Risk Factors Comparison 2024-03-26 to 2023-03-23 Form: 10-K

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Investing in our securities involves a high degree of risk. You should carefully consider the following risks and other information **included or incorporated by reference** in this Annual Report in evaluating us and our ~~Common~~ **common** ~~Stock~~ **stock** . Any of the following risks could materially and adversely affect our results of operations, our financial condition, and the market price of our Common Stock. Although the risk factors are grouped by general category, many of the risks described in a given category relate to multiple categories. The risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition. See " Cautionary Statement Regarding Forward- Looking Statements " in this Annual Report. If any of these risks actually materialize, our business, prospects, financial condition and results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Risk Factor Summary We are providing the following summary of the risk factors contained in this Annual Report to enhance the readability and accessibility of our risk factor disclosures. We encourage you to carefully review the full risk factors contained in this Annual Report in their entirety for additional information regarding the material factors that make an investment in our securities speculative or risky. These risks and uncertainties include, but are not limited to, the following: ~~we~~ **there is substantial doubt about our ability to continue as a going concern. We** have a history of operating losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability; we have a limited operating history, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance; if preclinical studies or clinical trials for our product candidates cannot be initiated or completed or if they are delayed or unsuccessful, we will be unable to meet our future development and commercialization goals; the disorders we seek to treat have low prevalence and it may be difficult to identify patients with these disorders, which may lead to delays in enrollment for our trials or slower commercial revenue if approved, and we may also face enrollment challenges as a result of other factors; our product candidates are novel and still in development. If we are unable to successfully develop, receive regulatory approval for and commercialize our current or future product candidates, our business will be harmed; we have ~~not tested any~~ **started testing one** of our product candidates in clinical trials. Success in early preclinical studies or clinical trials may not be indicative of results obtained in later preclinical studies and clinical trials; clinical trials required for our product candidates are expensive and time- consuming, and their ~~outcome~~ **outcomes** ~~is~~ **are** uncertain; we will need to raise additional capital, which may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates, and additional capital may not be available on favorable terms or at all, which may force us to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations; we are subject to extensive and costly government regulation; even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market; we rely on a license to use the technology that is material to our business and if the agreement underlying the license were to be terminated or if other rights that may be necessary for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition; we are subject to stringent and evolving U. S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions, litigation, **(including class actions) and mass arbitration demands,** fines and penalties, disruptions of our business operations, reputational harm, loss of revenue or profits and other adverse business consequences; and global and macroeconomic conditions, including worldwide economic, political and social instability could adversely affect our revenue, financial condition, or results of operations. Risks Related to Our ~~Business~~We ~~-~~**BusinessThere is substantial doubt about our ability to continue as a going concern. We** have a history of operating losses and expect to incur losses for the foreseeable future. We may never generate revenues or, if we are able to generate revenues, achieve profitability. We are focused on product development, and we have not generated any significant revenues to date. We have incurred losses in each year of our operations, and we expect to continue to incur operating losses for the foreseeable future. ~~These~~ **Since our inception we have incurred in** operating losses **which** have adversely affected and are likely to continue to adversely affect our working capital, total assets and shareholders' equity **. In addition, the impact of these events and conditions on our liquidity raise substantial doubt about our ability to continue as a going concern. We plan to raise additional capital primarily through public and / or private equity financings and / or convertible debt financings. However, financing may not be available to us in the necessary time frame, in amounts that we require, on terms that are acceptable to us, or at all. If we are unable to raise the necessary funds when needed, it may materially and adversely impact our ability to execute on our operating plans. If we become unable to continue as a going concern, we may have to dispose of assets and might realize significantly less than the values at which they are carried on our consolidated financial statements. These actions may cause our stockholders to lose all or part of their investment in our common stock** . We and our prospects should be examined in light of the risks and difficulties frequently encountered by new and early- stage companies in new and rapidly evolving markets. These risks include, among other things, the speed at which we can scale up operations, our complete dependence upon development of our product candidates that currently have no market acceptance, our ability to establish and expand our brand name ~~, our ability to expand our operations to meet the commercial demand of our clients~~ , our development of

and reliance on strategic and customer relationships and our ability to minimize fraud and other security risks. The process of developing our product candidates requires significant time, effort and expenses in preclinical, clinical and regulatory development. In addition, commercialization of our product candidates will require that we obtain necessary regulatory approvals and establish sales, marketing and manufacturing capabilities, either through internal hiring or through contractual relationships with others. We expect to incur substantial additional operating expenses over the next several years as our research, development, preclinical studies and clinical trial activities increase. Product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later- stage clinical trials. As a result, we expect that our research and development expenses will continue to increase in the foreseeable future as we (i) increase personnel costs, including stock- based compensation, (ii) continue preclinical development of our lead compounds, (iii) initiate clinical trials for certain product candidates, (iv) continue to discover and develop additional product candidates, and (v) pursue later stages of clinical development of product candidates. The amount of future losses and when, if ever, we will achieve profitability are uncertain. We have no products that have generated any commercial revenue, do not expect to generate revenues from the commercial sale of products in the foreseeable future, and might never generate revenues from the sale of products. Our ability to generate revenue and achieve profitability will depend on, among other things, successful completion of preclinical development and testing and clinical trials of our product candidates; obtaining necessary regulatory approvals from the FDA **and comparable foreign regulatory authorities** ; establishing manufacturing, sales and marketing arrangements with third parties; successfully commercializing our products; establishing a favorable competitive position; and raising sufficient funds to finance our activities. Many of these factors will depend on circumstances beyond our ~~control~~ **34control** . We might not succeed at any of these undertakings. If we are unsuccessful at some or all of these undertakings, our business, prospects and results of operations may be materially adversely affected. ~~35We~~ **We** have a limited operating history and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance. We are ~~a~~ **an early** ~~preclinical~~ **clinical** stage biopharmaceutical company with a limited operating history. Our operations to date have been primarily limited to organizing and staffing our company, expanding its operations, performing research, acquiring, developing and securing our in- licensed technology and preclinical development of our product candidates. We have **commenced our first Phase 1 clinical trial but** not yet ~~begun or~~ successfully completed any clinical trials, ~~completed Investigational New Drug (" IND ") enabling or Good Laboratory Practice (" GLP ") compliant studies for any of our product candidates,~~ manufactured our products candidates at ~~clinical or~~ commercial scale or conducted sales and marketing activities that will be necessary to successfully commercialize our product candidates **., if approved** . Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history or commercialized products. Our financial condition has varied significantly in the past and will continue to fluctuate from quarter- to- quarter or year- to- year due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include, among other factors described elsewhere in this Annual Report: ● our ability to obtain additional funding to develop our product candidates, the extent to which we are able to obtain such funding on favorable terms, and changes to our operations or strategy that may be necessitated due to the need for additional funding; ● our ability to conduct and complete preclinical studies, including GLP- compliant and IND- enabling preclinical studies; ● delays in the commencement, enrollment and timing of clinical trials; ● the success of our preclinical studies and clinical trials through all phases of development; ● any delays in regulatory review and approval of product candidates in clinical development; ● our ability to obtain and maintain regulatory approval for our product candidates in the United States and foreign jurisdictions; ● our ability to successfully commercialize product candidates for which we obtain regulatory approval, within expected timelines or at all; ● potential toxicity and / or side effects of our product candidates that could delay or prevent commercialization, limit the indications for any approved drug, require the establishment of risk evaluation and mitigation strategies (" REMS "), or **comparable foreign strategies, or** cause an approved drug to be taken off the market; ● our ability to establish or maintain collaborations, licensing or other arrangements; ● market acceptance of our product candidates; ● competition from existing products, new products or new therapeutic approaches that may emerge; ● the ability of patients or healthcare providers to obtain coverage of or sufficient reimbursement for our products; ● our ability to leverage our in- licensed technology platform to discover and develop additional product candidates; ● our ability and our licensors' abilities to successfully obtain, maintain, defend and enforce intellectual property rights important to our business; **35** ● the impact of political instability, natural disasters, events of terrorism and wars, including Russia' s invasion of Ukraine **and the conflict between Hamas and Israel** ; ~~36~~ ● the impact of other global and macroeconomic conditions, including ~~rising~~ **heightened** inflation and **high** interest rates **, liquidity concerns at and failures of banks and other financial institutions** , supply chain disruptions, fluctuating exchange rates, and increases in commodity, energy and fuel prices; and ● potential product liability claims. Accordingly, the results of any quarterly or annual periods should not be relied upon as indications of future operating performance. Risks Related to Product Development, Regulatory Approval, Manufacturing and CommercializationWe may conduct certain of our clinical trials for our product candidates outside of the U. S. which, among other risks, exposes us to the possibility that the FDA and other **comparable** foreign ~~equivalents~~ **regulatory authorities** may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business. We **are currently conducting** ~~expect to complete the preclinical development and submit the regulatory dossier to the Human Research Ethics Committee in Australia to initiate~~ a first- in- human Phase 1 clinical trial in our Parkinson' s disease program **in Australia** . Although the FDA may accept data from clinical trials conducted outside the **United States** ~~U. S.~~ , acceptance of this data is subject to certain conditions imposed by the FDA. Where data from foreign clinical trials are intended to serve as the basis for marketing approval in the **United States** ~~U. S.~~ , the FDA will not approve the application on the basis of foreign data alone unless those data are applicable to the U. S. population and U. S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on- site

inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. For studies that are conducted only at sites outside of the **United States** ~~U. S.~~ and not subject to an IND, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an on- site inspection if it deems such inspection necessary. For such studies not subject to an IND, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non- U. S. clinical trial was inadequate, which could require us to conduct additional clinical trials. There can be no assurance the FDA will accept data from clinical trials conducted outside of the **United States** ~~U. S~~. If the FDA does not accept data from our clinical trials of our product candidates conducted outside of the **United States** ~~U. S.~~, it would likely result in the need for additional clinical trials, which would be costly and time consuming and delay or permanently halt our development of our product candidates. Conducting clinical trials outside the **United States** ~~U. S.~~ also exposes us to additional risks, including risks associated with: ● additional foreign regulatory requirements; ● foreign exchange fluctuations; ● compliance with foreign manufacturing, customs, shipment and storage requirements; ● cultural differences in medical practice and clinical research; and ● diminished protection of intellectual property in some countries. By extension, clinical trials that are predominantly conducted in the United States or primarily based on feedback from the FDA may not result in sufficiently diverse patient populations to warrant approval in other countries (for example, Japan) or those other ~~health~~ **comparable foreign regulatory** authorities may have differences of opinion on appropriateness of trial design or differences in interpretation of some data. In those situations, approvals in other countries outside the United States may be delayed or never approved, which would materially detract from the commercial success of any impacted product candidates. ~~If~~ **36If** preclinical studies or clinical trials for our product candidates cannot be initiated or completed or if they are delayed or unsuccessful, we will be unable to meet our future development and commercialization goals. We rely and expect to continue to rely on third parties, including contract research organizations (“ CROs ”) and outside consultants, to conduct, supervise or monitor some or all aspects of preclinical studies and clinical trials ~~37involving~~ -- **involving** our product candidates. We have less control over the timing and other aspects of these preclinical studies and clinical trials than if we performed the monitoring and supervision entirely on our own. Third parties may not perform their responsibilities for our preclinical studies and clinical trials on our anticipated schedule or, for clinical trials, consistent with a clinical trial protocol. Delays in preclinical studies and clinical trials could significantly increase our product development costs and delay product commercialization. In addition, many of the factors that may cause, or lead to, a delay in the clinical trials may also ultimately lead to denial of regulatory approval of a product candidate. The commencement of clinical trials can be delayed for a variety of reasons, including delays in: ● demonstrating sufficient safety and efficacy to obtain regulatory approval to commence a clinical trial; ● reaching agreement on acceptable terms with prospective CROs and study sites; ● developing a stable formulation of a product candidate; ● manufacturing sufficient quantities of a product candidate; and ● obtaining institutional review board (“ IRB ”) approval **or ethic committee opinions** to conduct a clinical trial at a prospective site. Once a clinical trial has begun, it may be delayed, suspended or terminated by us or the FDA or other **comparable foreign** regulatory authorities due to a number of factors, including: ● ongoing discussions with the FDA or other **comparable foreign** regulatory authorities regarding the scope or design of our clinical trials; ● failure to conduct clinical trials in accordance with regulatory requirements; ● lower than anticipated recruitment or retention rate of patients in clinical trials; ● inspection of the clinical trial operations or study sites by the FDA or other **comparable foreign** regulatory authorities resulting in the imposition of a clinical hold; ● lack of adequate funding to continue clinical trials; ● negative results of clinical trials; ● investigational drug product out- of- specification; or ● nonclinical or clinical safety observations, including adverse events and SAEs. If clinical trials are unsuccessful, and we are not able to obtain regulatory approvals for our product candidates under development, we will not be able to commercialize these products, and therefore may not be able to generate sufficient revenues to support our business. The disorders we seek to treat have low prevalence and it may be difficult to identify patients with these disorders, which may lead to delays in enrollment for our trials or slower commercial revenue if approved, and we may also face enrollment challenges as a result of other factors. Genetically defined disorders generally, and especially those for which our current product candidates are targeted, have low incidence and prevalence. We expect to rely in part on relationships with clinical centers of ~~excellence~~ **37excellence** , key opinion leaders and patient advocacy groups to assist in identifying eligible patients, and any deterioration of those relationships could impede our ability to successfully enroll patients. Patient enrollment may be affected by other factors including: ● the severity of the disease under investigation; ~~38~~ ● design of the study protocol; ● the eligibility criteria for the trial; ● the perceived risks, benefits and convenience of administration of the product candidate being studied; ● our efforts to facilitate timely enrollment in clinical trials; ● the availability of other clinical trials being conducted for the same indication; ● the patient referral practices of physicians; and ● the proximity and availability of clinical trial sites to prospective patients. Our inability to enroll a sufficient number of patients with these diseases for our future clinical trials would result in significant delays and could require us to not initiate or to abandon clinical trials for one or more indications altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, which would cause the value of our company to decline and limit our ability to obtain additional financing. Additionally, the reported number of people in the ~~indication~~ **indications** we aim to treat, as well as the people with these diseases who have the potential to benefit from treatment with our product candidates, are based on estimates. The total addressable market opportunity for our product candidates will ultimately depend upon, among other things, the final approved product labeling for each of our product candidates, if our product candidates are approved for sale in our target indications, acceptance by the medical community and patient access, drug pricing and reimbursement. The number of patients globally may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business. Our product candidates are novel and still in development. If we are unable to successfully develop, receive regulatory

