- license to patent** rights ~~to STAR- 0215~~ and ~~future product candidates and technology may be subject, in part, to the~~ **other intellectual property** ~~terms and conditions of licenses~~ granted to us by ~~others~~ **Ichnos** . ~~We may become reliant upon~~ **In October, 2023, we entered into the License Agreement with Ichnos, pursuant to which Ichnos granted us an exclusive (even as to Ichnos and its affiliates), worldwide, and sublicensable right and** ~~licenses~~ **license** to certain patent rights and **related know- how to develop, manufacture, and commercialize Ichnos'** proprietary **OX40 portfolio. The OX40 portfolio includes Ichnos' proprietary OX40 antagonist monoclonal antibody, with the generic name telazorlimab and also referred to by Ichnos as " ISB 830 " as well as Ichnos' proprietary affinity matured next generation OX40 antagonist monoclonal antibody referred to by Ichnos as " ISB 830- X8 ". We are developing STAR- 0310, which was engineered from ISB 830- X8 with YTE half- life extension** technology **modification, for AD and potentially for other allergic and immunological diseases. STAR- 0310 is currently in preclinical development. Ichnos has also agreed not to develop or commercialize any product that directly modulates the OX40 receptor. Under the License Agreement, we agreed to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one product that contains or comprises a licensed compound in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan. The License Agreement imposes on us payment of development, regulatory and commercial milestones, as well as tiered royalties and other obligations. If we fail to comply with our obligations under the License Agreement, or we are subject to a bankruptcy, Ichnos may have the right to terminate the license, in which event we would not be able to market products covered by the License Agreement. Our business could suffer, for example, if the License Agreement terminates, if Ichnos fails to abide by the terms of the license, or if the licensed patents or other rights are found to be invalid or unenforceable. In the future, we may need to obtain licenses to intellectual property rights necessary to develop and commercialize our product candidates, including STAR- 0215 and STAR- 0310, or may need to amend existing or future licenses. If we are unable to obtain or amend such licenses at a reasonable cost or on reasonable terms, we may be unable to develop or commercialize our product candidates, which could harm our business significantly. As noted above, our License Agreement with Ichnos imposes, and we expect that future license agreements will impose, diligence obligations, milestone and royalty payments, indemnification and other obligations on us. If we fail to comply with our obligations under one or more of these licenses, our licensors, including Ichnos, may have the right to terminate the license agreement at issue. If one or more of these licenses is terminated, we may be unable to develop or commercialize our product candidates, including STAR- 0215 and STAR- 0310. Termination of any of our current or future license agreements or reduction or elimination of our licensed rights may require us to negotiate new or reinstated licenses with less favorable terms, even if available at all. In addition, our license agreements are, and future license agreements are likely to be, 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 the licensed rights, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over the license agreements or the in- licensed intellectual property prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. 60License agreements we may enter into in the future may be non- exclusive, or may not include all territories or fields of use of interest to us. Accordingly, third parties may also obtain licenses from such licensors to the same intellectual property rights they have licensed to us. As a result, the licenses granted to us may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates, which may permit competitors to develop and commercialize a competitive product. Furthermore, in some cases, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in- license** from third parties **. Therefore, we cannot be certain that any in- licensed patent rights will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, decide not to**

pursue litigation against third- party infringers, fail to prosecute infringement, or fail to defend against counterclaims of patent invalidity and unenforceability, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are ~~relevant to our STAR- 0215 product candidate~~ **the subject of such licensed rights could be adversely affected. Disputes may arise among us** and ~~possible~~ **our current and** future ~~product candidates. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we choose to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. Such license agreements would likely impose various development obligations, payment of royalties and fees based on achieving certain milestones, as well as other obligations. In addition, our~~ licensors ~~, in the future, may allege that we have materially breached our obligations under a certain license agreement and may therefore terminate that license agreement. If we fail to comply with our obligations under these agreements, the licensor may have the right to terminate the license. The termination of any such license agreements or failure to adequately protect such license agreements could prevent us from commercializing product candidates covered by the licensed intellectual property. Furthermore, our competitors may obtain the freedom to seek regulatory approval of, and to market products competitive with ours. Disputes may arise~~ regarding intellectual property subject to a licensing agreement, including: ● the scope of rights granted under the license agreement and other interpretation **-** related issues; ● **whether and** the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; ● ~~the~~ **our right to** ~~sublicensing~~ **sublicense** ~~of~~ patent and other rights **to third parties** under any collaboration relationships we might enter into in the future; ● our diligence obligations under the license agreement **with respect to the use of licensed technology to develop and commercialize our product candidates,** and what activities satisfy those diligence obligations; ● the ownership of inventions and know how resulting from the joint creation or use of intellectual property by our licensors and us; and ● the priority of invention of patented technology. If disputes over intellectual property that we have licensed **, or license in the future,** prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. ~~53We~~ **We** may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful. Competitors may infringe 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 whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. ~~Even~~ **61Even** 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. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. An intellectual property litigation could lead to unfavorable publicity that could harm our reputation and cause the market price of our common stock to decline. During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. In such event, the market price of our common stock may decline. If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing current and future product candidates. Our commercial success depends, in part, on our ability to develop, manufacture, **and** market **our current** ~~and STAR- 0215,~~ as well as any ~~other~~ future product candidates, without infringing the intellectual property and other proprietary rights of third parties. If any third- party patents or patent applications are found to cover **our current** ~~STAR- 0215~~ or any ~~other~~ future product candidates or their methods of use, or other aspects of **our current or future product candidates** ~~STAR- 0215 that we may elect to patent~~, we may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all, or we may incur significant legal fees or damages. ~~54In~~ **In** spite of our efforts to avoid obstacles and disruptions arising from third- party intellectual property, it is impossible to establish with certainty that our programs directed to **our current** ~~STAR- 0215~~ and any ~~other~~ future product candidates will be free of claims by third- party intellectual property holders. Even with modern databases and on- line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications. Even when a third- party patent is

identified, we may conclude upon a thorough analysis, that we do not infringe the patent or that the patent is invalid. If the third- party patent owner disagrees with our conclusion and we continue with the business activity in question, patent litigation may be initiated against us. Alternatively, we might decide to initiate litigation in an attempt to have a court declare the third-party patent invalid or non- infringed by our activity. In either scenario, patent litigation typically is costly and time- consuming, and the outcome is uncertain. The outcome of patent litigation is subject to uncertainties that cannot be quantified in advance, for example, the credibility of expert witnesses who may disagree on technical interpretation of scientific data. Ultimately, in the case of an adverse outcome in litigation, we could be prevented from commercializing a product or using certain aspects of our technology platform as a result of patent infringement claims asserted against us. This could have a material adverse effect on our business. There is a substantial amount of intellectual property litigation in the biopharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to ~~STAR- 0215 or~~ **our** ~~any~~ **current or** future product candidates, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The biopharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that any current or future product candidates, products, methods, processes ~~or,~~ modeling or similar work 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 is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. For example, we are aware of a U. S. patent directed to an antibody that binds plasma kallikrein. In the event that the owner of this patent were to bring an infringement action against us, we may have to argue that STAR- 0215, its manufacture or use does not infringe a valid claim of this patent. We cannot guarantee that a court would find in our favor on questions of infringement or validity. Furthermore, even if our arguments are successful, 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 significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. ~~If~~ **62If** 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 product candidate 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 product candidate. 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 any future product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business. Our involvement in litigation, and in, e. g., any interference, derivation, reexamination, inter partes review, opposition or post- grant proceedings or other intellectual property proceedings in the United States, or other jurisdictions, may divert management time from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following: ● stop selling, manufacturing or using our products in the United States or other jurisdictions that use the subject intellectual property; ● obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non- exclusive thereby giving our competitors access to the same technologies licensed to us; ● redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; ~~or55~~ **or** ● pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed. Along with patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our manufacturing processes. We seek to protect these trade secrets, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, CROs, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants. Trade secrets and confidential know- how are difficult to maintain as confidential. Although we use reasonable efforts to protect our trade secrets, any party with whom we have executed a confidentiality agreement may breach that agreement and disclose our proprietary information, including our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. Accordingly, we may not be able to obtain adequate remedies for such breaches, despite any legal action that we might take against persons making such unauthorized disclosures. In addition, courts outside the United States sometimes are less willing than United States courts to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our business and competitive position could be harmed. Those with whom we collaborate on research and development related to current and future product candidates may have rights to publish