approval for and commercialize our current or future product candidates, our business will be harmed. Because the **Magellan ™** ~~SEE- Tx ®~~ platform remains untested and our product candidates are in early stages of development, they will require extensive preclinical and clinical testing. Our product candidates will require significant additional development, preclinical and IND-enabling studies and clinical trials, regulatory clearances and additional investment by us or our collaborators before they can be commercialized. Our drug development methods may not lead to commercially viable drugs for any of several reasons. For example, we may fail to identify appropriate targets or compounds, our product candidates may fail to be safe and effective in clinical trials, or we may have inadequate financial or other resources to pursue development efforts for our product candidates. Also, third parties we rely on for preclinical development, such as the providers of supercomputer time needed for our **Magellan ™** ~~SEE- Tx ®~~ platform and collaborators that provide us with materials and resources may fail to fulfill their obligations to us in a timely manner or at all and the development of our product candidates could be significantly delayed as a result. In addition, we are still developing proof of concept for our product candidates in animals and positive data from animal models may not be predictive of positive human results and patients may have side effects that were not observed in animals. Further, we and our product candidates are subject to extensive regulation by the FDA and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, selling, adverse event reporting and recordkeeping. Obtaining FDA **and comparable foreign regulatory authority** approval is a lengthy, expensive and uncertain process. If required regulatory registrations or approvals are delayed, denied, withdrawn **, suspended or varied** or if the regulatory authorities question the efficacy of our new small molecules as a treatment, such events are likely to have a material adverse effect on our business, results of operations, cash flows, financial condition and / or prospects. ~~We have not tested any of our product candidates in clinical trials. Success~~ **38Success** in early preclinical studies or clinical trials may not be indicative of results obtained in later preclinical studies and clinical trials. We ~~have not tested any of our product candidates in clinical trials. Success in early preclinical studies or any clinical trials we may conduct not be indicative of results obtained in later preclinical studies and clinical trials. 39We~~ will be required to demonstrate through adequate and well- controlled clinical trials that our product candidates are safe and effective, with a favorable benefit- risk profile, for use in their target indications before we can seek regulatory approvals for their commercial sale. Trial designs and results from early- phase trials are not necessarily predictive of future clinical trial designs or results, and initial positive results we may observe may not be confirmed in later- phase clinical trials. Our product candidates may also fail to show the desired safety and efficacy in later stages of clinical development even if they successfully advance through initial clinical trials. We may not be able to demonstrate the safety and efficacy of our STAR molecules in our clinical trials. Even if our clinical trials demonstrate acceptable safety and efficacy of STAR molecules for a targeted disease, the labeling we obtain through negotiations with the FDA or **comparable** foreign regulatory authorities may not include data on secondary endpoints and may not provide us with a competitive advantage over other products approved for the same or similar indications. Many companies in the biotechnology industry have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development and there is a high failure rate for product candidates proceeding through clinical trials. We may face similar setbacks or failures. Different methodologies, assumptions and applications we utilize to assess particular safety or efficacy parameters may yield different statistical results. Even if we believe the data collected from clinical trials of our product candidates are promising, these data may not be sufficient to support approval by the FDA or **comparable** foreign regulatory authorities. Preclinical and clinical data can be interpreted in different ways. Accordingly, the FDA or **comparable** foreign regulatory authorities could interpret these data in different ways from us or our partners, which could delay, limit or prevent regulatory approval. If our study data do not consistently or sufficiently demonstrate the safety or efficacy of any of our product candidates, then the regulatory approvals for such product candidates could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be withheld **, varied** or withdrawn. Regulatory delays or rejections may also be encountered as a result of many other factors, including changes in regulatory policy during the period of product development. The approach we are taking to discover and develop our product candidates is novel and may never lead to marketable products. We have concentrated our efforts and research and development activities on our novel small molecules for potential treatment of rare and genetic diseases caused by protein misfolding and **Magellan ™** ~~SEE- Tx ®~~, our target identification platform. Our future success depends on the successful development of such product candidates, including our ability to successfully complete IND- enabling and GLP- compliant preclinical studies, and the effectiveness of our platform. The scientific discoveries that form the basis for our efforts to discover and develop new drugs are relatively new. The scientific evidence to support the feasibility of developing drugs based on these discoveries is both preliminary and limited. Skepticism as to the feasibility of developing small molecules of this type that can cross the blood- brain barrier generally has been, and may continue to be, expressed in scientific literature. In addition, decisions by other companies with respect to their therapeutic development efforts may increase skepticism in the marketplace regarding the potential for potential therapeutics. There are currently no companies with approved drugs for these indications that have the ability to cross the blood- brain barrier. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and human resources, we are currently focusing primarily on development of our Parkinson' s and Gaucher disease programs. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable products. 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 such product candidate. ~~40Clinical~~ **39Clinical**

trials required for our product candidates are expensive and time- consuming, and their outcome is uncertain. To obtain FDA **or comparable foreign regulatory authority** approval to market a new pharmaceutical product, we must demonstrate proof of safety and effectiveness in humans. To meet these requirements, we must conduct " adequate and well controlled " clinical trials. Conducting clinical trials is a lengthy, time- consuming, and expensive process. The length of time may vary substantially according to the type, complexity, novelty, and intended use of the product candidate, and often can be several years or more per study. Delays in clinical trials for our product candidates may cause us to incur additional operating expenses. The commencement and rate of completion of clinical trials may be delayed by many factors, including, for example: inability to manufacture sufficient quantities of stable and qualified materials under current good manufacturing practices (" cGMPs ") for use in clinical trials; slower than expected rates of patient recruitment; failure to recruit a sufficient number of patients, which is a common issue in studies for rare disorders such as the indications we are currently pursuing; modification of clinical trial protocols; changes in regulatory requirements for clinical trials; the lack of effectiveness during clinical trials; the emergence of unforeseen safety issues; delays, suspension, or termination of the clinical trials due to the investigatory authority responsible for overseeing the trial at a particular trial site; and government or regulatory delays or " clinical holds " requiring suspension or termination of the studies. Our clinical trials may be conducted in patients with neurodegenerative diseases, and in some cases, our product candidates are expected to be used in combination with approved therapies that themselves have significant adverse event profiles. During the course of treatment, these patients could suffer adverse medical events or die for reasons that may or may not be related to our product candidates. Any safety issues that arise with respect to our product candidates may delay or prevent clinical development. The failure of clinical trials to demonstrate safety and effectiveness for the desired indications could harm the development of that product candidate and other product candidates that use a similar therapeutic approach. This failure could cause us to abandon a product candidate and could delay development of other product candidates. Any delay in, or termination of, our clinical trials would delay our ability to obtain regulatory approvals for and commercialize our product candidates and generate product revenues. Any change in, or termination of, our clinical trials could materially harm our business, financial condition and results of operations. We have limited experience as a company conducting clinical trials and may be unable to complete pivotal clinical trials for any product candidates we may develop. **Our** ~~We are not yet a clinical stage company and our~~ success is dependent upon our ability to initiate and successfully complete clinical trials and obtain regulatory approval for and commercialization of our product candidates. We have not demonstrated an ability to perform the functions necessary for the approval or successful commercialization of any product candidate. The successful commercialization of any product candidate may require us to perform a variety of functions, including: ● continuing to undertake preclinical development; ● obtaining approval to commence clinical trials; ● successfully planning and enrolling subjects in clinical trials; ● participating in regulatory approval processes; ● formulating and manufacturing products; and ● conducting sales and marketing activities. We have limited experience designing, conducting and enrolling subjects in clinical trials. ~~While certain members of our management and staff have significant experience in conducting clinical trials, to date, we have not successfully begun or completed any clinical trials as a company.~~ Until recently, our operations have been limited primarily to organizing and staffing our company, expanding its operations, performing research, acquiring, developing and securing our in- licensed technology and preclinical development of our product candidates. These operations provide a limited basis to assess our ability to develop and commercialize our product candidates. ~~41Because~~ **40Because** of this lack of experience, any ~~future~~ clinical trials we may conduct may not be completed on time, if at all. Large- scale trials require significant additional financial and management resources, monitoring and oversight, and reliance on third- party clinical investigators, consultants or contract research organizations (" CROs "). Relying on third- party clinical investigators, CROs and manufacturers, which are all also subject to governmental oversight and regulations, may also cause us to encounter delays that are outside of our control. In addition, we ~~are still in the drug discovery and preclinical development stage for our product candidates and have not yet begun discussions with the FDA as to the design, structure and number of clinical trials that our product candidates would require for approval. Consequently, we~~ may be unable to successfully and efficiently advance any candidates we select for clinical trials or execute and complete necessary GLP- compliant preclinical and IND- enabling studies in a way that leads to IND submission **, successful development** and **ultimately commercial** approval of any product candidate. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of any product candidates that we develop. Failure to commence or complete, or delays in, future planned clinical trials, could prevent us from or delay us in commercializing our product candidates. We are subject to extensive and costly government regulation. Product candidates employing our technology are subject to extensive and rigorous domestic government regulation including regulation by the FDA, the Centers for Medicare and Medicaid Services, other divisions of the United States Department of Health and Human Services, the United States Department of Justice, state and local governments and their respective foreign equivalents. The FDA **and comparable foreign regulatory authorities** ~~regulates~~ - **regulate** the research, development, preclinical studies and clinical trials, manufacture, safety, effectiveness, record- keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import and export of biopharmaceutical products. If products employing our technologies are marketed abroad, they will also be subject to extensive regulation by foreign governments, whether or not they have obtained the FDA' s **or comparable foreign regulatory authorities'** approval for a given product and its uses. Such foreign regulation may be equally or more demanding than corresponding United States regulation. Government regulation substantially increases the cost and risk of researching, developing, manufacturing and selling our products. The regulatory review and approval process, which includes preclinical studies and clinical trials of each product candidate, is lengthy, expensive, and uncertain. We or our collaborators must obtain and maintain regulatory authorization to conduct clinical trials. We or our collaborators must obtain regulatory approval for each product we intend to market, and the manufacturing facilities used for the products must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive preclinical and clinical data and other supporting information for each proposed therapeutic indication

in order to establish the product' s safety and efficacy, and in the case of biologics also potency and purity, for each intended use. The development and approval process takes many years, requires substantial resources, and may never lead to the approval of a product. Even if we are able to obtain regulatory approval for a particular product, the approval may limit the indicated medical uses for the product, may otherwise limit our ability to promote, sell, and distribute the product, may require that we conduct costly post- marketing surveillance, and / or may require that we conduct ongoing post- marketing studies. Material changes to an approved product, such as, for example, manufacturing changes or revised labeling, may require further regulatory review and approval. Once obtained, any approvals may be withdrawn **, suspended or varied** , including, for example, if there is a later discovery of previously unknown problems with the product, such as a previously unknown safety issue. If we, our collaborators, or our manufacturers fail to comply with applicable regulatory requirements at any stage during the regulatory process, such noncompliance could result in, among other things delays in the approval of applications or supplements to approved applications; refusal of a regulatory authority, including the FDA, to review pending market approval applications or supplements to approved applications; warning letters; fines; import and / or export restrictions; product recalls or seizures; injunctions; total or partial suspension of production **, distribution, manufacturing or clinical trials** ; civil penalties; withdrawals **, suspension or variation** of previously approved marketing applications or licenses; recommendations by the FDA or **comparable foreign** other regulatory authorities against governmental contracts; and / or criminal prosecutions. If we decide to pursue a Fast Track Designation **, or comparable foreign regulatory procedures,** for some of our product candidates, it may not lead to a faster development or regulatory review or approval process. We may seek Fast Track Designation **, or comparable foreign regulatory procedures,** for one or more of our product candidates. If a drug is intended for the treatment of a serious or life- threatening condition and the drug ~~demonstrates~~ **41demonstrates** the potential to address unmet medical ~~42needs~~ -- **needs** for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, the FDA may decide not to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program. **The EMA has a similar program called PRIME.** If we decide to seek Orphan Drug Designation for some of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity. As part of our business strategy, we may seek Orphan Drug Designation for one or more of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and ~~Europe~~ **European countries** , may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug 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 in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as a tax credit. Opportunities for grant funding toward clinical trial costs may also be available for clinical trials of drugs for rare diseases, regardless of whether the drugs are designated for the orphan use. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances. Even if we obtain Orphan Drug Designation for our product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan- designated indication due to the uncertainties associated with developing pharmaceutical products. If a competitor with a product that is determined by the FDA to be the same as one of our product candidates obtains marketing approval before us for the same indication we are pursuing and obtains orphan drug exclusivity, our product candidate may not be approved until the period of exclusivity ends unless we are able to demonstrate that our product candidate is clinically superior. Even after obtaining approval, we may be limited in our ability to market our product. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan- designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different principal molecular structural features can be approved for the same condition. **In the EU, Regulation (EC) No. 141 / 2000, as implemented by Regulation (EC) No. 847 / 2000 provides that a medicinal product can be designated as an orphan drug by the European Commission if its sponsor can establish that: (i) the product is intended for the diagnosis, prevention or treatment of life- threatening or chronically debilitating conditions; (ii) either (a) such conditions affect not more than 5 in 10, 000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (iii) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition. Orphan medicinal product designation, entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten- year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have**

also complied with an agreed pediatric investigation plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. 42The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products. Orphan Drug Designation **in the United States, or orphan medicinal product designation the EU,** neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation **in the United States, or orphan medicinal product designation the EU,** for our product candidates, we may never receive such designation. We do not have, and may never obtain, the regulatory approvals we need to market our product candidates. Following completion of clinical trials, the results are evaluated and, depending on the outcome, an NDA is submitted to the FDA to obtain the FDA' s approval of the product and authorization to commence commercial marketing. In responding to an NDA, the FDA may require additional testing or information, may require that the product labeling be modified, may impose post- approval study and other commitments or reporting requirements or other restrictions on product distribution, or may deny the application. The FDA has established performance goals for review of NDAs: six months for priority applications and ten months for standard applications. However, the FDA is not required to complete its review within these time periods. The timing of final review by the FDA and action varies greatly but can take years in some cases and may involve the input of an FDA advisory committee of outside experts. Product sales in the United States may commence only when an NDA is approved. **Comparable procedures and limitations are applicable in the EU and in other jurisdictions.** To date, we have not applied for or received the regulatory approvals required for the commercial sale of any of our products in the United States or in any foreign jurisdiction. None of our product candidates have been determined to be safe and effective, and we have not submitted an ~~IND or an~~ NDA to the FDA or an equivalent application to any **comparable** foreign regulatory authorities for any of our product candidates. ~~43It~~ **It** is possible that none of our product candidates will be approved for marketing. Failure to obtain regulatory approvals, or delays in obtaining regulatory approvals, may adversely affect the successful commercialization of any drugs or biologics that we or our partners develop, may impose additional costs on us or our collaborators, may diminish any competitive advantages that we or our partners may attain, and / or may adversely affect our receipt of revenues or royalties. Our product candidates may cause serious adverse events (" SAEs ") or undesirable side effects which may delay or prevent marketing approval, or, if approval is received, require them to be taken off the market, require them to include safety warnings or otherwise limit their sales. SAEs or undesirable side effects from our product candidates could arise either during development or, if approved, after the approved product has been marketed. The results of future clinical trials may show that our product candidates cause SAEs or undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in delay of, or failure to obtain, marketing approval from the FDA and other **comparable foreign** regulatory authorities. If any of our product candidates cause SAEs or undesirable side effects or suffer from quality control issues: ● regulatory authorities may impose a clinical hold or REMS, **or comparable foreign regulatory strategies,** which could result in substantial delays, significantly increase the cost of development, and / or adversely impact our ability to continue development of the product; ● regulatory authorities may require the addition of statements, specific warnings, or contraindications to the product label, or restrict the product' s indication to a smaller potential treatment population; **43** ● we may be required to change the way the product is administered or conduct additional clinical trials; ● we may be required to implement a risk minimization action plan, which could result in substantial cost increases and have a negative impact on our ability to commercialize the product; ● we may be required to limit the participants who can receive the product; ● we may be subject to limitations on how we promote the product; ● we may, voluntarily or involuntarily, initiate field alerts for product recall, which may result in shortages; ● sales of the product may decrease significantly; ● regulatory authorities may require us to take our approved product off the market; ● we may be subject to litigation or product liability claims, and ● our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from the sale of our products. Even if approved, our products will be subject to extensive post- approval regulation. Once a product is approved, numerous post- approval requirements apply. Among other things, the holder of an approved NDA is subject to periodic and other monitoring and reporting obligations by the FDA, including obligations to monitor and report adverse events and instances of the failure of a product to meet the specifications in the NDA. Application holders must submit new or supplemental applications and obtain the FDA' s approval for certain changes to the approved product, product labeling, or manufacturing process. Application holders must also submit advertising and other promotional material to the FDA and report on ongoing clinical trials. ~~44Depending~~ -- **Depending** on the circumstances, failure to meet these post- approval requirements can result in criminal prosecution, fines, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre- marketing product approvals or refusal to allow us to enter into supply contracts, including government contracts. In addition, even if we comply with the FDA' s and others' requirements, new information regarding the safety or effectiveness of a product could lead the FDA to modify or withdraw product approval. **Equivalent requirements and penalties are provided in the EU both at EU level and at national**

level in individual EU Member States. Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market. Even if the FDA **or a comparable foreign regulatory authority** approves one or more of our product candidates, physicians and patients may not accept it or use it. Even if physicians and patients would like to use our products, our products may not gain market acceptance among healthcare payors such as managed care formularies, insurance companies or government programs such as Medicare or Medicaid **or comparable foreign programs** . Acceptance and use of our products will depend upon a number of factors including: perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drug or device product; cost- effectiveness of our product relative to competing products; availability of reimbursement for our product from government or other healthcare payors; and effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any. The degree of market acceptance of any pharmaceutical product that we develop will depend on a number of factors, including: ● cost- effectiveness; **44** ● the safety and effectiveness of our products, including any significant potential side effects (including drowsiness and dry mouth), as compared to alternative products or treatment methods; ● the timing of market entry as compared to competitive products; ● the rate of adoption of our products by doctors and nurses; ● product labeling or product insert required by the FDA **and comparable foreign regulatory authorities** for each of our products; ● reimbursement policies of government and third-party payors, and the willingness of patients to pay out of pocket in the absence of adequate third- party payor coverage and reimbursement; ● effectiveness of our sales, marketing and distribution capabilities and the effectiveness of such capabilities of our collaborative partners, if any; and ● unfavorable publicity concerning our products or any similar products. Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of these products to find market acceptance would harm our business and require us to seek additional financing, which may not be available. **Climate change, climate change- related regulation and sustainability concerns could adversely affect our businesses and the operations of our subsidiaries, and any actions we take or fail to take in response to such matters could damage our reputation. Investor advocacy groups, certain institutional investors, investment funds, other market participants and other stakeholders have focused increasingly on the Environmental, Social and Governance (" ESG") practices of companies, including those associated with climate change. These parties have placed increased importance on the importance on the implications of the social cost of their investments. If our ESG practices do not meet investor or other industry stakeholder expectations and standards, which continue to evolve, our reputation and associate retention may be negatively impacted based on an assessment of our ESG practices. Any sustainability disclosures we make may include our policies and practices on a variety of social and ethical matters, including corporate governance, environmental compliance, employee health and safety practices, human capital management, product quality, supply chain management, and workforce inclusion and diversity. It is possible that stakeholders may not be satisfied with our ESG practices or the speed of their adoption, or that we may not sufficiently communicate our ESG practices to stakeholders. We could also incur additional costs and require additional resources to monitor, report, and comply with various ESG practices. In addition, investors may decide to refrain from investing in us as a result of their assessment of our approach to and consideration of the ESG factors. In addition, we may face physical risks associated with climate change. These physical risks include risks to our manufacturing and supply chain from flooding, severe storms, wildfires, droughts or extreme temperatures, all of which could increase costs and impair our ability to meet our operational demands in a timely manner. To date, we have not experienced material losses or disruptions to our operations related to climate change, and we do not anticipate that these risks will have a material impact to our Company in the near term. We are also subject to changing rules and regulations promulgated by a number of governmental and self- regulatory organizations, including the SEC, Nasdaq and the Financial Accounting Standards Board. These rules and regulations continue to evolve in scope and complexity and many new requirements have been created in response to laws enacted by Congress, making compliance more difficult and uncertain. Concern over severe weather may also result in new or additional legal or regulatory requirements designed to mitigate the effects of severe weather on the environment and businesses. If such laws or regulations are more stringent than current legal or regulatory obligations, we may experience disruption in, or an increase in the costs associated with sourcing, manufacturing and distribution of our products, as well as an increase in costs associated with monitoring, tracking and reporting ESG related information to regulatory bodies, which may adversely affect our business, results of operations or financial condition. These changing rules, regulations and stakeholder expectations may result in increased general and administrative expenses and increased management time and attention spent complying with or meeting such 45regulations and expectations. For example, the State of California recently passed the Climate Corporate Data Accountability Act and the Climate- Related Financial Risk Act that, if implemented, will impose broad climate- related disclosure obligations on certain companies doing business in California. Other U. S. states' legislatures are considering enactment of similar rules and regulations. In addition, the European Union (" EU ") enacted the Corporate Sustainability Reporting Directive (" CSRD ") legislation in January 2023 which requires certain reporting and disclosure relating to ESG matters for companies whose business and assets exceed certain thresholds within EU countries. Developing and acting on initiatives within the scope of ESG, and collecting, measuring and reporting ESG related information and metrics can be costly, difficult and time consuming and is subject to evolving reporting standards, including the SEC' s climate- related reporting requirements, and similar proposals by other international regulatory bodies. We may also communicate certain initiatives and goals, regarding environmental matters, diversity, responsible sourcing and social investments and other ESG related matters, in our SEC filings or in other public disclosures. These initiatives and goals within the scope of ESG could be difficult and expensive to implement, the technologies needed to implement them may not be cost effective and may not advance at a sufficient pace, and we could be criticized for the accuracy, adequacy or completeness of the disclosure. Further, statements about our ESG- related**

initiatives and goals, and progress against those goals, may be based on standards for measuring progress that are still developing, internal controls and processes that continue to evolve, and assumptions that are subject to change in the future. Risks Related to Our Financial Condition and Capital Requirements; CompetitionWe will need to raise additional capital, which may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates, and additional capital may not be available on favorable terms or at all, which may force us to delay, reduce the scope of or eliminate our research and development programs, reduce our commercialization efforts or curtail our operations. To develop and bring our product candidates to market, we must commit substantial resources to costly and time-consuming research, preclinical studies and clinical trials and marketing activities. Until such time, if ever, as we can generate substantial product revenue, we expect to seek additional funding to meet our operational needs and capital requirements. While we believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the ~~second~~ **first** quarter of ~~2024~~ **2025**, we have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner ~~45than~~ -- **than** we expect, including if our business or operations change in a manner that consumes available resources more rapidly than we anticipate. Our requirements for additional capital will depend on many factors, including: ● **changes in direction of our research and development programs; ●** the time and expense for preclinical studies and clinical trials for our product candidates; ● the time and costs involved in obtaining regulatory approval for our product candidates; ● the cost increases and other potential impacts of macroeconomic factors, including heightened inflation and rising interest rates, **liquidity concerns at and failures of banks and other financial institutions,** exchange rate fluctuations, supply chain disruptions and increases in commodity, energy and fuel prices **, ;** ~~;~~ ● ~~-~~costs associated with protecting our intellectual property rights; ● successful commercialization of our product candidates **; ● competitive and technical advances; ● patent development or regulatory changes**; ● development of marketing and sales capabilities; ● payments received under current and future collaboration agreements, if any; and ● market acceptance of our products **. 46Our ability to continue operations after our current cash resources are exhausted depends on our ability to obtain additional financing or to achieve profitable operations, as to which no assurances can be given. Cash requirements may vary materially from those now planned because of changes in direction of our research and development programs, competitive and technical advances, patent developments, regulatory changes or other developments. If adequate additional funds are not available when required, or if we are unsuccessful in entering into partnership agreements for further development of our pipeline, management may need to curtail our development efforts and planned operations to conserve cash**. We expect to finance our operations through a combination of equity offerings, debt financings, government or private party grants, collaborations, strategic alliances and licensing arrangements. We do not currently have any other committed external sources of funds. To the extent we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interest will or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights as a common stockholder. In addition, if we obtain debt financing, a substantial portion of our operating cash flow may be dedicated to the payment of principal and interest on such indebtedness, thus limiting funds available for our business activities. In addition, debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams or product candidates, grant licenses on terms that may not be favorable to us or commit to future payment streams. We will require substantial additional funds to support our research and development activities, and the anticipated costs of preclinical studies and clinical trials, regulatory approvals and eventual commercialization. Such additional sources of financing may not be available on favorable terms, if at all, including as a result of actions taken by central banks to counter inflation, volatility in the capital markets **, liquidity concerns at and failures of banks and other financial institutions** and related market uncertainty. If we do not succeed in raising additional funds on acceptable terms ~~,~~ **or if** we ~~may be unable to commence~~ **are unsuccessful in entering into partnership agreements** ~~or~~ **for further** ~~complete clinical trials or obtain approval of any product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product~~ development **of our pipeline** , ~~forego sales and marketing~~ **we may need to curtail our development** efforts and ~~forego attractive business opportunities~~ **planned operations to conserve cash**. Our continued operations may be in jeopardy and we may be forced to cease operations and sell or otherwise transfer all or substantially all of our remaining assets. We face intense competition in the markets targeted by our product candidates. Many of our competitors have substantially greater resources than we do, and we expect that all of our product candidates under development will face intense competition from existing or future drugs. We expect that all of our product candidates under development, if approved, will face intense competition from existing and future drugs marketed by large companies. These competitors may successfully market products that compete with our products, successfully identify product candidates or develop products earlier than we do, or develop products that are more effective, have fewer side effects or cost less than our products. Additionally, if a competitor receives FDA approval before we do for a drug that is similar to one of our product candidates, FDA approval for our product candidate may be precluded or delayed due to periods of non- patent ~~46exclusivity~~ -- **exclusivity** and / or the listing with the FDA by the competitor of patents covering its newly- approved drug product. Periods of non- patent exclusivity for new versions of existing drugs can extend up to three and one- half years **. In the EU, following grant of a related marketing authorization, innovative medicinal products generally benefit from eight years of data exclusivity and ten years of market exclusivity. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator' s data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product. After this period, an application for marketing authorization for a generic or biosimilar product may be submitted, and the innovator' s data may be referenced. The**