data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient ~~or~~ **63or** inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized. Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries **could increase those uncertainties and costs. For example** , ~~including~~ the Leahy- Smith America Invents Act **of 2011** , or the Leahy- Smith Act, ~~signed into law in September 2011, could increase those uncertainties and costs. The Leahy- Smith Act~~ included a number of significant changes to United States patent law **,** ~~. These include~~ **including** 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, for example, via post grant review and inter partes review proceedings at the USPTO. In addition, the Leahy- Smith Act transformed the United States patent system into a " first to file " system ~~. The first- to- file provisions, however, only became effective in March 2013~~ . However, the Leahy- Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and 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 harm our business, results of operations and financial condition. The United States Supreme Court has ruled on several patent cases, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations **; including the scope of patent protection for antibodies** . Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the Congress, the United States courts, the USPTO and the relevant law- making bodies in other countries, the laws and regulations governing patents could change in 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. ~~56Intellectual~~ -- **Intellectual** property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative: ● others may be able to make antibodies that are the same as or similar to STAR- 0215 **, STAR- 0310** or any other future product candidates but that are not covered by the claims of patents that we own or have rights to; ● we or our licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by our pending patent application; ● we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; ● it is possible that our pending patent rights will not lead to issued patents, or that patents, if granted, may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; ● our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license; **64** ● we may not develop additional technologies that are patentable; and ● third parties may allege that our development and commercialization of STAR- 0215 **, STAR- 0310** or any other future products may infringe their intellectual property rights, the outcome of which may have an adverse effect on our business. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submissions, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering any future product candidates, our competitive position would be adversely affected. ~~57We~~ **We** may obtain only limited geographical protection with respect to certain patent rights, which may diminish the value of our intellectual property rights in those jurisdictions and prevent us from enforcing our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. Accordingly, we may not file for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national / regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology. The requirements for patentability may differ in certain

countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us. In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by changes in foreign intellectual property laws. For example, the European Union ~~is scheduled to open~~ **opened** a Unified Patent Court, or UPC, ~~during~~ **in June** 2023. The UPC **is** ~~will be~~ a common patent court ~~to~~ **that** ~~hear~~ **hears** patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents, should they be granted, in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce our European patents or defend their validity. We may decide to opt out our patent applications, if filed, and our European patents, if granted, from the UPC. If certain formalities and requirements are not met, however, our European patent applications, if filed, and European patents, if granted, could be challenged for non- compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patent applications or granted patents will avoid falling under the jurisdiction of the UPC, even if we decide to opt out of the UPC. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In these countries, the patent ~~owner~~ **65owner** may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business, results of operations and financial condition may be adversely affected. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities in those jurisdictions is inadequate. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we may not be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate. ~~58We~~ **We** may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property. Many of our employees, including our senior management, were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non- disclosure and non- competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. In addition, while we typically require our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel. Risks Related to Regulatory Approval and Other Legal Compliance MattersEven if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of STAR- 0215 **, STAR- 0310** or any other future product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate. The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of biopharmaceutical products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities, which regulations differ from country to country. We, and any future collaborators, are not permitted to market our product candidates in the United States or in other countries until we, or they, receive approval of a BLA from the FDA, which

would be required for approval of STAR- 0215 **and STAR- 0310** , or NDA or marketing approval from applicable regulatory authorities outside the United States. Product candidates in the development phase are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties, including third- party clinical research organizations, to assist us in this process. The process of obtaining marketing approvals, both in the United States and abroad, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity ~~and 66~~**and** novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use. ~~59In~~ **In** addition, changes in or the enactment or promulgation of additional statutes, regulations or guidance during preclinical or clinical development, or comparable changes in the regulatory review process for each submitted product application, may cause delays in the approval or rejection of an application. For example, ~~on~~ **in December 2022, with the passage of FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other " pivotal study " of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late- stage clinical trials of FDA- regulated products. Further, in** January ~~31,~~ 2022, the new Clinical Trials Regulation (EU) No 536 / 2014 became effective in the European Union and replaced the prior Clinical Trials Directive 2001 / 20 / EC. **This** ~~The new~~ regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the ~~new~~ coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one ~~EU~~ **European Union** Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a ~~new~~ clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the ~~EU~~ **European Union** Member States and the public. We **are seeking approval of our ongoing STAR- 0215 clinical trials, and if the results from the ALPHA- STAR trial are favorable, we plan to seek approval of the STAR- 0215 Phase 3 clinical study in the European Union pursuant to this regulation, but we** have ~~not previously~~ **yet to** ~~secured~~ **secure such an** authorization ~~to conduct clinical studies in the EU pursuant to this new regulation~~ and ~~, accordingly,~~ there is ~~a risk~~ **no assurance** that we ~~may~~ **will** be ~~delayed in commencing~~ **able to secure** such ~~studies. Further~~ **an authorization for our ongoing or future clinical trials of STAR- 0215** , **STAR- 0310 or any future product candidates.** ~~regulatory~~ **Regulatory** authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable **. Further, under the Pediatric Research Equity Act, or PREA, an NDA or BLA, or supplement to an NDA or BLA, for certain drugs and biological products must contain data to assess the safety and efficacy of the drug or biological product in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action. Finally, our ability to develop and market new drug products may be impacted by ongoing litigation challenging the FDA' s approval of mifepristone. Specifically, on April 7, 2023, the U. S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. In reaching that decision, the district court made a number of findings that may negatively impact the development, approval and distribution of drug products in the United States. Among other determinations, the district court held that the plaintiffs were likely to prevail in their claim that the FDA had acted arbitrarily and capriciously in approving mifepristone without sufficiently considering evidence bearing on whether the drug was safe to use under the conditions identified in its labeling. Further, the district court read the standing requirements governing litigation in federal court as permitting a plaintiff to bring a lawsuit against the FDA in connection with its decision to approve an NDA or establish requirements under a REMS based on a showing that the plaintiff or its members would be harmed to the extent that FDA' s drug approval decision effectively compelled the plaintiffs to provide care for patients suffering adverse events caused by a given drug. 67In April 2023, the district court decision was stayed, in part, by the U. S. Court of Appeals for the Fifth Circuit and the U. S. Supreme Court entered a stay of the district court' s decision, in its entirety, pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit and the disposition of any petition for a writ of certiorari to the U. S. Supreme Court. The Court of Appeals for the Fifth Circuit held oral argument in the case in May 2023 and, in August**

2023, issued its decision. The court declined to order the removal of mifepristone from the market, finding that a challenge to the FDA' s initial approval in 2000 is barred by the statute of limitations. But the Court of Appeals did hold that the plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious. In September 2023, the Justice Department and a manufacturer of mifepristone filed petitions for a writ of certiorari, requesting that asked the U. S. Supreme Court to review the Appeals Court decision. In December 2023, the U. S. Supreme Court granted these petitions for writ of certiorari for the appeals court decision . Any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations. In order to market and sell our products in the European Union and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We, and any future collaborators, may not obtain approvals from regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our products in any market. In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non- United States regulatory approvals and compliance with non- United States regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non- United States approvals required to market our product candidates outside the United States or if we fail to comply with applicable non- United States regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and prospects may be adversely affected. Additionally, we could face heightened risks with respect to ~~seeking~~ **obtaining** marketing ~~approval~~ **authorization** in the United Kingdom as a result of the ~~2020~~ withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The ~~United Kingdom and European Union entered into a Trade and Cooperation Agreement in connection with Brexit that sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, the consequences of Brexit the impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom remains unclear. 60As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to European Union rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012 / 1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of European Union law instruments governing medicinal products that pre- existed prior to the United Kingdom' s withdrawal from the European Union. Since a significant proportion of the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval, and commercialization of product candidates in the United Kingdom. For example, the~~ United Kingdom is no longer ~~covered by~~ **part of** the ~~centralized procedures for obtaining~~ **European Single Market and** European Union ~~- wide marketing authorization from the EMA~~ **Customs Union. As of January 1** , **2021, the Medicines** and **Healthcare** ~~a separate marketing authorization will be required to market product~~ **products** ~~candidates~~ **Regulatory Agency, or MHRA, became responsible for supervising medicines and medical devices** in **Great Britain, comprising England, Scotland and Wales under domestic law, whereas under** the **terms of the Northern Ireland Protocol, Northern Ireland is currently subject to European Union rules. The** United Kingdom ~~. Until December 31~~ **and European Union have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol** , ~~2023~~ **including with respect to the regulation of medicinal products in the United Kingdom. Once implemented** , ~~it is possible for~~ **the changes introduced by the Windsor Framework will see** the MHRA ~~to rely on a decision taken by~~ **be responsible for approving all medicinal products destined for** the **UK** ~~European Commission on the approval of a new marketing --- market authorization via~~ **(i. e., Great Britain and Northern Ireland), and** the ~~centralized procedure~~ **EMA will no longer have any role in approving medicinal products destined for Northern Ireland** . Any delay in obtaining, or an inability to obtain, any marketing ~~approvals~~ **authorizations** , as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for ~~any~~ **our** product candidates, which could significantly and materially harm our business **. In addition** , **foreign regulatory authorities may change their approval policies and new regulations may be enacted.** ~~or~~ **For instance,** ~~prevent us from commercializing any product candidate in the United Kingdom and / or the~~ European Union ~~and restrict our ability~~ **pharmaceutical legislation is currently undergoing a complete review process, in the context**

of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission' s proposal for revision of several legislative instruments related to ~~generate revenue~~ **medicinal products (among other things, potentially reducing the duration of regulatory data protection** and ~~achieve~~ **revising the eligibility for expedited pathways) was published in April 2023. The proposed revisions 68remain to be agreed** and ~~sustain profitability~~ **adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however have a significant impact on the pharmaceutical industry and our business in the long term** . We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation, or political instability in particular foreign economies and markets (such as the war between Ukraine and Russia **and the conflict in the Middle East**); compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States. We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for any future product candidates. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States. We, or any future collaborators, may seek orphan drug designations and may be unable to obtain such designations. Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA' s regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. ~~61In~~ **In** 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA, which among other things, codified the FDA' s pre- existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017, but have not yet been approved or licensed by FDA. The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term " same disease or condition " means the designated " rare disease or condition " and could not be interpreted by the FDA to mean the " indication or use. " Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the " indication or use. " Although there have been legislative proposals to overrule this decision, they have not been enacted into law. ~~On~~ **In** January ~~23,~~ 2023, the FDA announced that, in matters beyond the scope of the court' s order, the FDA will continue to apply its existing regulations tying orphan- drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted. ~~In~~ **69In** addition, to obtain orphan drug designation in the European Union, we would need to demonstrate that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. There is no assurance that we would be able to meet that standard for STAR- 0215 **, STAR- 0310** or any other product candidate. In particular, there is no assurance that STAR- 0215 will be able to show, to the satisfaction of European Union regulatory authorities, that it is of significant benefit to HAE patients given the currently available commercial products for HAE in the European Union and the additional products that are ahead of STAR- 0215 in clinical development for HAE. Any product candidate for which we obtain marketing approval would remain subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved. Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post- marketing testing and

surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a REMS. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability. We must also comply with requirements concerning advertising and promotion for any product candidate for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product' s approved labeling. **The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post- approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.** In September 2021 the FDA published final regulations which describe the types of evidence that the FDA will consider in determining the intended use of a drug or biologic. Moreover, with the passage of the Pre- Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. ~~62Nonetheless~~ **In addition** , ~~we~~ **in October 2023, the FDA published draft guidance outlining the agency' s non- binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non- misleading, factual and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. We** will **need** ~~not be able~~ to **carefully navigate the FDA' s various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing** ~~promote~~ **promotion** ~~any~~ **of our** products ~~we develop for indications or uses for which they are not approved. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post- approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws~~ . In addition, later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including: ● restrictions on such products, manufacturers or manufacturing processes; ● restrictions on the labeling or marketing of a product; ● restrictions on distribution or use of a product; ● requirements to conduct post- marketing studies or clinical trials; ● warning letters or untitled letters; **70** ● withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of products; ● damage to relationships with collaborators; ● unfavorable press coverage and damage to our reputation; ● fines, restitution or disgorgement of profits or revenues; ● suspension or withdrawal of marketing approvals; ● refusal to permit the import or export of our products; ● product seizure; ● injunctions or the imposition of civil or criminal penalties; and ● litigation involving patients using our products. Non- compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union' s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Further, the marketing and promotion of authorized drugs, including industry- sponsored continuing medical education and advertising directed toward the prescribers of drugs and / or the general public, are strictly regulated in the European Union, notably under Directive 2001 / 83EC, as amended, and are also subject to European Union Member State laws. Direct- to- consumer advertising of prescription medicines is prohibited across the European Union. ~~63Accordingly~~ -- **Accordingly** , assuming we, or any future collaborators, receive marketing approval for one or more of our product candidates, we, and any future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and any future collaborators, are not able to comply with post- approval regulatory requirements, our or any future collaborators' ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post- approval regulations may have a negative effect on our operating results and financial condition. We may seek certain designations for our product candidates, including Breakthrough Therapy, RMAT Therapy, Fast Track and Priority Review designations in the United States, and **the PRIority MEdicines, or** PRIME **,** ~~Designation~~ **designation** in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process. We may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy and Regenerative Medicine Advanced Therapy, or RMAT, product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough and RMAT therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for