market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial marketing authorization of the reference product in the EU. The overall ten- year period may, occasionally, be extended for a further year to a maximum of eleven years if, during the first eight years following authorization of the reference product, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing 47therapies. There is, however, no guarantee that a product will be considered by the EU' s regulatory authorities to be a new chemical / biological entity, and products may not qualify for data exclusivity. In the EU, there is also a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of a related application for marketing authorization. Guidelines from the EMA detail the type and quantity of supplementary data to be provided for different types of biological product . These competitive factors could require us to conduct substantial new research and development activities to establish new product targets, which would be costly and time consuming. These activities would adversely affect our ability to commercialize products and achieve revenue and profits. Competition and technological change may make our product candidates and technologies less attractive or obsolete. We compete with companies that are pursuing other forms of treatment for the same or similar indications we are pursuing, including established pharmaceutical and biotechnology companies and that have greater financial and other resources. While we are not currently aware of any other companies that are taking the same therapeutic approach to protein folding disorders similar to the ones we are pursuing, we are aware of companies developing products for the same target indications. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated among a smaller number of competitors. Other companies may succeed in developing products earlier than us, obtaining FDA **or comparable foreign regulatory authority** approval for products more rapidly, or developing products that are more effective than our product candidates. Research and development by others may render our technology or product candidates obsolete or noncompetitive, or result in treatments or cures superior to any therapy we develop. For example, other companies may succeed in developing a technology that addresses protein misfolding and proves to be more effective or is more readily accepted than STARs. We face competition from companies that internally develop competing technology or acquire competing technology from universities and other research institutions. As these companies develop their technologies, they may develop competitive positions that may prevent, make futile, or limit our product commercialization efforts, which would result in a decrease in the revenue we would be able to derive from the sale of any products. We may not be able to obtain marketplace acceptance for any of our product candidates as readily as these or other competing treatments. Furthermore, if our competitors' products are approved before ours, it could be more difficult for us to obtain approval from the FDA **or comparable foreign regulatory authorities** , and if they are commercialized before ours they may establish a strong market position before we are able to enter the market. Even if our products are successfully developed and approved for use by all governing regulatory bodies, physicians and patients may not accept our products as a treatment of choice. The pharmaceutical research industry is diverse, complex, and rapidly changing, and inherently involves significant and numerous business risks. The effects of competition, intellectual property disputes, market acceptance, and FDA **and comparable foreign regulatory authority** regulations, among other factors described herein, preclude us from forecasting revenues or income with certainty or even confidence. Our business and operations may be adversely affected by health epidemics or pandemics. Our business and operations may be adversely affected by pandemics or epidemics, including due to business interruptions caused by travel restrictions, quarantines, " stay- at- home " and" shelter- in- place" orders, shutdowns requested or mandated by governmental authorities, or staffing shortages while employees quarantine as a result of exposure to or transmission of the virus. ~~Previously~~ **In addition, health epidemics or pandemics could cause significant disruption in the operations of third- party manufacturers, CROs and other third parties upon whom we rely. For example** , the COVID- 19 pandemic **presented** ~~resulted in the declaration of~~ a ~~global pandemic~~ **substantial public health** and ~~adversely~~ **economic challenge around the world and** affected ~~economic activity across virtually all sectors and industries on a local, national, and global scale. It resulted in travel and other restrictions in order to reduce the spread of the disease, including government- imposed prohibitions on non- essential operations at physical locations, gatherings and events and travel. As a result of such restrictions, we had implemented a work- from- home policy allowing~~ employees ~~who can work from home to do so. Following the lifting of pandemic- era restrictions~~ , **patients** ~~we have transitioned to a hybrid work schedule of in- office work and at- home work consistent with business needs and job requirements. Business travel was previously suspended but is now reduced compared to pre- pandemic levels as online and teleconference technology has been adopted and continues to be used regularly. In addition~~ , **communities** ~~COVID- 19 restrictions impacted our third- party manufacturers, including one in China,~~ and ~~has previously disrupted, and may in the future disrupt, our ability to obtain manufacturing services. While restrictions have been lifted in places where we operate, future similar government orders or other restrictions on the conduct of~~ business operations ~~and travel related to~~ **, as well as** the **global economy and financial marketsThe** COVID- 19 pandemic ~~may negatively~~ **and the resulting post- pandemic environment has** ~~impact~~ **impacted** ~~productivity~~ **clinical site activation** and **patient enrollment** ~~may disrupt 47our ongoing and planned research and development activities~~ . ~~Furthermore, the~~ **Clinical trial sites have experienced limited capacity and staffing shortages in a post-** COVID- 19 **environment, partially due to personnel having been reassigned during the** pandemic ~~has caused~~ **, resulting in** a ~~broad negative~~ **backlog of patient enrollment and delayed site initiations across the industry. Our inability to successfully recruit and retain patients and principal investigators and site staff could adversely** impact ~~globally on capital markets and economies worldwide. The COVID- 19 pandemic continues to evolve, and the extent to which it may impact our business is uncertain and difficult to predict. The magnitude of the negative effects of COVID- 19 will depend, in part, on the length and severity of any restrictions imposed, as well as on the emergence, infectiousness and severity of new~~

~~variants. New health epidemics or~~ **our expected future clinical trial operations** ~~pandemics may emerge that result in similar or more severe disruptions to our business~~ . ~~Risks~~ **48Risks** Related to Our Intellectual Property We rely on a license to use the technology that is material to our business and if the agreements underlying the licenses were to be terminated or if other rights that may be necessary for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition. We are significantly dependent upon our license with Minoryx Therapeutics S. L. (the " Minoryx License "), as described in the section " Business ~~–~~ – Strategic **Transactions;** Collaboration and Licensing Arrangements ~~–~~ – Minoryx Therapeutics, S. L. " in our Annual Report. The Minoryx License grants us exclusive, worldwide rights to certain patents and related intellectual property. If we breach the terms of the Minoryx License, for example, by failing to comply with any material terms thereof, Minoryx may have the right to terminate the license. If we were to lose our license under this agreement, we would not be able to market certain of our products and technology, which would likely require us to cease our current operations and have an immediate material adverse effect on our business, operating results and financial condition. Our success depends substantially upon our ability to obtain and maintain intellectual property protection relating to our products and technologies. We are currently seeking patent protection for numerous compounds and methods of treating diseases. There is no assurance that these patents will be issued, and no assurance that, if they do issue, they will prevent other companies from competing with us. Our ability to obtain and enforce patents that may issue from any pending or future patent applications is uncertain and involves complex legal, scientific and factual questions. Thus, we cannot be sure that any patents will issue from any pending or future patent applications owned by or licensed to us. Even if patents do issue, we cannot be sure that the claims of these patents will be held valid or enforceable by a court of law, will provide us with any significant protection against competing products, or will afford us a commercial advantage over competitive products. If, at some point in the future, one or more products resulting from our product candidates is approved for sale by the FDA and we do not have adequate intellectual property protection for those products, competitors could duplicate them for approval and sale in the United States without repeating the extensive testing required of us to obtain FDA approval. If we fail to protect our intellectual property rights, our ability to pursue the development of our technologies and products would be negatively affected. Our success will depend in part on our ability to obtain, maintain and protect intellectual property rights related to our product candidates. If we do not adequately maintain or protect our intellectual property, competitors may be able to use our technologies to produce and market drugs in direct competition with us and erode our competitive advantage. Furthermore, some foreign countries lack rules and methods for defending intellectual property rights and do not protect proprietary rights to the same extent as the United States. Many companies have had difficulty protecting their proprietary rights in these foreign countries. For example, the legal systems in India, China and certain other developing countries do not favor the enforcement of patents and other intellectual property rights. We may not be able to prevent misappropriation of our proprietary rights and intellectual property rights in these and other countries. In addition, the patent process is subject to numerous risks and uncertainties, and we may not be successful in protecting our products by obtaining and defending patents related to them. These risks and uncertainties include the following: patents that may be issued or licensed may be challenged, invalidated, or circumvented, or otherwise may not provide us any competitive advantage; our competitors, many of which have substantially greater resources than we and many of which have made significant investments in competing technologies, may seek, or may already have obtained, patents that will limit, interfere with, or eliminate our ability to make, use, and sell our potential ~~48products~~ -- **products** either in the United States or in international markets; there may be significant pressure on the United States government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful as a matter of public policy regarding worldwide health concerns; and countries other than the United States may have less robust patent laws than those upheld by United States courts, allowing foreign competitors the ability to exploit these laws to create, develop, and market competing products using our technologies and patents. ~~Moreover~~ **49Moreover** , any patents issued to us may not provide us with meaningful protection, or others may challenge, circumvent or narrow our patents. Third parties may also independently develop products similar to our products, duplicate our unpatented products or design around any patents or proprietary technologies on products we develop. Additionally, extensive time is required for development, testing and regulatory review of a potential product. While extensions of patent terms due to regulatory delays may be available, it is possible that, before any of our product candidates can be commercialized, any related patent, even with an extension, may expire or remain in force for only a short period following commercialization, thereby reducing any advantages to us of the patent. In addition, the PTO and patent offices in other jurisdictions have often required that patent applications concerning pharmaceutical and / or biotechnology- related inventions be limited or narrowed substantially to cover only the innovations specifically exemplified in the patent application, thereby limiting the scope of protection against competitive challenges. Thus, even if we or our licensors are able to obtain patents, the patents may be substantially narrower than anticipated, which could deprive us of rights necessary for the successful commercialization of our product candidates. Our success depends on our patents and patent applications that may be licensed exclusively to us and other patents and patent applications to which we may obtain assignment or licenses. We may not be aware, however, of all patents, published applications or published literature that may affect our business either by blocking our ability to commercialize our product candidates, by preventing the patentability of our product candidates by us or our licensors, or by covering the same or similar technologies. These patents, patent applications, and published literature may limit the scope of our future patent claims or adversely affect our ability to market our product candidates. We have not conducted any formal search of patents issued to third parties, and third- party patents containing claims covering our product candidates that predate our patents may exist. Because of the number of patents issued and patent applications filed in our technical areas or fields, our competitors or other third parties may assert that our product candidates are covered by United States or foreign patents held by them. In addition to patents, we rely on a combination of trade secrets, confidentiality, nondisclosure and other contractual provisions, and security measures to protect our confidential