the treatment of a serious or life - threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product' s application before the application is complete. This rolling review may ~~be~~ **71be** available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective **. The FDA has granted Fast Track designation to STAR- 0215 for the treatment of HAE** . We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months. **These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may, among other things, later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. In the European Union, we may seek PRIME designation for some of our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA' s role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a Committee for Medicinal Products for Human Use rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA' s grant of a marketing authorization.** We may ~~also~~ seek **approval of our product candidates from the FDA or comparable foreign regulatory authorities through the use of accelerated development pathways. If we are not able to use such pathways, we may be required to conduct additional clinical trials beyond those that are contemplated, which would increase the expense of obtaining, and delay or prevent the receipt of, necessary marketing approvals. Moreover, even if we receive** accelerated approval **from the FDA ~~for~~ or ~~one~~ comparable foreign regulatory authorities, if ~~or~~ our ~~more of~~ confirmatory trials do not verify clinical benefit, ~~our~~ or if we do not comply with rigorous post- marketing requirements, the FDA or comparable foreign regulatory authorities may seek to withdraw accelerated approval. Under the FDCA and implementing regulations, the FDA may grant accelerated approval to a** product ~~candidates~~ **candidate designed to ~~. Drug or biologic products studied for their safety and effectiveness in treating~~ --- treat a** serious or life-threatening **condition ~~illnesses and~~** that ~~provide~~ **provides** meaningful therapeutic benefit over **available therapies upon ~~existing treatments may receive accelerated approval. Accelerated approval means that~~** a **determination ~~product candidate may be approved on the basis of adequate and well-controlled clinical trials establishing~~** that the product candidate has an effect on a surrogate endpoint **or intermediate clinical endpoint** that is reasonably likely to predict ~~a~~ clinical benefit **. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease , such as irreversible morbidity or mortality. ~~or~~ For ~~on~~ the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or ~~the~~ other ~~basis~~ measure that is thought to predict clinical benefit, but is not itself a measure** of **clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than** an effect on ~~a clinical endpoint other~~ **irreversible morbidity or mortality ~~than~~ that ~~survival or~~ is reasonably likely to predict an effect on** irreversible morbidity or mortality or other clinical benefit **measurement ~~, taking into account the severity, rarity and prevalence~~** of ~~the condition and the availability or lack of alternative treatments. As~~ a **therapeutic effect ~~condition of approval, the FDA may require~~** that ~~a sponsor of a drug or biologic product candidate receiving~~ **is considered reasonably likely to predict the clinical benefit. Prior to seeking such** accelerated approval **, we ~~perform adequate and well~~ will ~~controlled post- marketing~~ continue to seek feedback from the FDA or comparable foreign regulatory agencies and otherwise evaluate our, or their, ability to seek and receive such accelerated approval. 72There can be no assurance that the FDA or foreign regulatory agencies will agree with our surrogate endpoints or intermediate clinical endpoints in any of our** clinical trials **~~. In~~ , or that we will decide to pursue or submit any ~~addition~~ additional NDAs ~~, the FDA currently requires as a condition for~~ or BLAs seeking** accelerated approval ~~pre-~~ **. Similarly, there can be no assurance that, after feedback from the FDA or comparable foreign regulatory agencies, we will continue to pursue or apply for accelerated** approval ~~of promotional materials~~ **. Furthermore, for any submission of an application for accelerated approval, there can be no assurance that such submission will be accepted for filing or that**

any expedited development, review or approval will be granted on a timely basis, or at all. Finally, there can be no assurance that we will satisfy all FDA requirements, including new provisions that govern accelerated approval. For example, ~~With~~ **with** passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation **(i)** authorized the FDA to ~~:~~ require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded ~~;~~**, (ii)** ~~require~~ **requires** a sponsor of a product granted accelerated approval to submit progress reports on its post- approval studies to the FDA every six months ~~(~~ until the study is completed **and (iii** ~~; and~~ **authorizes the FDA to** use expedited procedures to withdraw accelerated approval of an NDA or **a** BLA after the confirmatory trial fails to verify the product' s clinical benefit. Further, FDORA requires the FDA to publish on its website ~~"~~ the rationale for why a post- approval study is not appropriate or necessary ~~"~~ whenever it decides not to require such a study upon granting accelerated approval. **We will need to fully comply with** ~~These~~ **these** ~~designations~~ **and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval. In the European Union, a " conditional " marketing authorization may be granted in cases where all the required safety and efficacy data** are **not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can become a " standard " marketing authorization. However, if the conditions are not fulfilled** within the ~~discretion of~~ **timeframe set by** the ~~FDA~~ **EMA, the marketing authorization will cease to be renewed** . Accordingly, ~~even if we believe that one~~ **a failure to obtain and maintain accelerated approval or any other form** of **expedited development, review or approval for** our product candidates **,** ~~meets the criteria for~~ **or withdrawal** ~~these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt~~ of ~~such designation for~~ a product candidate ~~may not~~ **, would** result in a ~~faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may, among other things, later decide that the product candidates no~~ longer ~~meet the conditions for qualification or decide that the~~ time period **until commercialization** ~~for FDA review or approval will not be shortened. 64In the European Union, we may seek PRIME designation for some~~ of ~~our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA' s role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or even if~~ such ~~a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a~~ product candidate ~~must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims. The benefits of a PRIME designation include the appointment of a Committee for Medicinal Products for Human Use rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application~~ . **could increase the cost of** ~~early dialogue and scientific advice at key~~ development ~~milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any~~ of ~~our~~ **such** product ~~candidates~~ - **candidate and could harm** ~~, the designation may not result in a materially faster development process, review or~~ **our competitive position in** ~~approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase~~ the **marketplace** ~~likelihood of EMA' s grant of a marketing authorization~~ . We may seek a Rare Pediatric Disease **priority review voucher, or** PRV **,** for our current and future product candidates. A BLA or NDA for our current and future product candidates may not, however, meet the eligibility criteria for a PRV, even if the BLA or NDA is approved. With enactment of the ~~FDASIA~~ **Food and Drug Administration Safety and Innovation Act of 2012** and subsequent legislation, Congress authorized the FDA to award PRVs to sponsors of certain rare pediatric disease product applications that meet the criteria specified in the law. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives approval for a new drug or biologic for a rare pediatric disease may qualify for a PRV, which can be redeemed for priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product that receives a PRV may transfer, including by sale, the PRV to another sponsor and that PRV may be further transferred any number of times before it is used. A PRV entitles the holder to designate a single human drug application submitted under Section 505 (b) (1) of the FDCA or Section 351 of the ~~PHSA~~ **Public Health Service Act** as qualifying for a priority review. An FDA priority review may expedite the review process of a marketing application reducing the review time from ten months after formal acceptance of the file to six months after formal acceptance of the file. In order for a sponsor to receive a PRV in connection with approval of a BLA or NDA, the investigational product must be designated by the FDA as a product for a rare pediatric disease prior to submission of the marketing application. A rare pediatric disease is a disease that is serious or life- threatening and which primarily affects individuals aged from birth to 18 years and fewer than 200, 000 people in the United States. Alternatively, the disease may affect more than 200, 000 people in the United States if there is no reasonable expectation that the cost of developing and making available in the United States a product for such disease or condition will be recovered from sales in the United States of such product. In addition, to qualify for a PRV, the sponsor must request the voucher and the BLA or NDA must itself be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the product intended for that population, not seek approval

for a different adult indication in the original rare pediatric disease product application and be for a product that does not include a previously approved active ingredient. ~~There~~ **73There** can be no assurance that the FDA will determine that a BLA or NDA for one or more of our product candidates meets the eligibility criteria for a PRV upon approval of the marketing application. Further, under the current statutory sunset provisions for the Rare Pediatric Disease PRV Program, the FDA may only award a PRV for an approved rare pediatric disease product application if the rare pediatric disease designation was granted by September 30, 2024. Moreover, the FDA may not award any rare pediatric disease PRVs after September 30, 2026. Accordingly, if we do not receive rare pediatric disease designation and approval of a BLA or NDA by these dates, respectively, and if the Rare Pediatric Disease PRV program is not further extended by Congressional action, we may not receive a PRV. Since a PRV may be sold for substantial amounts of money, or used by us to expedite approval of another marketing application, our business may be harmed if we do not qualify for a PRV in connection with approval of an NDA or BLA. ~~65We~~ **We** and our contract manufacturers are subject to significant regulation. The manufacturing facilities on which we rely may not continue to meet regulatory requirements, which could materially harm our business. All entities involved in the preparation of product candidates, including drug substance, drug product and device combinations that may be used in combination with our product candidates, for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical trials must be manufactured in accordance with ~~cGMP~~ **cGMPs** . These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a BLA or NDA on a timely basis and must adhere to the FDA' s current ~~GLP~~ **good laboratory practices** and cGMP regulations enforced through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our contract manufacturers must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidate. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted. The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our contract manufacturers. If any such inspection or audit identifies failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or time- consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility, which may lead to temporary or permanent supply shortages. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we of our third- party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre- existing approval. Any such consequence would severely harm our business, financial condition and results of operations. Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, competing priorities or other disruptions to these agencies' operations, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies, including government agencies and regulatory authorities outside the United States, on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. ~~Disruptions~~ **74Disruptions** or competing priorities at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations ~~. 66Separately, in response to the COVID- 19 pandemic in 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA' s inability to complete required inspections for their applications. As of May 26, 2021, the FDA noted it was continuing to ensure timely reviews of applications for medical products during the pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to continue its current pace and review timelines could be extended, thus the FDA may be unable to complete such required inspections during the review period. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID- 19 pandemic and may experience delays in their regulatory activities. On January 30, 2023, the Biden Administration announced~~