and proprietary information. These measures may not adequately protect our trade secrets or other proprietary information. If they do not adequately protect our rights, third parties could use our technology, and we could lose any competitive advantage we may have. In addition, others may independently develop similar proprietary information or techniques or otherwise gain access to our trade secrets, which could impair any competitive advantage we may have. Patent protection and other intellectual property protection is crucial to the success of our business and prospects, and there is a substantial risk that such protections will prove inadequate. We may be involved in lawsuits to protect or enforce our patents, which could be expensive and time consuming. The pharmaceutical industry has been characterized by extensive litigation regarding patents and other intellectual property rights, and companies have employed intellectual property litigation to gain a competitive advantage. We may become subject to infringement claims or litigation arising out of present and future patents and other proceedings of our competitors. The defense and prosecution of intellectual property suits are costly and time- consuming to pursue, divert the attention of our management and scientific personnel, and their outcome is uncertain. Litigation may be necessary to determine the enforceability, scope, and validity of the proprietary rights of others. An adverse determination in litigation to which we may become a party could subject us to significant liabilities, require us to obtain licenses from third parties, or restrict or prevent us from selling our products in certain markets. Although patent and intellectual property disputes might be settled through licensing or similar arrangements, the costs associated with such arrangements may be substantial and could include our paying large, fixed payments and ongoing royalties. Furthermore, the necessary licenses may not be available on satisfactory terms or at all. ~~49Competitors~~ -- **Competitors** may infringe our patents, and we may file infringement claims to counter infringement or unauthorized use. Third parties may assert that our patents are invalid and / or unenforceable in these proceedings. Such litigation can be expensive, particularly for a company of our size, and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. An adverse determination of any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. ~~Third~~ **50Third** parties may also assert that our patents are invalid in patent office administrative proceedings. These proceedings include oppositions in the European Patent Office and inter partes review and post- grant review proceedings in the PTO. The success rate of these administrative challenges to patent validity in the United States is higher than it is for validity challenges in litigation. Interference or derivation proceedings brought before the PTO may be necessary to determine priority of inventions disclosed in our patents or patent applications. Determining whether a product infringes a patent, as well as priority of inventions and other patent- related disputes, involves complex legal and factual issues and the outcome is often uncertain. During these proceedings, it may be determined that we do not have priority of invention for one or more aspects in our patents or patent applications and could result in the invalidation in part or whole of a patent or could put a patent application at risk of not issuing. Even if successful, an interference or derivation proceeding may result in substantial costs and distraction to our management. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or interference or derivation proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors or securities analysts perceive these results to be negative, the price of our common stock could be adversely affected. Also, a third party may assert that our patents are invalid or unenforceable. There are not currently any unresolved communications, allegations, complaints or threats of litigation that claim our patents are invalid or unenforceable. Any litigation or claims against us, whether or not merited, may result in substantial costs, place a significant strain on our financial resources, divert the attention of management and harm our reputation. An adverse decision in litigation or administrative proceedings could result in inadequate protection for our product candidates and / or reduce the value of any license agreements we have with third parties. If we infringe the rights of third parties, we could be prevented from selling products or forced to pay damages and defend against litigation. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: obtain licenses, which may not be available on commercially reasonable terms or at all; abandon an infringing product candidate; redesign our products or processes to avoid infringement; stop using the subject matter claimed in the patents held by others; pay damages; and / or defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware, and which may result in issued patents that our future products would infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. We have licensed **certain** ~~all of the~~ rights, assets and technology related to the **Magellan ™** ~~SEE- Tx ®~~ platform from Minoryx and we believe that they owned all of such rights prior to our license. Although, to our knowledge, no third party has asserted a claim of infringement or other claim against us, others may hold or claim to hold proprietary or other rights that could prevent our **Magellan ™** ~~SEE- Tx ®~~ platform from being developed or marketed. Any legal action against us claiming damages and seeking to enjoin commercial activities relating to our **Magellan ™** ~~SEE- Tx ®~~ platform or our processes could subject us to potential liability for damages and require us to obtain a license to continue to manufacture or market any future product candidates based upon the **Magellan ™** ~~SEE- Tx ®~~ platform. We may not prevail in any such actions and any license required under any of these patents may not be made available on commercially acceptable terms, if at all. In addition, ~~50we~~ **we** may not be able to redesign any future product candidates or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our future product candidates, which could harm our business, financial condition and operating results. ~~Risks~~ **51Risks** Related to Third Parties and CollaboratorsWe **currently** ~~intend to~~ rely on **, and intend to rely on in the future,** third parties to conduct, supervise and monitor our clinical

trials, and if those third parties perform in an unsatisfactory manner, it may harm our business. We **currently** ~~expect to~~ rely on **, and expect to rely on in the future,** CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we will have agreements governing their activities, we will have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that our clinical trials are conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs will not relieve us of our regulatory responsibilities. We and our CROs are required to comply with the FDA' s Good Clinical Practices (" GCPs ") **and foreign equivalents** 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 clinical trial participants are protected. The FDA **and comparable foreign regulatory authorities** ~~enforces~~ **enforce** these GCPs through periodic inspections of study sponsors, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA **or comparable foreign regulatory authorities** may require us to perform additional clinical trials before approving any marketing applications. Upon inspection, the FDA **or comparable foreign regulatory authorities** may determine that our clinical trials did not comply with **applicable** GCPs **requirements** . In addition, our clinical trials will require enrollment and participation of a sufficiently large number of patients to evaluate the effectiveness and safety of our product candidates. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of participants, our clinical trials may be delayed or we may be required to repeat such clinical trials, which would delay the regulatory approval process. Our CROs are not our employees, and we are not able to control whether or not they devote sufficient time and resources to our clinical trials. These CROs 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 harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for such product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed. We **currently rely on and** intend to rely **in the future** on third parties to manufacture the compounds used in our studies, and we intend to rely on them for the manufacture of any approved products for commercial sale. If these third parties do not manufacture our product candidates in sufficient quantities and at an acceptable cost, clinical development and commercialization of our product candidates could be delayed, prevented or impaired. We have no manufacturing facilities and we intend to rely on third- party contract manufacturing organizations (" CMOs ") to manufacture some or all of our product candidates in future clinical trials and our products that reach commercialization. Initiation and completion of our clinical trials and commercialization of our product candidates requires the manufacture of a sufficient supply of our product candidates. If, for any reason, we become unable to rely on these third parties for the manufacture of our product candidates, either for clinical trials or, in the event any of our product candidates are approved, for commercial quantities, then we would need to identify and contract with additional or replacement third- party manufacturers to manufacture compounds for preclinical, clinical and commercial purposes, which we may not be able to do on reasonable terms or at all, or we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back- up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to ~~51change~~ **change** CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. ~~We~~ **52We** will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidates according to any specifications previously submitted to the FDA or another **comparable foreign** regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials. We believe that there are a variety of manufacturers that we may be able to retain to produce these products. However, we may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacture if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third- party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected. In addition, once we retain a manufacturing source, if our manufacturers do not perform in a satisfactory manner, we may not be able to develop or commercialize potential products as planned. Certain specialized manufacturers are expected to provide us with modified and unmodified pharmaceutical compounds, including finished products, for use in our preclinical studies and clinical trials. Some of these materials are available from only one supplier or vendor. Any interruption in or termination of service by such sole source suppliers could result in a delay or interruption in manufacturing until we locate an alternative source of supply. Any delay or interruption in our future supply chain and manufacturing operations (or failure to locate a suitable replacement for such suppliers) as a result of pandemics or epidemics, global geopolitical conflicts or broader global supply chain disruptions, may

affect their ability to deliver products to us in a timely manner and, could materially adversely affect our business, prospects, or results of operations. For example, supply chain issues ~~have~~ occurred ~~and may continue to occur~~ as a result of the COVID- 19 pandemic ~~,~~ **and may continue to occur due to** the war between Ukraine and Russia **, the conflict between Hamas** and **Israel and any** sanctions resulting therefrom, and global geopolitical tension, including as a result of impacts on energy availability and prices and natural materials availability and prices. We also have a third- party manufacturer in China, which may be impacted by heightened tensions between the United States and China. If we fail to contract for manufacturing on acceptable terms or if third- party manufacturers do not perform as we expect, our development programs could be materially adversely affected. This may result in delays in filing for and receiving FDA **or comparable foreign regulatory authority** approval for one or more of our products or prevent such approval entirely. Any such delays or failures to obtain regulatory approval could cause our prospects to suffer significantly. Failure by our third- party manufacturers to comply with the regulatory guidelines set forth by the FDA **or comparable foreign regulatory authorities** with respect to our product candidates could delay or prevent the completion of clinical trials, the approval of any product candidates or the commercialization of our products. Third- party manufacturers must be inspected by the FDA **and comparable foreign regulatory authorities** for cGMP compliance before they can produce commercial products. We may be in competition with other companies for access to these manufacturers' facilities and may be subject to delays in manufacture if the manufacturers give other clients higher priority than they give to us. If we are unable to secure and maintain third- party manufacturing capacity, the development and sales of our products and our financial performance may be materially affected. Manufacturers are obligated to operate in accordance with **requirements mandated by the** FDA ~~- mandated requirements~~ **or comparable foreign regulatory authorities** . A failure of any of our third- party manufacturers to establish and follow cGMP requirements and to document their adherence to such practices may lead to significant delays in the availability of material for clinical trials, may delay or prevent filing or approval of marketing applications for our products, and may cause delays or interruptions in the availability of our products for commercial distribution following **approval by the** FDA ~~approval~~ **or a comparable foreign regulatory authority** . This could result in higher costs to us or deprive us of potential product revenues. Drug manufacturers are subject to ongoing periodic unannounced inspections by the FDA, the Drug Enforcement Administration (" DEA ") and corresponding state and foreign ~~agencies~~ **regulatory authorities** to **monitor and** ~~ensure~~ **53ensure** strict compliance with ~~52cGMP~~ -- **cGMP** requirements and other requirements under federal drug laws, other government regulations and corresponding foreign **laws, regulations and** standards. If we or our third- party manufacturers fail to comply with applicable regulations, sanctions could be imposed on us, including fines, injunctions, civil penalties, failure by the government **or competent regulatory authorities** to grant marketing approval of drugs, delays, suspension **, variation** or withdrawal of approvals, seizures or recalls of product **, shutdown of the manufacturer, invalidation of drug lots or processes** , operating restrictions **, product recalls** and criminal prosecutions. Corporate and academic collaborators may take actions to delay, prevent, or undermine the success of our products. Our operating and financial strategy for the development, clinical testing, manufacture, and commercialization of product candidates is heavily dependent on our entering into collaborations with corporations, academic institutions, licensors, licensees, and other parties and we may not be successful in establishing such collaborations. Some of our existing collaborations are, and future collaborations may be, terminable at the sole discretion of the collaborator. Replacement collaborators might not be available on attractive terms, or at all. The activities of any collaborator will not be within our control and may not be within our power to influence. Any collaborators may not perform their obligations to our satisfaction, or at all, we may not derive any revenue or profits from such collaborations, and any collaborators may ultimately compete with us. If any collaboration is not pursued, we may require substantially greater capital to undertake development and marketing of our proposed products and may not be able to develop and market such products effectively, if at all. In addition, a lack of development and marketing collaborations may lead to significant delays in introducing proposed products into certain markets and / or reduced sales of proposed products in such markets. Data provided by collaborators and others upon which we rely that has not been independently verified could turn out to be false, misleading, or incomplete. We rely on third- party vendors, scientists and collaborators to provide us with significant data and other information related to our projects, clinical trials and our business. If such third parties provide inaccurate, misleading or incomplete data, our business, prospects and results of operations could be materially adversely affected. If we fail to establish marketing, sales and distribution capabilities, or fail to enter into arrangements with third parties, we will not be able to create a market for our product candidates. Our strategy for our product candidates is to control, directly or through contracted third parties, all or most aspects of the product development process, including marketing, sales and distribution. Currently, we do not have any sales, marketing or distribution capabilities. In order to generate sales of any product candidates that receive regulatory approval, we must either acquire or develop an internal marketing and sales force with technical expertise and with supporting distribution capabilities or make arrangements with third parties to perform these services for us. The acquisition or development of a sales and distribution infrastructure would require substantial resources, which may divert the attention of our management and key personnel and defer our product development efforts. To the extent that we enter into marketing and sales arrangements with other companies, our revenues will depend on the efforts of others. These efforts may not be successful. If we fail to develop sales, marketing and distribution channels, or enter into arrangements with third parties, we will experience delays in product sales and incur increased costs. Sales of pharmaceutical products largely depend on the reimbursement of patients' medical expenses by government health care programs and private health insurers. Without the financial support of the government or third- party payors, the market for our products will be limited. These third- party payors are increasingly challenging the price and examining the cost effectiveness of medical products and services. Recent proposals to change the health care system in the United States have included measures that would limit or eliminate payments for medical products and services or subject the pricing of medical treatment products to government control. Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third- party payors may not reimburse sales of our products or enable our collaborators to sell them at profitable prices. Our business strategy might

involve out- licensing product candidates to or collaborating with larger firms with experience in marketing and selling pharmaceutical products. We may not be able to successfully establish marketing, sales, or distribution relationships and such relationships, if established, may not be successful. Further, we may not be successful in gaining market acceptance for our products. To the extent that we enter into any marketing, ~~sales~~ **54sales** , or distribution arrangements with third parties, our product revenues will be lower than if we marketed and sold ~~53our~~ -- **our** products directly, and any revenues we receive will depend upon the efforts of such third- parties. If we are unable to establish such third- party sales and marketing relationships, or choose not to do so, we will have to establish and rely on our own in- house capabilities. We, as a company, have no experience in marketing or selling pharmaceutical products and currently have no sales, marketing, or distribution infrastructure. To market any of our products directly, we would need to develop a marketing, sales, and distribution force that both has technical expertise and the ability to support a distribution capability. The establishment of a marketing, sales, and distribution capability would significantly increase our costs, possibly requiring substantial additional capital. In addition, there is intense competition for proficient sales and marketing personnel, and we may not be able to attract individuals who have the qualifications necessary to market, sell, and distribute our products. We may not be able to establish internal marketing, sales, or distribution capabilities. If we are unable to, or choose not to establish these capabilities, or if the capabilities we establish are not sufficient to meet our needs, we will be required to establish collaborative marketing, sales, or distribution relationships with third parties. If any of our existing or future collaborative partners do not satisfy their obligations, or if we are unable to enter into collaboration agreements with partners on favorable terms, we will be unable to develop our partnered product candidates. We may not have day- to- day control over the activities of our existing and future collaborative partners with respect to any of our partnered product candidates. Any collaborative partner may not fulfill its obligations under our collaboration agreements. If a collaborative partner fails to fulfill its obligations under an agreement with us, we may be unable to assume the development of the products covered by that agreement or enter into alternative arrangements with a third party. In addition, we may encounter delays in the commercialization of the product candidate that is the subject of the agreement. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements will be dependent on the efforts of our collaborative partner. We could also become involved in disputes with a collaborative partner, which could lead to delays in or termination of our development and commercialization programs and time- consuming and expensive litigation or arbitration. In addition, any such dispute could diminish our collaborators' commitment to us and reduce the resources they devote to developing and commercializing our products. Conflicts or disputes with our collaborators, and competition from them, could harm our relationships with our other collaborators, restrict our ability to enter future collaboration agreements and delay the research, development or commercialization of our product candidates. If any collaborative partner terminates or breaches its agreement, or otherwise fails to complete its obligations in a timely manner, our chances of successfully developing or commercializing these product candidates would be materially and adversely affected. We may not be able to enter into collaboration agreements with partners on terms favorable to us, or at all. Our inability to enter into collaborative arrangements with collaborative partners, or our failure to maintain such arrangements, would limit the number of product candidates that we could develop and ultimately decrease our sources of any future revenues. We face risks in connection with existing and future collaborations with respect to the development, manufacture and commercialization of our product candidates. We face a number of risks in connection with our current and future collaborations. Our collaboration agreements are subject to termination under various circumstances. Our collaborators may change the focus of their development and commercialization efforts or may have insufficient resources to effectively assist in the development of our products. Any future collaboration agreements may have the effect of limiting the areas of research and development that we may pursue, either alone or in collaboration with third parties. Further, disagreements with collaborators, including disagreements over proprietary rights, contract interpretation, or the preferred course of development, might cause delays, might result in litigation or arbitration, or might result in termination of the research, development or commercialization of our products. Any such disagreements would divert management attention and resources and be time- consuming and costly. ~~54General~~ **55General** Risk ~~FactorsWe~~ **FactorsAs** ~~previously identified material weaknesses in our internal~~ **a public company, we are obligated to develop and maintain proper and effective** ~~control~~ **controls** over financial reporting **. If we** ~~and may identify additional material weaknesses in the future or otherwise~~ fail to maintain **proper** ~~an~~ **and** effective system of internal controls **over financial reporting** ~~, which may result~~ in ~~material misstatements of~~ **the future,** our **ability to produce accurate and timely** financial statements **could be impaired, which could harm** ~~or our cause~~ **operating results, investors' views of** us ~~to fail to meet~~ **and, as a result, the value of** our **securities** ~~periodic reporting obligations~~ . Our management is responsible for establishing and maintaining adequate **system of** internal control over financial reporting, as defined in Rule 13a- 15 (f) under the Exchange Act. In addition, Section 404 of the Sarbanes- Oxley Act of 2002 (Section 404) and related SEC rules require management to furnish a report on the effectiveness of our internal control over financial reporting. Effective internal controls are necessary for us to provide reliable financial reports and help us to prevent fraud. The process of implementing our internal controls and complying with Section 404 is expensive and time consuming and requires significant continuous attention of management. We cannot be certain that these measures will ensure that we maintain adequate controls over our financial processes and reporting in the future. **If** ~~For example, in our IPO, we previously disclosed material weaknesses relating to the following: (1) lack of sufficient accounting and supervisory personnel who have the appropriate level of technical accounting experience and training, and (2) lack of adequate procedures and controls to ensure that accurate financial statements can be prepared and reviewed on a timely basis, which we remediated as of December 31, 2021 and December 31, 2022, respectively. While we believe the remediation efforts both addressed the identified material weaknesses and also enhanced our overall financial control environment, if~~ we fail to maintain the adequacy of our internal controls, including any failure to implement new or improved controls, or if we experience difficulties in their implementation, our business and financial results could be harmed and we would be required to disclose material weaknesses in future filings with the SEC, which could adversely affect our business, investor confidence in

our company and the market price of our common stock and could subject us to litigation or regulatory enforcement actions. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the market value of our common stock. Global and macroeconomic conditions, including economic, political and social instability could adversely affect our revenue, financial condition, or results of operations. The global credit and financial markets have recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, disruptions in access to bank deposits and lending commitments due to bank failures, ~~declines in economic growth, increases in unemployment rates,~~ supply chain disruptions, ~~rising~~ **heightened** interest rates **and inflation** , stock volatility ~~and record inflation~~ , as well as uncertainty about economic stability. Such conditions may continue or worsen in the future. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including Russia' s invasion of Ukraine **and the conflict between Hamas and Israel** , terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the ~~one~~ **war** in Ukraine **and the conflict between Hamas and Israel** , may also adversely impact the financial markets and the global economy, and any economic countermeasures by affected countries and others could exacerbate market and economic instability **. In 2018 and 2019, the United States imposed tariffs on goods imported from China and certain other countries. Although the United States and China signed a new trade agreement in January 2020, most of the previously- implemented tariffs on goods imported from China remain in place. Additional tariffs or further retaliatory trade measures taken by China or other countries in response, could affect the demand for any of our products, impact the competitive position of our products, prevent us from being able to sell products in certain countries or otherwise adversely impact our results of operations** . There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy, as well as our suppliers' ability to provide us with raw materials and components, may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions, which could directly affect our ability to attain our operating goals on schedule and on budget, including requiring us to delay or abandon certain development plans, and could have a material adverse effect on our growth strategy, financial performance and stock price. In addition, there is a risk that one or more of our current suppliers, may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget. We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth. As we advance our product candidates through preclinical studies and clinical trials, and develop new product candidates, we will need to increase our product development, scientific, regulatory and compliance and administrative ~~55headcount~~ -- **headcount** to manage these programs. In addition, **to continue** to meet our obligations as a public company, **and particularly after we will no longer qualify as an emerging growth company,** we will need to increase our general and ~~administrative 56~~**administrative** capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we: ● successfully attract and recruit new employees with the expertise and experience we will require; ● manage our clinical programs effectively, which we anticipate being conducted at numerous clinical sites; ● develop a marketing, distribution and sales infrastructure in addition to a post-marketing surveillance program if we seek to market our products directly; and ● continue to improve our operational, manufacturing, quality assurance, financial and management controls, reporting systems and procedures. If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected. We depend upon our key personnel and our ability to attract and retain qualified employees. Our future growth and success will depend in large part on our continued ability to attract, retain, manage and motivate our employees. The loss of the services of a significant portion of our workforce or any member of our senior management or the inability to hire or retain qualified personnel could adversely affect our ability to execute our business plan and harm our operating results. Because of the specialized nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. In particular, the loss of one or more of our senior executive officers could be detrimental to us if we do not have an adequate succession plan or if we cannot recruit suitable replacements in a timely manner. While our senior executive officers are parties to employment agreements with us, these agreements do not guarantee that they will remain employed with us in the future. In addition, ~~in many cases,~~ these ~~agreements do not~~ **our arrangements with our senior executive officers include only limited, if any,** ~~restrict~~ **restrictions on** our senior executive officers' ability to compete with us after their employment is terminated. The competition for qualified personnel in the pharmaceutical field is intense, and there is a limited pool of qualified potential employees to recruit. Due to the intense competition for talent, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. We may also face increased costs in attracting and retaining personnel as a result of ~~rising~~ **heightened** global inflation. To incentivize valuable employees to join and remain at our company, in addition to salary and other employee benefits, we have provided stock option and restricted stock unit awards that vest over time **and, in some instances, subject to the achievement of performance milestones** . The value to employees of such awards may be significantly affected by movements in our stock price, and current market conditions and extreme stock price volatility may diminish our ability to incentivize employees through the use of such awards. If we are unsuccessful in our recruitment and retention efforts, our business may be harmed. Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. Our employment ~~agreements~~ **arrangements** generally include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work at all or for a sufficient duration of time to prevent members of our management team from competing with us. If we are unable to enforce these covenants not to compete, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our competitiveness may

be diminished. ~~56If~~ **57If** we are unable to hire additional qualified personnel, our ability to grow our business may be harmed. Over time we will need to hire additional qualified personnel with expertise in drug development, product registration, clinical, preclinical and nonclinical research, quality compliance, government regulation, formulation and manufacturing, financial matters and sales and marketing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and our search for such personnel may not be successful. Attracting and retaining qualified personnel will be critical to our success. Our relationships with customers, physicians, and third- party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws, and other healthcare laws and regulations **including comparable foreign laws and regulations**. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Healthcare providers and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, principal investigators, consultants, customers and third- party payors may subject us to various federal and state fraud and abuse laws and other healthcare laws, including, without limitation, the federal Anti- Kickback Statute, the federal civil and criminal false claims laws and the law commonly referred to as the Physician Payments Sunshine Act and regulations **, and foreign equivalent laws and regulations**. These laws will impact, among other things, our proposed clinical research, sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the federal government and the states in which we conduct or may conduct our business **, as well as foreign data privacy and security laws and regulations**. The laws that will affect our operations include, but are not limited to: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for the purchase, recommendation, leasing or furnishing of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs; ● federal civil and criminal false claims laws, including, without limitation, the False Claims Act, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; ● HIPAA, which created new federal criminal statutes that prohibit a person from, among other things, knowingly and willfully executing a scheme or making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e. g., public or private); ● HIPAA, as amended by HITECH and its implementing regulations, and as amended again by the final HIPAA omnibus rule, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to HIPAA, published in January 2013, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and certain health care providers, and their respective business associates and covered subcontractors; ● federal transparency laws, including the federal Physician Payments Sunshine Act, which is part of the Patient Protection and Affordable Care Act (" ACA "), that require 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 Centers for Medicare & Medicaid Services (" CMS "), information related to: (i) payments or other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; and (ii) ownership and investment interests held by physicians and their immediate family members; ~~57~~ **58** ● state and foreign law equivalents of each of the above federal laws, state laws **and foreign law equivalents** that require manufacturers to report information related to payments and other transfers of value to physicians and other healthcare ~~providers~~ **professionals** or marketing expenditures, ~~and~~ state laws **and foreign law equivalents** that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or **competent regulatory authority or** to adopt compliance programs as prescribed by ~~state~~ **applicable** laws and regulations, or that otherwise restrict payments that may be made to healthcare ~~providers~~ **professionals**; and ● state and foreign laws that 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. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. 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, fines, disgorgement, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid **or comparable foreign programs**, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and the curtailment or restructuring of our operations. The risk of us being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and / or reporting requirements increases

the possibility that a healthcare company may run afoul of one or more of the requirements. Coverage and adequate reimbursement may not be available for our current or any future product candidates, which could make it difficult for us to sell profitably, if approved. Market acceptance and sales of any product candidates that we commercialize, if approved, will depend in part on the extent to which reimbursement for these drugs and related treatments will be available from third- party payors, including government health administration authorities, managed care organizations and other private health insurers. Third- party payors decide which therapies they will pay for and establish reimbursement levels. Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor- by- payor basis. One payor' s determination to provide coverage for a drug does not determine whether or not another payor will also provide coverage, and adequate reimbursement, for the drug. Additionally, a third- party payor' s decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Each payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy, and on what tier of its formulary it will be placed. The position on a payor' s list of covered drugs, or formulary, generally determines the co- payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Even if favorable coverage and reimbursement status is attained for any product candidate for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. Patients who are prescribed treatments for their conditions and providers prescribing such services generally rely on third- party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our drugs unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our drugs. **59Outside the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost- containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and / or branded products available through parallel import to keep healthcare costs down.** A primary trend in the U. S. healthcare industry and elsewhere is cost containment. Third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Coverage and reimbursement may not be available for any drug that we commercialize and, if reimbursement is available, it is ~~58uncertain~~ **uncertain** what the level of reimbursement will be. Inadequate coverage and reimbursement may impact the demand for, or the price of, any drug for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our current and any future product candidates that we develop. Healthcare legislative reform measures may have a negative impact on our business and results of operations. In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post- approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U. S. pharmaceutical industry. The ACA has been subject to judicial and Congressional challenges. For example, on June 17, 2021 the U. S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Prior to the U. S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (" IRA ") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the " donut hole " under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out- of- pocket cost and through a newly established manufacturer discount program **, it also allows the U** . ~~It~~ **S. government to negotiate Medicare Part B and Part D pricing for certain high- cost drugs and biologics without generic or biosimilar competition, require companies to pay rebates to Medicare for drug prices that increase faster than inflation, and delay the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries. The implementation of the IRA** is **currently** ~~possible that the ACA will be~~ subject to ~~judicial~~ **ongoing litigation challenging the constitutionality of the IRA' s Medicare drug price negotiation program. The effect of IRA on** ~~or~~ **our business and** ~~Congressional challenges in~~ the ~~future~~ **healthcare industry in general is not yet known** . Other legislative changes have been proposed and adopted since the ACA was enacted, including aggregate