~~that it will end the public health emergency declarations related to COVID- 19 on May 11, 2023. On March 13, 2023, the FDA announced that it will end 22 COVID- 19- related policies when the public health emergency ends on May 11, 2023 and allow 22 to continue for 180 days. The FDA plans to retain 24 COVID- 19- related policies with appropriate changes and four whose duration is not tied to the end of the public health emergency. At this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates~~ . If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets. Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our product candidates that do receive marketing approval. In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed. In March 2010, President Obama signed into law the **Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively, the** ACA ~~. In addition, other legislative changes have been proposed and adopted since the ACA was enacted~~ . In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act ~~, or the CARES Act. Pursuant to subsequent legislation, these Medicare sequester reductions were suspended and reduced in 2021 and 2022 but, as of July 1, 2022, the full 2 % cut has resumed~~ . The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4 %. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4 % Statutory Pay- As- You- Go Act of 2010 (PAYGO) sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4 % cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act ~~'~~ **'** s health care offset title includes Section 4163, which extends the 2 % Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031. Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act **of 2017** , or TCJA, in 2017, Congress repealed the " individual mandate. " The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, in December 2018, a U. S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA and therefore because the mandate was repealed as part ~~67of~~ **of** the TCJA, the remaining provisions of the ACA are invalid as well. ~~The~~ **In June 2021, the** U. S. Supreme Court ~~heard this case and in June 2021,~~ dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. ~~The~~ **75The** Trump Administration also took executive actions to delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden revoked those orders and issued a new executive order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this order, federal agencies are directed to re- examine: policies that undermine protections for people with pre- existing conditions, including complications related to COVID- 19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents **. In the European Union, on December 13, 2021, Regulation No 2021 / 2282 on Health Technology Assessment, or HTA, amending Directive 2011 / 24 / EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January 2025 onwards, with preparatory and implementation- related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among European Union Member States in assessing health technologies, including new medicinal products as well as certain high- risk medical devices, and provide the basis for cooperation at the European Union level for joint clinical assessments in these areas. It will permit European Union Member States to use common HTA tools, methodologies and procedures across**

the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual European Union Member States will continue to be responsible for assessing non- clinical (e. g., economic, social and ethical) aspects of health technology, and making decisions on pricing and reimbursement . We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and / or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates. The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed. The prices of prescription pharmaceuticals have been the subject of considerable discussion in the United States. There have been several recent Congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid. In 2020 President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician- administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, **Centers for Medicare & Medicaid Services, or** CMS **,** issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence- based care. ~~In~~ **76In** addition, in October 2020, **the Department of Health and Human Services, or** HHS **,** and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program ~~, or SIP,~~ to import certain prescription drugs from Canada into the United States. ~~The final rule is currently~~ **That regulation was challenged in a lawsuit by** the ~~subject~~ **Pharmaceutical Research and Manufacturers** of ~~ongoing litigation~~ **America, or PhRMA** , but ~~at least six~~ **the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Nine** states (~~Vermont,~~ Colorado, Florida, Maine **, New Hampshire** , New Mexico, **North Dakota, Texas, Vermont** and **Wisconsin** ~~New Hampshire~~) have passed laws allowing for the importation of drugs from Canada ~~with~~ **. Certain of** ~~the~~ **these** ~~intent of developing SIPs for review~~ **states have submitted Section 804 Importation Program proposals** and **are awaiting FDA** approval ~~by~~ **. In January 2024,** the FDA **approved Florida' s plan for Canadian drug importation** . Further, on November 20, 2020, HHS finalized a regulation that would eliminate the current safe harbor Medicare drug rebates and create new safe harbors for beneficiary point- of- sale discounts and ~~PBM~~ **pharmacy benefit manager** service fees. It originally was set to go into effect on January 1, 2022, but ~~with passage of the rule Inflation Reduction Act~~ has been delayed by Congress until January 1, 2032. In September 2021, acting pursuant to an executive order signed by President Biden, the ~~Department of Health and Human Services, or~~ HHS ~~,~~ released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments. **In** ~~68More recently, on~~ August ~~16,~~ 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The IRA has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation ~~(first due in 2023)~~ ; and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025) that would require manufacturers to cover a portion of these costs. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single- source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high- cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if

prices are set after such products have been on the market for nine years. Further, the IRA subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the IRA by offering a price that is not equal to or less than the negotiated " maximum fair price " under the law or for taking price increases that exceed inflation. The IRA also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The IRA also caps Medicare out- of- pocket drug costs at an estimated $ 4, 000 a year in 2024 and, thereafter beginning in 2025, at $ 2, 000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or " catastrophic period " of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100 % of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co- insurance and co- payment costs, expanding eligibility for lower income subsidy plans, price caps on annual out- of- pocket expenses, and the requirement that manufacturers cover a portion of these costs, each of which could have potential pricing and reporting implications. **77In June 2023, Merck & Co. filed a lawsuit against the HHS and CMS asserting that, among other things, the IRA' s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Subsequently, a number of other parties, including the U. S. Chamber of Commerce, Bristol Myers Squibb Company, PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results.** Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, ~~if approved,~~ any of which could adversely affect our business, results of operations and financial condition. In addition, at the federal level in the **United States** ~~U. S.~~, in February 2023, CMS announced a model that would allow CMS to pay less for drugs and biologics approved through FDA' s accelerated approval pathway before a clinical benefit has been confirmed by the required confirmatory studies. If implemented, this would impact the price that CMS would pay for Medicare Part B drugs and biologics that fit within CMS' s criteria for lower payments. Implementation of this model could result in reduced reimbursement for our products and also lead to further and more expansive pricing pressure from CMS and other U. S. payors, any of which could adversely affect our business, results of operations and financial condition. At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. ~~69In~~ **In** the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost- effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed. **The insurance coverage and reimbursement status of newly approved products is uncertain. Our product candidates, if approved, may become subject to unfavorable pricing regulations, third- party coverage and reimbursement practices or healthcare reform initiatives, which would harm our business. Failure to obtain or maintain coverage and adequate reimbursement for any of our product candidates for which we obtain approval could limit our ability to market those products and decrease our ability to generate revenue. The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs and other medical products vary widely from country to country. In the United States, healthcare reform legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a product before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenue we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more products or product candidates, even if any product candidates we may develop obtain marketing approval. 78Our ability to successfully commercialize our products and product candidates also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations.**

Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Sales of any product we successfully develop will depend substantially, both domestically and abroad, on the extent to which the costs of such product will be paid by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or reimbursed by government health administration authorities, private health coverage insurers and other third- party payors. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize any product we may successfully develop. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medicines, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for any product we may successfully develop. Accordingly, in markets outside the United States, the reimbursement for products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenues and profits. There is also significant uncertainty related to the insurance coverage and reimbursement of newly approved products and coverage may be more limited than the purposes for which the medicine is approved by the FDA or comparable foreign regulatory authorities. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for products exists among third- party payors and coverage and reimbursement levels for products can differ significantly from payer to payer. As a result, the coverage determination process is often a time consuming and costly process that may require us to provide scientific and clinical support for the use of any product we may successfully develop to each payer separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Reimbursement agencies in Europe may be more conservative than CMS. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors any product we may successfully develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize product candidates and our overall financial condition. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable reimbursement rates from third- party payors for any product we may successfully develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Increasingly, third- party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We **cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. In order to obtain reimbursement, physicians may need to show that patients have superior treatment outcomes with our products compared to standard of care drugs, including lower- priced generic versions of standard of care drugs. We expect to experience pricing pressures in connection with the sale of any of our product candidates, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. 79We** may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings. Healthcare providers, third- party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers and third- party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Potentially applicable United States federal and state healthcare laws and regulations include the following: Anti- Kickback Statute. The federal Anti- Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. **A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation.** False Claims Laws. The federal false claims laws, including the

civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. **In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.** HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health ~~Act, or the HITECH~~ Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. False Statements Statute. The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children' s Health Insurance Program, with specific exceptions, to report annually to the HHS information related to physician and healthcare provider payments and other transfers of value and physician ownership and investment interests. Analogous State and Foreign Laws. Analogous state laws and regulations, such as state anti- kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non- governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances. ~~70The~~ -- **The** provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. ~~Efforts~~ **80Efforts** to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, corporate integrity or other similar forms of agreements or decrees, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations. We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage and use of personally- identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, European Union and the United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects. There are numerous U. S. federal and state laws and regulations related to the privacy and security of personal information **that may impact certain of our business operations** . ~~In particular~~ **For example** , regulations promulgated pursuant to HIPAA establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical, and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity, and availability of electronic protected health information. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future. If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume

significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced, or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures, and systems. ~~71In 2018 California passed into~~ **There are other privacy and security** ~~law~~ **laws that also may be applicable to our business activities now or in** the ~~CCPA~~ **future. For example** , ~~which took effect~~ on January 1, 2020, **the California Consumer Privacy Act, or CCPA took effect** and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA' s requirements are similar to those found in the **European Union' s General Data Protection Regulation, or** GDPR, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt- out of **the** " sales " of their personal information. The CCPA contains significant penalties for companies that violate its requirements. **The** ~~In November 2020,~~ California **Privacy Rights Act,** ~~voters passed a ballot initiative for~~ **or** ~~the~~ CPRA, ~~which~~ went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional GDPR- like provisions including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created **an** ~~a new~~ enforcement agency – the California Privacy Protection Agency – whose sole responsibility is ~~to~~ **81to** enforce the CPRA **and other California privacy laws** , which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities. In addition **to California** , **eleven** other states ~~, including Virginia, Colorado, Utah, and Connecticut, already~~ have passed ~~state~~ **comprehensive** privacy laws **similar to the CCPA and CPRA** . **These** ~~Virginia' s privacy law~~ **laws** ~~also went into~~ **are either in** effect **or** ~~on January 1, 2023, and the laws in the other three states~~ will go into effect ~~later in~~ **sometime before the end of 2026. Like the CCPA and CPRA,** ~~the~~ **these** ~~year~~ **laws create obligations related to the processing of personal information, as well as special obligations for the processing of " sensitive " data, which includes health data in some cases. Some of the provisions of these laws may apply to our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2024 legislative sessions that will go into effect in 2025 and beyond, including New Hampshire and New Jersey** . Other states will be considering ~~these~~ **similar** laws in the future, and Congress has also been debating passing a federal privacy law. **There are also states that are specifically regulating health information that may affect our business. For example, Washington state passed a health privacy law in 2023 that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data, and more states (such as Vermont) are considering such legislation in 2024.** These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the **European Economic Area, or** EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross- border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and / or fines of up to 20 million Euros or up to 4 % of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill. The GDPR places restrictions on the cross- border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the ~~EU~~ **European Union** to other countries. In July 2020 the **Court of Justice of the European Union, or the** CJEU **,** invalidated the EU- U. S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long- term viability of an alternative means of data transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. While we were not self- certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners. Additionally, in October 2022 **,** President Biden signed an executive order to implement the EU- U. S. Data Privacy Framework, which ~~would serve~~ **serves** as a replacement to the EU- U. S. Privacy Shield. The European ~~Commission~~ **Union** initiated the process to adopt an adequacy decision for the EU- U. S. Data Privacy Framework in December 2022 **,** ~~. It is unclear if~~ and ~~when~~ the **European Commission adopted the adequacy decision in July 2023. The adequacy decision permits U. S. companies who self- certify to the EU- U. S. Data Privacy** ~~framework~~ **Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they** will be ~~finalized and whether it will be~~ **challenging the EU- U. S. Data Privacy Framework. If these** ~~challenged~~ **challenges** ~~in court~~ **are successful, they may not only impact the EU- U. S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer**

mechanisms . The uncertainty around this issue ~~may further~~ **has the potential to** impact our business ~~operations and activities in~~ **. Following the withdrawal of the UK from** the European Union ~~. Following the withdrawal of the United Kingdom from the European Union~~ , the **UK** ~~U. K.~~ Data Protection Act 2018 applies to the processing of personal data that takes place in the **UK** ~~United Kingdom~~ and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the **UK** ~~United Kingdom~~ and the European Union have determined, through separate " adequacy " decisions, that data transfers between the two jurisdictions are in compliance with the **UK** ~~U. K.~~ Data Protection Act and the GDPR, respectively. **The UK and the U. S. have also agreed to a U. S.- UK " Data Bridge ", which functions similarly to the EU- U. S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the UK to the United States. In addition to the UK, Switzerland is also in the process of approving an adequacy decision in relation to the Swiss- U. S. Data Privacy Framework (which would function similarly to the EU- U. S. Data Privacy Framework and the U. S.- UK Data Bridge in relation to data transfers from Switzerland to the United States).** Any changes or updates to these **developments** ~~adequacy decisions~~ have the potential to impact our business. ~~Beyond~~ **82Beyond** GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, if approved, through increased compliance costs, costs associated with contracting, and potential enforcement actions. ~~72While we continue to address the implications of the recent changes to data~~ **Data** ~~privacy regulations, data~~ privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non- compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government- imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects. We are subject to United States and foreign anti- corruption and anti- money laundering laws with respect to our operations and non- compliance with such laws can subject us to criminal and / or civil liability and harm our business. We are subject to the ~~FCPA~~ **Foreign Corrupt Practices Act** , the United States domestic bribery statute contained in 18 U. S. C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, third- party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and / or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third- party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities. Noncompliance with anti- corruption and anti- money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and / or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management' s attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order, or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti- bribery laws of European Union Member States and the U. K. Bribery Act 2010. Violations of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization, and / or the regulatory authorities of the individual European Union Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the European Union Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment. ~~73If~~ **83If** 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 significantly harm our business. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and

the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and biological materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. 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, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions. Our employees, independent contractors, CROs, consultants, contract manufacturers, commercial partners, vendors and principal investigators may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, contract manufacturers, commercial partners, vendors and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government 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, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions. Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations, third- party payor reimbursement practices or healthcare reform initiatives that could harm our business. The commercial success of any product that we may develop will depend substantially, both domestically and abroad, on the extent to which the costs of such product will be paid by third- party payors, including government health administration authorities and private health coverage insurers. If coverage and reimbursement is not available, or reimbursement is available only to limited levels, we, or any future collaborators, may not be able to successfully commercialize such product. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors and coverage and reimbursement for products can differ significantly from payor to payor. ~~74There~~ **84There** is significant uncertainty related to third- party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Many countries outside the United States, including many countries in the European Union, require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted and can be lengthy, involve extensive negotiations and potentially result in price caps, significant discounts or other budgetary control measures, which could correspondingly impact pricing and reimbursement in other markets through so- called informal or formal reference pricing schemes. These reviews and negotiations could ultimately result in a pricing and reimbursement structure for a drug that a company deems inadequate and therefore elects not launch in such markets. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability or the ability of any future collaborators to recoup our or their investment in one or more product candidates, even if any future product candidates obtain marketing approval. Patients who are provided medical treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize any product will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third- party payors. Third- party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell any products we develop profitably. These payors may not view our products, if any, as

cost- effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost- control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices for any future products decrease or if governmental and other third- party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer. There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services. In addition, increasingly, third- party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. For example, to obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost- effectiveness of our product to other available therapies. We cannot be sure that coverage will be available for any product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government- funded and private payors for any product candidate for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. ~~75Risks --~~ **Risks** Related to TaxationChanges in tax law could adversely affect our business and financial condition. The rules dealing with U. S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U. S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us and our stockholders. Many such changes have been made and changes are likely to continue to occur in the future. For example, the TCJA was enacted in 2017 and significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35 % to a flat rate of 21 %, a limitation of the tax deduction for net interest expense ~~to~~ **85to** 30 % of adjusted earnings (except for certain small businesses), a limitation of the deduction for net operating losses **arising in taxable years beginning after December 31, 2017** to 80 % of current year taxable income and an elimination of net operating loss carrybacks (though any net operating losses generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely), and the modification or repeal of many business deductions and credits. As part of Congress' response to the COVID- 19 pandemic, **economic relief legislation** ~~the Families First Coronavirus Response Act, or the FFCR Act,~~ was enacted **in** ~~on March 18,~~ 2020 ~~, the CARES Act was enacted on March 27, 2020,~~ and ~~COVID- 19 relief provisions were included in the Consolidated Appropriations Act,~~ 2021 ~~or CAA, which was enacted on December 27, 2020. All contain~~ **containing** ~~numerous~~ tax provisions. ~~In particular~~ **The IRA was also signed into law in August 2022. The IRA introduced new tax provisions** , **including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by** the ~~CARES Act, among~~ **publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or** other **property (** ~~things, suspends the~~ **other than stock** ~~80 % limitation on the deduction for net operating losses in taxable years beginning before January 1, 2021, permits a 5- year carryback~~ of ~~net operating losses arising in taxable years beginning after December 31, 2017 and before January 1, 2021, and generally caps~~ the **company itself)** ~~limitation on the deduction for net interest expense at 50 % of adjusted taxable income for taxable years beginning in 2019 and 2020. As a result of the changes in the U. S. presidential administration and control of the U. S. Senate~~ , ~~additional~~ **subject to a de minimis exception. Thus, the excise** tax **could apply** ~~legislation may also be enacted. For example, President Biden has proposed~~ to **certain transactions that are not traditional stock repurchases** ~~increase the U. S. corporate income tax rate from its current 21 %, implement a minimum tax on book income and increase taxation of international business operations, among numerous other corporate tax reform proposals~~ . In addition, certain tax laws that are specific to the biopharmaceutical industry, such as the orphan drug tax credit, which was enacted as part of the Orphan Drug Act, have been limited over time and continuing limitations or restrictions of the tax credit and changes to other tax laws applicable to our business could negatively impact our business and results of operations **. Additional tax legislation may also be enacted, and regulatory guidance under the TCJA continues to be forthcoming** . It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in 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 or in the interpretation thereof. Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations. In general, under Sections 382 and 383 of the Code, a corporation that undergoes an " ownership change " is subject to limitations on its ability to utilize its pre- change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5 % of a corporation' s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Under Section 382, the annual limitation is determined by first multiplying the value of the corporation' s stock at the time of the ownership change by the applicable long- term tax- exempt rate, and then could be subject to additional adjustments, as required. As a result of, among other transactions, the shares issued in January 2021 related to the acquisition of Quellis and the February 2021 Financing, we

believe we have experienced several historical ownership changes, as defined by Section 382. As a result, our utilization of the federal and state net operating loss carryforwards or research and development tax credit carryforwards are subject to annual limitation under Sections 382 and 383. Our analysis of Section 382 indicates that a significant portion of our Federal and state net operating loss carryforwards and research and development tax credit carryforwards are limited, such that a significant portion of them are anticipated to not be available or expire before utilization. ~~76Risks~~ -- **Risks** Related to Employee Matters, Managing Growth and Information TechnologyOur future success depends on our ability to retain our senior management and key employees. We are highly dependent on our executive officers and key employees. If we are unable to retain our executive officers or other key employees, replacing them may be difficult and costly, and may take an extended period of time because of the nature of our current business strategy and the limited number of individuals in our industry with the relevant breadth of skills and experience. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate replacements for our executive officers or key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We rely on consultants and advisors, including financial, legal, scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us. **86We may experience difficulty in locating, attracting and retaining experienced and qualified personnel, which could adversely affect our business. We will need to attract, retain and motivate experienced clinical development and other personnel, particularly in the greater Boston area, as we expand our clinical development activities and prepare for potential commercialization of our product candidates. Personnel with the required skills and experience may be scarce or may not be available at all in this geographic region. In addition, competition for these skilled personnel is intense and recruiting and retaining skilled employees is difficult, particularly for a development- stage company such as ours. If we are unable to attract and retain qualified personnel, our clinical development activities and preparation for potential commercialization of our product candidates may be adversely affected. Even if we are successful in identifying and attracting qualified employees, recent market changes, including labor shortages, and rising inflation have increased employee- related costs substantially, which may negatively affect our operating results.** Security breaches and other disruptions to our information technology systems could compromise our information, disrupt our business and expose us to liability, which would cause our business and reputation to suffer. In the ordinary course of our business, we collect, process and store sensitive data, including intellectual property, as well as our proprietary business information, employee data and personally identifiable information of clinical trial participants in accordance with informed consents covering such information **as well as personal information of other individuals** . We also rely to a large extent on computer and information technology systems to operate our business **. Remote working arrangements could impact employees' productivity and morale, strain our technology resources and introduce operational risks. Additionally, the risk of cyber- attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks** . We have outsourced elements of our confidential information processing and information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. The secure maintenance of this information is important to our operations and business strategy. Despite our security measures, our information technology infrastructure, and that of our vendors and third- party providers, may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our vendors and third- party providers could be susceptible to third party attacks on our and their information security systems, which attacks are of ever- increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, hacktivists, nation states and others. **The risk of a security breach or disruption through cyber- attacks has generally increased as the number, intensity and sophistication of attempted attacks from around the world have increased.** If a ransomware attack or other cybersecurity incident occurs, either internally or at our vendors or third- party technology service providers, we could be prevented from accessing our data or systems, which may cause interruptions or delays in our business operations, cause us to incur remediation costs, subject us to demands to pay a ransom, or damage our reputation, regardless of whether we pay the ransom amount. Additionally, the risk of cyber- attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks. While we continue to build and improve our information technology security systems and infrastructure, there can be no assurance that our efforts will prevent service interruptions, breakdowns or security breaches. For example, we have detected common types of attempts to attack our information technology systems and data using means that have included phishing. Any service interruptions or security breaches of our information technology systems may substantially impair our ability to operate our business and could compromise our networks, or those of our vendors and third- party providers, and the information stored could be accessed, publicly disclosed, lost or stolen. We may be required to expend significant resources (including financial), fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to detect (including performing required forensics), mitigate and remediate actual and potential vulnerabilities. Relevant laws, regulations, industry standards and contractual obligations may require us to implement specific security measures or use industry- standard or reasonable measures to protect against security breaches. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs, security breaches and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, data loss or corruption, delays, cessation of service and other harm to our business and our competitive position. If the information technology systems of our third- party vendors become subject to disruptions or