reductions to Medicare payments to providers of up to 2 % per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through ~~2031~~ **2032** , unless additional Congressional action is taken. ~~Under current legislation the actual reduction in Medicare payments will vary from 1 % in 2022 to up to 4 % in the final fiscal year of this sequester. Additionally~~ **60Additionally** , there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent congressional inquiries, Presidential executive orders and proposed and enacted federal and state legislation designed to bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for products. For example, in July 2021, the Biden administration released an executive order, " Promoting Competition in the American Economy, " with multiple provisions aimed at prescription drugs. In response to Biden' s executive order, on September 9, 2021, the U. S. Department of Health and Human Services (" HHS ") released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. In addition, the IRA, among other things, (1) directs HHS to negotiate the price of certain **high expenditure** single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although ~~they~~ **the** ~~may be~~ **Medicare drug price negotiation program is currently** subject to legal challenges **. HHS has and will continue to issue and update guidance as these programs are implemented** . It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. ~~Further~~ **In addition** , **in response to** the Biden ~~Administration~~ **administration** ~~released an additional~~ **' s October 2022** executive order **,** on ~~October~~ **February** 14, ~~2022~~ **2023** , ~~directing~~ HHS **released** ~~to submit~~ a report ~~on how~~ **outlining three new models for testing by** the Center for Medicare and Medicaid Innovation ~~can~~ **which will** be ~~further leveraged~~ **evaluated on their ability** to ~~test~~ **lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that they will continue to seek** new ~~models for lowering~~ **legislation measures to control** drug costs ~~for Medicare and Medicaid beneficiaries~~ . Moreover, changes to the political landscape in the United States may impact the market sentiment surrounding the pharmaceutical industry. ~~59We~~ **In addition, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost- effectiveness of our products to other available therapies. The Health Technology Assessment, or HTA, of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021 / 2282 on HTA, amending Directive 2011 / 24 / EU, was adopted in the EU. This Regulation, which entered into force in January 2022 will apply as of January 2025. It is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU Member States will continue to be responsible for assessing non- clinical (e. g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected. We** expect that these and 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 receive for any approved drug. Any reduction in reimbursement from Medicare or other ~~government~~ **comparable foreign** programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our drugs. 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. ~~If~~ **61If** we obtain approval to commercialize any approved products outside of the United States, a variety of risks associated with international operations could materially adversely affect our business. If any of our product candidates are approved for commercialization outside of the United States, we intend to enter into agreements with third parties to market them on a worldwide basis or in more limited geographical regions. We expect that we will be subject to additional risks related to entering into international business relationships, including: ● different regulatory requirements for drug approvals; ● reduced protection for intellectual property rights, including trade secret and patent rights; ● unexpected changes in tariffs, export controls, sanctions, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign taxes, including withholding of taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; ●

workforce uncertainty in countries where labor unrest is more common than in the United States; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; ● potential noncompliance with the U. S. Foreign Corrupt Practices Act, the U. K. Bribery Act 2010 and similar anti- bribery and anticorruption laws in other jurisdictions; ● business interruptions resulting from geopolitical actions, including war (such as Russia' s invasion of Ukraine **and the conflict between Hamas and Israel**) and terrorism, or natural disasters including earthquakes, hurricanes, floods and fires, economic or political instability, sanctions, or public health emergencies, ~~such as the novel COVID- 19 coronavirus~~ and related shelter- in- place orders, travel, social distancing and quarantine policies, boycotts, curtailment of trade and other business restrictions; and ● difficulty in importing and exporting clinical trial materials and study samples. We are subject to U. S. and certain foreign anti- corruption, anti- money laundering, export and import controls, and sanctions laws and regulations. Non- compliance with such laws can subject us to criminal and / or civil liability and harm our business. We are subject to the U. S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly ~~60and~~ -- **and** prohibit companies and their employees, agents, and contractors, from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. 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 and / or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, or other partners even if we do not explicitly authorize or have actual knowledge of such activities. ~~We~~ **62We** are also subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls. Export controls and trade sanctions laws and regulations may restrict or prohibit altogether the provision, sale, or supply of our product candidates to certain governments, persons, entities, countries, and territories, including those that are the target of comprehensive sanctions or an embargo. We cannot ensure that all of our employees, agents, contractors or those of our affiliates, will comply with all applicable laws and regulations. Violations of anti- corruption, anti- money laundering, import and export control, or sanctions laws and regulations could result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, breach of contract and fraud litigation, reputational harm, and other consequences. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidates that we may develop. We will face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials and will face an even greater risk if we commercialize any of our product candidates. If we cannot successfully defend ourselves against claims that our product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any product candidates that we may develop; ● injury to our reputation and significant negative media attention; ● initiation of investigations by regulators; ● withdrawal of clinical trial participants; ● significant time and expenses to defend the related litigation; ● diversion of management and scientific resources from our business operations; ● substantial monetary awards to trial participants or patients; ● loss of revenue; and ● the inability to commercialize any product candidates that we may develop. We currently hold limited product liability insurance coverage. We will need to purchase additional product liability insurance coverage as we expand our clinical trials, and if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. If we are unable to obtain insurance at an acceptable cost or otherwise protect against potential product liability claims, we will be exposed to significant liabilities, which may materially and adversely affect our business and financial position. If we are sued for any injury allegedly caused by our or our collaborators' products, our liability could exceed our total assets and our ability to pay the liability. A product liability claim or series of claims brought against us would decrease our cash and could cause our stock price to fall. ~~61We~~ **We** are subject to stringent and evolving U. S. and foreign laws, regulations, rules, contractual obligations, policies **, contractual** and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation **(including class actions) and mass arbitration demands** ; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences. In the ordinary course of business, we **collect, receive, store,** process **, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process)** personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third- party data. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal information by us and on our behalf. ~~In~~ **63In** the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, consumer protection laws (e. g. **,** Section 5 of the Federal Trade Commission Act) and other similar laws (e. g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of protected health information. ~~As another~~ **Several states have also enacted comprehensive data privacy laws, which either became effective in 2023 or will become effective within the next couple of years. These state comprehensive data privacy laws provide individuals with certain rights concerning their personal information, including the right to access, correct, or delete certain personal information, and opt- out of certain data processing activities, such as targeted advertising, profiling, and automated decision- making. One** example ~~,~~ **of** ~~the~~ **these**

comprehensive state data privacy laws is, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 (“ CPRA ”) (collectively, “ CCPA **”)** , **which** applies to the personal information of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such California residents to exercise certain rights related to their personal information **, such as those noted above** . The CCPA ~~allows~~ **provides** for administrative fines for noncompliance (up to $ 7, 500 per violation) and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal information we maintain about California residents. In addition, the CPRA expanded the CCPA’ s requirements, including by adding a new right for individuals to correct their personal information and establishing a new regulatory agency, the California Privacy Protection Agency, to implement and enforce the law ~~, which could increase the risk of enforcement~~ . **These new comprehensive** ~~Several other states have also enacted~~ data privacy laws ~~. For example, Virginia passed~~ **(including the CCPA) and individuals’ exercise of** ~~the~~ **their rights under** ~~Consumer Data Protection Act, Colorado passed the~~ **these laws may impact** ~~Colorado Privacy Act, Connecticut passed the Connecticut Data Privacy Act and Utah passed the Utah Consumer Privacy Act, all of which became or~~ **our** ~~will become effective in 2023~~ **business and ability to provide our products and services** . In addition, **other** data privacy and security laws have been proposed **and others have been passed** at the federal, state, and local levels in recent years. While some of these laws exempt data processed in the context of clinical trials, these developments may nonetheless further complicate compliance efforts **, and increase legal risk and compliance costs for us and the third parties upon whom we rely** . Outside the United States, an increasing number of laws, regulations, and industry standards apply to data privacy and security. For example, the **European Union’ s General Data Protection Regulation (** EU GDPR **)** and the **United Kingdom GDPR (** UK GDPR **) (collectively** , **GDPR)** impose strict requirements for processing personal information, and violators of these laws face significant penalties. For example, under ~~the EU~~ GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros **under the EU GDPR** (17. 5 million British Pounds under the UK GDPR) or 4 % of annual global revenue **, in either case** , whichever is greater, or we may be subject to private litigation related to processing of personal information brought by classes of data subjects or consumer protection organizations authorized at law to represent. In addition, the Swiss Federal Act on Data Protection, or ~~DPA~~ **FADP** , also applies to the collection and processing of personal information, including health- related information, by companies located in Switzerland, or in certain circumstances, by companies located outside of Switzerland. The ~~DPA~~ **FADP** has been revised ~~,~~ and **adopted by the Swiss Parliament. Companies must comply with** the revised version **of the FADP** and its revised ordinances ~~will enter into~~ **, which may result in an increase of costs of compliance, risks of noncompliance and penalties** ~~force~~ -- **for noncompliance** ~~in September 2023~~ . In ~~addition~~ **the ordinary course of business** , we may ~~be unable to~~ transfer personal information from Europe and other jurisdictions to the United States or other countries ~~due to data localization requirements or limitations on cross- border data flows~~ . Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal information to other countries. In particular, the European Economic Area (**“** EEA **”**), the ~~United Kingdom (~~ UK ~~)~~ and Switzerland have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws it **generally** believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross- border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and UK to the United States in compliance with law, such as the EEA and UK’ s standard contractual clauses **, the UK’ s International Data Transfer Agreement / Addendum, and the EU- U. S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U. S.- based organizations who self- certify compliance and participate in the Framework)** , these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal information to the United States. If there is no lawful manner for us to transfer personal information from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally- compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions **(such as Europe)** at significant expense, increased exposure to regulatory actions, substantial ~~62fines~~ -- **fines** and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal information necessary to operate our business. Some European regulators have prevented companies from transferring personal information out of Europe for allegedly violating the EU ~~GDPR~~ **64GDPR** ’ s cross- border data transfer limitations **. For example, in May 2023, the Irish Data Protection Commission determined that a major social media company’ s use of the standard contractual clauses to transfer personal data from Europe to the United States was insufficient and levied a 1. 2 billion Euro fine against the company and prohibited the company from transferring personal data to the United States. Our employees and personnel may use generative artificial intelligence (“ AI ”) technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages** . In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. Furthermore, we publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self- regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to

investigation, enforcement actions by regulators, or other adverse consequences. Obligations related to data privacy and security **(and consumers' data privacy expectations)** are quickly changing in an increasingly stringent fashion, creating some uncertainty as to the effective future legal framework. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires significant resources and may necessitate changes to our information technologies, systems, and practices and to those of any third parties that process personal information on our behalf. Although we endeavor to comply with all applicable data privacy and security obligations, we may at times fail (or be perceived to have failed) to do so. Moreover, despite our efforts, our personnel or third parties upon whom we rely may fail to comply with such obligations, which could negatively impact our business operations and compliance posture. For example, any failure by a third- party processor to comply with applicable law, regulations, or contractual obligations could result in adverse effects, and proceedings against us by governmental entities or others. If we or the third parties upon which we rely fail, or are perceived to have failed, to address or comply with data privacy and security obligations, we could face significant consequences. These consequences may include, but are not limited to, government enforcement actions (e. g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class **actions** ~~- related claims~~) **and mass arbitration demands** ; additional reporting requirements and / or oversight; bans on processing personal information; orders to destroy or not use personal information; and imprisonment of company officials. **In particular, plaintiffs have become increasingly more active in bringing privacy- related claims against companies, including class actions and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.** Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations. **Issues relating to the use of artificial intelligence and machine learning could adversely affect our business and operating results. Magellan ™ is our platform technology that leverages AI- supported structural biology, proprietary algorithms and physics- based models powered by the cutting- edge CSCS Swiss National Supercomputing Centre to explore novel allosteric binding pockets on disease- implicating proteins. Issues relating to the use of new and evolving technologies such as AI and machine learning may cause us to experience brand or reputational harm, competitive harm, legal liability, and new or enhanced governmental or regulatory scrutiny, and we may incur additional costs to resolve such issues. As with many innovations, AI presents risks and challenges that could undermine or slow its adoption, and therefore harm our business. For example, perceived or actual technical, legal, compliance, privacy, security, ethical 65or other issues relating to the use of AI may cause public confidence in AI to be undermined, which could harm our business reputation. In addition, litigation or government regulation related to the use of AI may also adversely impact our and others' abilities to develop and offer products that use AI, as well as increase the cost and complexity of doing so. Developing, testing and deploying AI systems may also increase the cost profile of our product offerings due to the nature of the computing costs involved in such systems, which could impact our project margin and adversely affect our business and operating results. Further, market demand and acceptance of AI technologies are uncertain, and we may be unsuccessful in our product development efforts.** If our information technology systems or data, or those of third parties upon which we rely, ~~or our data~~ are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences. In the ordinary course of our business, we or the third parties upon which we rely process proprietary, confidential, and sensitive data, including personal information (such as health- related data), **business plans, financial information,** intellectual property, and trade secrets (collectively, sensitive information) ~~.~~ **, and, as a result, we and the third parties upon which we rely face a variety of evolving** ~~Cyberattacks~~ **threatsCyberattacks** , malicious internet- based activity, ~~and~~ online and offline fraud **, and other similar activities** are prevalent and continue to increase. These threats are becoming increasingly difficult to detect. These threats come from a variety of sources, including traditional computer " hackers, " threat actors, " hacktivists, " **organized crime threat actors,** personnel (such as through theft or misuse), sophisticated nation states, and nation- state- supported actors. Some actors now engage and are expected to continue to engage in cyber- attacks, including without limitation nation- state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, including the war in Ukraine **and the conflict between Hamas and Israel** , we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including cyber- attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social- engineering attacks (including through **deep fakes, which may be increasingly more difficult to identify as fake, and** phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial- of- service attacks **,** ~~(such as~~ credential ~~63stuffing~~ **stuffing** ~~)~~, credential harvesting, personnel misconduct or error, ransomware attacks, supply- chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures **, attacks enhanced or facilitated by AI** , and other similar threats. In particular, ransomware attacks, including by organized criminal threat actors, nation- states, and nation- state- supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions in our operations **, ability to provide our products or services** , loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws

or regulations prohibiting such payments. Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working from home, while in transit and in public locations. Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program. **In addition, our reliance on third- party service providers could introduce new cybersecurity risks and vulnerabilities, including supply- chain attacks, and other threats to our business operations.** We rely upon third- party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, third- party providers of cloud- based infrastructure, encryption and authentication technology, employee email, content delivery to customers, and other functions **. We also rely on third- party service providers to provide other products, services, or otherwise to operate our business** . Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information ~~security~~ **66security** measures in place. If our third- party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third- party service providers fail to satisfy their privacy or security- related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Additionally, supply- chain attacks have increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or our third- party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third- party information technology systems that support us and our services. Any of the previously identified or similar threats could cause a security incident or other interruption. A security incident or other interruption could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business. We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Certain data privacy and security obligations may require us to implement and maintain specific security measures, industry- standard or reasonable security measures to protect our information technology systems and sensitive information. While we **and our third party services providers** have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities in our information technology systems, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. ~~These~~ **Un- remediated high risk or critical** vulnerabilities pose material risks to our business ~~. Despite our efforts to identify and address vulnerabilities, if any, in our information technology systems, our efforts may not be successful~~ . Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities. Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences. If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences. These consequences may include: government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and / or oversight; restrictions on processing sensitive information (including personal information); litigation (including class ~~claims~~ **actions**); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. ~~64Our~~ -- **Our** contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations **. In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position. Additionally, our sensitive Company information could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnels', or vendors' use of generative AI technologies. Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non- performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank (" SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (" FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair our ability to access near- term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in 67economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile**

business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short- term liquidity risk and make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers, and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget. In addition, any further deterioration in the macroeconomic economy or financial services industry, could lead to losses or defaults by our suppliers, which in turn, could have a material adverse effect on our current and / or projected business operations and results of operations and financial condition . Risks Related to Ownership of Our Common StockThe market price for our common stock has been and likely will continue to be volatile, and your investment in our securities could decline in value. Our stock price has been highly volatile since our IPO and is likely to continue to be volatile. The stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. ~~In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of the impact of the COVID- 19 pandemic and other market factors.~~ The market price for our common stock may be influenced by many factors, including: ● results from, and any delays in our preclinical studies and any other future clinical development programs, including any delays related to the health epidemics or pandemics ~~such as the COVID- 19 pandemic~~ or other factors outside of our control; ● actual or anticipated changes in estimates as to financial results, development timelines and other company milestones or recommendations by securities analysts; ● announcements of changes to our operational focus, including changes to the programs we are actively developing; ● announcements by our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments; ● announcements of technological innovations or new products by us or our competitors; ● announcement of FDA **or comparable foreign regulatory authority** approval or disapproval of our product candidates or other product- related actions; ● developments involving our discovery efforts and clinical trials; ● developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees; ● developments involving our efforts to commercialize our products, including developments impacting the timing of commercialization; ● announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general; ● public concerns as to the safety or efficacy of our product candidates or our competitors' products; ● changes in government regulation of the pharmaceutical or medical industry; **68** ● changes in the reimbursement policies of third- party insurance companies or government agencies; ● actual or anticipated fluctuations in our operating results; ● changes in financial estimates or recommendations by securities analysts; ● developments involving corporate collaborators, if any; ~~65~~ ● changes in accounting principles; ● general economic, industry and market conditions, ~~increasing~~ **heightened** inflation and measures taken by central banks to combat inflation, exchange rate fluctuations, supply chain disruptions and increasing commodity, energy and fuel prices; ● the impact of political instability, natural disasters, events of terrorism and / or war, such as the war **in Ukraine and the conflict** between ~~Ukraine~~ **Hamas** and ~~Russia~~ **Israel** , and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China; and ● the loss of any of our key scientific or management personnel. In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities and in particular, biotechnology and pharmaceutical companies. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management' s attention and resources, which could adversely affect our business, operating results and financial condition. Stock market volatility and declines in the price of our common stock also increase the likelihood that we may fail to meet the minimum price requirements for continued listing on the Nasdaq Global Market. If the Nasdaq Global Market delists our securities from trading on its exchange for failure to meet the listing standards, we and our stockholders could face significant negative consequences, including: ● limited availability of market quotations for our securities; ● a determination that the common stock is a " penny stock " which will require brokers trading in the common stock to adhere to more stringent rules, possibly resulting in a reduced level of trading activity in the secondary trading market for shares of common stock; ● a limited amount of analyst coverage; and ● a decreased ability to issue additional securities or obtain additional financing in the future. We incur and will continue to incur increased 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, and particularly after we will no longer qualify as an emerging growth company, we incur and will continue to incur significant legal, accounting and other expenses that we did not incur previously. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on U. S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These rules and regulations are often subject to varying interpretations, 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. ~~While~~ **69While** we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, we are required, pursuant to Section 404 of the Sarbanes- Oxley Act, to furnish a report by management on, among other things, the

effectiveness of our internal control over financial reporting. The process to document and evaluate our internal control over financial reporting, is both costly and challenging. In this regard, we need to continue to dedicate internal resources, validate through testing that controls are functioning as designed and maintain a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial ~~66reporting~~ **reporting** is effective as required by Section 404. 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. We are an " emerging growth company, " and the reduced reporting requirements applicable to emerging growth companies may make our common stock less attractive to investors. We qualify as an " emerging growth company, " as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These provisions include, but are not limited to: being permitted to report only two years of audited financial statements and only two years of related selected financial data and management' s discussion and analysis of financial condition and results of operations disclosure; an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act; reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements and proxy statements; and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. As a result, the information we provide might be different from the information that is available for other public companies. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and the market price of our common stock may be more volatile. We will remain an emerging growth company until the earliest of (i) December 31, 2026, (ii) the first fiscal year after our annual gross revenue exceeds $ 1. 07 billion, (iii) the date on which we have, during the immediately preceding three- year period, issued more than $ 1. 00 billion in non- convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non- affiliates exceeds $ 700 million as of the end of the second quarter of that fiscal year. Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited. We have incurred substantial losses during our history, do not expect to become profitable in the foreseeable future and may never achieve profitability. **Net operating losses, or NOLs, of our Swiss subsidiary can be carried forward for seven years and will begin to expire commencing from 2025 for the NOLs generated in 2017 under applicable Swiss tax law.** Under applicable U. S. federal income tax law, our federal ~~net operating loss, or~~ NOL ~~,~~ carryforwards generated in tax years beginning on or before December 31, 2017, are only permitted to be carried forward for 20 years. Our federal NOL carryforwards generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOL ~~carryforward~~ **carryforwards** may be limited. It is uncertain if and to what extent various states will conform to U. S. federal income tax law with respect to the treatment of NOL carryforwards. In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, if a corporation undergoes an " ownership change, " generally defined as a greater than 50 % change (by value) in its equity ownership over a three- year period, the corporation' s ability to use its pre- change NOL carryforwards ~~,~~ and other pre- change tax attributes (such as research tax credits) to offset its post- change income or taxes may be limited. We have experienced ownership changes in the past. In addition, we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside of our control. As a result, if we earn net taxable income, our ability to use our pre- change NOL carryforwards to offset taxable income may be limited, which could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of ~~NOLs~~ **NOL** carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed by us. ~~Changes~~ **70Changes** in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition, or results of operations. New tax laws, statutes, rules, regulations, or ordinances could be enacted at any time. For instance, the recently enacted **IRA** ~~Inflation Reduction Act~~ imposes, among other rules, a 15 % minimum tax on the book income of certain large corporations and a 1 % excise tax on certain corporate stock repurchases. Further, existing tax laws, statutes, rules, regulations, or ordinances could be interpreted differently, changed, repealed, or modified at any time. Any such enactment, interpretation, change, repeal, or modification could adversely affect us, possibly with retroactive effect. In particular, changes in corporate tax rates, the realization of our net deferred tax assets, the taxation of foreign earnings, and the deductibility of expenses under the Tax **Cuts and Jobs** Act, as amended by the Coronavirus Aid, Relief, and ~~67Economic~~ **Economic** Security Act or any future tax reform legislation, could have a material impact on the value of our deferred tax assets, result in significant one- time charges, and increase our future tax expenses. We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment. We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend

to sell, substantial amounts of our common stock in the public market, the market price of our common stock could decline significantly. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock. We also expect that significant additional capital may be needed in the future to continue our research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. The rights of the holders of our securities may be impaired by the potential issuance of preferred stock. Our articles of incorporation give our board of directors the ability to designate and issue preferred stock in one or more series. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the relative voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could have the effect of discouraging, delaying or preventing a change of control of us. The possible impact on takeover attempts could adversely affect the price of our securities. Although we have no present intention to designate any series, or issue any shares, of preferred stock, other than pursuant to the IPO, we may do so in the future. If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. Our research coverage by industry and financial analysts is currently limited. Even if our analyst coverage increases, if one or more of the analysts who cover us downgrade our ~~stock~~ **71stock** , our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. ~~68Anti --~~ **Anti** - takeover provisions in our organizational documents and Delaware law might discourage or delay attempts to acquire us that you might consider favorable. Our amended and restated certificate of incorporation (the " Amended Charter ") and amended and restated bylaws (the " Amended Bylaws ") contain provisions that may make the merger or acquisition of us more difficult without the approval of our board of directors. Among other things, these provisions: ● allow us to authorize the issuance of undesignated preferred stock in connection with a stockholder rights plan or otherwise, the terms of which may be established and the shares of which may be issued without stockholder approval, and which may include super voting, special approval, dividend, or other rights or preferences superior to the rights of the holders of common stock; ● provide that our bylaws may be amended or repealed only by a majority vote of our board of directors or by the affirmative vote of the holders of at least 66 2 / 3 % of the votes which all our stockholders would be entitled to cast in any annual election of directors; and ● establish advance notice requirements for nominations for elections to our board of directors or for proposing matters that can be acted upon by stockholders at stockholder meetings. Further, as a Delaware corporation, we are also subject to provisions of Delaware law, which may impair a takeover attempt that our stockholders may find beneficial. These anti- takeover provisions and other provisions under Delaware law could discourage, delay, or prevent a transaction involving a change in control of us, including actions that our stockholders may deem advantageous, or could negatively affect the market price of our common stock. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing and to cause us to take other corporate actions our stockholders desire. Our Amended Charter provides that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for substantially all disputes between us and our stockholders and federal district courts will be the sole and exclusive forum for Securities Act claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our Amended Charter provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, or other employees to us or to our stockholders; (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law (the " DGCL "), the Amended Charter or the Amended Bylaws or as to which the DGCL confers exclusive jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim governed by the internal affairs doctrine, provided that the exclusive forum provisions will not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction. Our Amended Charter ~~will~~ further ~~provide~~ **provides** that, unless we consent in writing to the selection of an alternative forum, the federal district courts are the sole and exclusive forum for the resolution of any complaint asserting a right under the Securities Act, subject to a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. The choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Alternatively, if a court were to find the choice of forum provisions contained in our Amended Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. **72** ~~Provisions in our organizational documents regarding exculpation and indemnification of our directors and officers may result in substantial expenditures by us and may discourage lawsuits against our directors and officers. Our Amended Charter and Amended Bylaws provide for the elimination, to the maximum extent permissible under Delaware law, of the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty. These provisions may discourage us, or our stockholders through derivative litigation, from bringing a lawsuit~~

~~against any of our current or former directors or officers for any breaches of their fiduciary duties, even if such legal actions, if successful, might benefit us or our stockholders. In addition, our Amended Charter and 69~~