security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. ~~77Any~~ **87Any** such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business. Although we maintain cyber liability insurance **,** ~~of $ 1. 0 million in the aggregate~~ it may not be sufficient in type or amount to cover us against claims related to security breaches, cyber- attacks and other related breaches **. Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information and personal data. Issues in the use of artificial intelligence, combined with an uncertain regulatory environment, may result in reputational harm, liability or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If any of our vendors experiences an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business** . Risks Related to Our Common StockOur principal stockholders own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval. Our holders of 5 % or more of our capital stock and their respective affiliates beneficially own in excess of **40** ~~20. 0~~ % of our outstanding common stock. These stockholders, acting together or on their own, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that investors may feel are in their best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with each investor' s interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock. The price of our common stock has been and is likely to continue to be highly volatile, which could result in substantial losses for our stockholders. Our stock price has been and is likely to continue to be highly volatile. For example, when we announced our acquisition of Quellis, our stock price increased by approximately 70 % in one day. In the twelve months ending February ~~28~~ **29** , ~~2023~~ **2024** , the last business day in February, our stock price has traded at a high of $ 15. ~~79~~ **66** and a low of $ ~~2~~ **4** . ~~46~~ **26** . The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our investors may lose some or all of their investments. The market price for our common stock may be influenced by many factors, including: ● the timing and results of clinical trials of STAR- 0215 **, STAR- 0310** or any future product candidate; ● commencement or termination of collaborations for any development programs we may pursue; ● failure or discontinuation of any of any development programs we may pursue; ● the success of existing or new competitive products or technologies; ● results of clinical trials of product candidates of competitors; **88** ● regulatory or legal developments in the United States and other countries; ● developments or disputes concerning patent applications, issued patents or other proprietary rights; ● the recruitment or departure of key personnel; ● the level of expenses related to a product candidate or clinical development program; ● the results of any additional efforts to develop additional product candidates or products; ● actual or anticipated changes in estimates as to financial results or recommendations by securities analysts that cover our stock; ~~78~~ ● announcement or expectation of additional financing efforts; ● announcement of collaborations, licenses, acquisitions or other comparable forms of transactions; ● sales of our common stock by us, our insiders or other stockholders; ● variations in our financial results or those of companies that are perceived to be similar to us; ● changes in the structure of healthcare payment systems; ● market conditions in the pharmaceutical and biotechnology sectors; ● general economic, industry and market conditions, including political instability, war or instability from ~~an outbreak of~~ **public health crises,** ~~pandemic~~ **pandemics** or **epidemics** ~~contagious disease, such as the ongoing COVID- 19 pandemic~~ ; and ● the other factors described in this " Risk Factors " section. Additionally, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management' s attention and resources, which could harm our business. We have incurred and will continue to incur ~~increased~~ **significant** costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company we have incurred and will continue to incur significant legal, accounting and other expenses ~~that we did not incur as a private company~~ . The Sarbanes- Oxley Act of 2002, or SOX, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. ~~We expect that our~~ **In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including those related to climate change and other environmental, social and governance focused disclosures, are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time consuming. Our** management and other

personnel ~~will continue to~~ devote a substantial amount of time towards maintaining compliance with ~~these~~ -- **the corporate governance** ~~requirements. These requirements increase our legal~~ and ~~financial compliance costs~~ **public disclosure rules** and **regulations that are applicable to us** ~~make some activities more time- consuming~~ and ~~costly~~ **will continue to do so** . These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. **In addition, if we cease to be a smaller reporting company, we will need to comply with significant additional disclosure and other obligations.** ~~Pursuant~~ **89Pursuant** to Section 404 of SOX, we are required to furnish reports by our management on our internal control over financial reporting with our Annual Reports on Form 10- K with the SEC. If we cease to be a smaller reporting company with less than $ 100 million in annual revenue, we will also be required to include attestation reports on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404 of SOX. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. ~~79A~~ **A** significant portion of our total outstanding shares may be sold into the market in the near future, which could cause the market price of our common stock to decline significantly, even if our business is doing well. Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of February ~~28~~ **29** , ~~2023~~ **2024** , we had outstanding ~~27~~ **54** , ~~970~~ **903** , ~~516~~ **061** shares of common stock and 31, 107 shares of Series X Preferred Stock, which are convertible into 5, 184, 591 shares of common stock. **We** ~~Pursuant to our obligations under a registration rights agreement entered into in connection with the acquisition of Quellis and the February 2021 Financing, we~~ have registered under the Securities Act of 1933, as amended, or the Securities Act, 15, 399, 967 shares of our common stock issued to the former Quellis stockholders or issued or issuable upon conversion of the Series X Preferred Stock. As a result, such shares are freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any significant sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. ~~As~~ **The number** of **shares of common stock underlying our** ~~February 28, 2023, we also had~~ outstanding warrants **is significant in relation** to **our currently outstanding** ~~purchase 1, 031, 820 shares of~~ common stock ~~at~~ **, which could have** a ~~weighted average~~ **negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock and this could adversely impact the consideration our other stockholders would receive. As part of our registered offering of common stock in October 2023, we issued common stock warrants to purchase an aggregate of 7, 368, 738 shares of our common stock, and pre- funded warrants to purchase up to an aggregate of 1, 571, 093 shares of our common stock. Each pre- funded warrant has an** exercise price ~~of $ 60. 90~~ per share **of common stock equal to $ 0. 001 per share. Each pre- funded warrant is exercisable from the date of issuance until exercised in full solely by means of a cashless exercise. Each common stock warrant has an exercise price per share of common stock equal to $ 8. 025. Each common stock warrant is exercisable from the date of issuance until October 16** , **2028. Each common stock warrant is exercisable solely by means of a cash exercise, except that the common stock warrant is exercisable via cashless exercise if at the time of exercise, a registration statement registering the issuance of the shares of common stock underlying the common stock warrants under the Securities Act is not then effective. The common stock warrants include certain rights upon " fundamental transactions " as described in the common stock warrants, including the right of the holders thereof to receive from us or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction in the amount of the Black Scholes value (as described in such common stock warrants) of the unexercised portion of the applicable common stock warrants on the date of the consummation of such fundamental transaction. A holder of common stock warrants (together** with ~~expiration dates~~ **its affiliates) may not exercise any portion of a common stock warrant to the extent that the holder would beneficially own more than 4. 99 % (or, at the election of the holder, 9. 99 %) of our outstanding common stock immediately after exercise. 90Although these warrants issued in October 2023 are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, entrench our management and our board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future** between **us** ~~June 21~~ , ~~2023~~ **on the one** ~~and~~ **hand** ~~December 14~~ , ~~2030~~ **and the holders of these warrants, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline significantly** . We have

registered the issuance of shares upon exercise of these warrants under registration statements. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public ~~marked~~ **market** upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur. **Given the amount and terms of these warrants, we may find it more difficult to raise** ~~Additionally -- we have an ongoing sales agreement with Jefferies LLC, pursuant to which we could issue and sell shares of common stock under an at-~~ **additional equity capital on favorable terms or** ~~market offering program~~ **all while the these warrants are outstanding**. We do not anticipate paying any cash dividends on our capital stock in the foreseeable future, accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment. We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. Any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline. The trading market for our common stock will likely depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline. Risks Relating to our Certificate of Incorporation and BylawsProvisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our investors might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: ● establish a classified board of directors such that all members of the board are not elected at one time; ~~80~~ ● allow the authorized number of our directors to be changed only by resolution of our board of directors; ● limit the manner in which stockholders can remove directors from the board; **91** ● establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings; ● require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; ● limit who may call a special meeting of stockholder meetings; ● authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a " poison pill " that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and ● require the approval of the holders of at least 75 % of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws. In addition, as of February ~~28~~ **29**, ~~2023~~ **2024**, there are 31, 107 shares of our Series X Preferred Stock outstanding that we issued in connection with the acquisition of Quellis and the February 2021 Financing. Except as otherwise required by law, the Series X Preferred Stock does not have voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series X Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock or alter or amend the Certificate of Designation that authorized the Series X Preferred Stock, amend or repeal any provision of, or add any provision to, our Certificate of Incorporation or bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X Preferred Stock, (ii) issue further shares of Series X Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series X Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders. ~~81~~ **92**