Risk Factors Comparison 2025-03-06 to 2024-03-22 Form: 10-K

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The following risk factors are not exhaustive and investors are encouraged to perform their own investigation with respect to the business, prospects, financial condition and operating results of Revelation and our business, prospects, financial condition and operating results. You should carefully consider the following risk factors in addition to the other information included in this Annual Report on Form 10- K, including our audited financial statements and related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " We may face additional risks and uncertainties that are not presently known to us, or that we currently deem immaterial, which may also impair our business, prospects, financial condition or operating results. The following discussion should be read in conjunction with our audited financial statements and notes to the financial statements included herein. Unless the context otherwise requires, references herein to " Program Products " refers to Revelation' s GEM- ~~SSI, GEM-~~ AKI ~~and~~ **,** GEM- CKD **, and GEM- PSI** programs. Risks Related to Our Business Although our financial statements have been prepared on a going concern basis, we have a limited operating history and no products approved for commercial sale. We have incurred net losses since our inception, we anticipate that we will continue to incur significant losses for the foreseeable future, and even if we were to generate revenue, we may never achieve or maintain profitability. We are a clinical stage biopharmaceutical company with a limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability. We commenced our operations in May 2020, and, to date, our operations have been limited to organizing and staffing our Company, business planning, raising capital, conducting research and development activities, including early clinical study, and providing general and administrative support for these operations. Investment in biopharmaceutical product development and diagnostic device is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate and / or diagnostic device will fail to demonstrate adequate effect and / or an acceptable safety profile, gain regulatory approval or become commercially viable. We currently have no products approved for commercial sale, we have not generated any revenue from product sales to date and we continue to incur significant research and development and other expenses related to our ongoing operations. We have limited experience as a Company conducting clinical studies and no experience as a Company commercializing any products. We are not profitable and have incurred net losses since our inception. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~25~~ **40** . 5 million. Consequently, predictions about our future success or viability may not be as accurate as they would be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We have spent, and expect to continue to spend, significant resources to fund research and development of, conduct clinical studies, and seek regulatory approvals for, our Program Products, and any future product candidates. We expect to incur substantial and increasing operating losses over the next several years as our research, development, preclinical testing and clinical study activities increase. As a result, our accumulated deficit will also increase significantly. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have, had and will continue to have a material adverse effect on our stockholders' equity and working capital. **We** ~~Additionally, taking into consideration the net proceeds of approximately $ 5. 4 million received in connection with the public offering completed in February of 2024, we~~ do not anticipate that our current cash and cash equivalents balance will be sufficient to sustain operations within one- year after the date that our audited financial statements for December 31, ~~2023~~ **2024** were issued, which raises substantial doubt about our ability to continue as a going concern. In our own required quarterly assessments, we may continue to conclude that there is substantial doubt about our ability to continue as a going concern, and future reports from our independent registered public accounting firm may also contain statements expressing substantial doubt about our ability to continue as a going concern. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about going concern, investors or other financing sources may be unwilling to provide additional funding on commercially reasonable terms or at all. Our ability to raise more equity capital will depend in part on our ability to amend our certificate of incorporation to authorize additional shares of common stock. The net losses we incur may fluctuate significantly from quarter- to- quarter such that a period- to- period comparison of our results of operations may not be a good indication of our future performance. We have no products approved for marketing in any jurisdiction, **and** our Program Products are in early stages of development. We have never generated any revenue from product sales. Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic collaboration partners, to successfully complete the development of and obtain the regulatory and marketing approvals necessary to commercialize one or more of our Program Products. We do not anticipate generating revenue from product sales in the next couple of years. Even if we eventually generate product revenue, we may never be profitable and, if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. We may not be able to raise additional funding on acceptable terms, or at all. Failure to obtain funding on acceptable terms and on a timely basis may require us to curtail, delay or discontinue our product development efforts or other operations. Raising additional funding may cause dilution to our stockholders. Developing our Program Products is expensive, and we expect our research and development expenses to increase substantially in connection with our ongoing activities, particularly as we advance our Program Products through clinical studies, manufacturing and regulatory approval. We expect to finance future cash needs through public or private equity or debt offerings or product collaborations. We do not have any committed external source of funds. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all,

and the terms of any financing may adversely affect the interests or rights of our stockholders. Even if we believe that we have sufficient funds for our current or future operating plans, we may seek additional capital if market conditions are favorable or if we have specific strategic considerations. The issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may affect the value of your investment. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of such securities may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt. If we do not raise additional capital, we may not be able to expand our operations or otherwise capitalize on our business opportunities, our business and financial condition will be negatively impacted, and we may need to: • significantly delay, scale back or discontinue research and discovery efforts and the development or commercialization of our Product Programs and future program candidates or cease operations altogether; • seek strategic alliances for research and development programs when we otherwise would not, or at an earlier stage than we would otherwise desire or on terms less favorable than might otherwise be available; or • relinquish, or license on unfavorable terms, our rights to technologies or any product candidates that we otherwise would seek to develop or commercialize ourselves. Unfavorable global economic conditions, including any adverse macroeconomic conditions or geopolitical events, including the COVID- 19 pandemic, the conflict between Ukraine and Russia, and recent bank failures affecting the financial services industry, could adversely affect our business, financial condition, results of operations or liquidity, either directly or through adverse impacts on certain of the third parties on which we rely to conduct certain aspects of our preclinical studies or clinical trials. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks, and uncertainty about economic and geopolitical stability. A severe or prolonged economic downturn, or additional global financial or political crises, could result in a variety of risks to our business, including delayed clinical trials or preclinical studies, delayed approval of our product candidates, delayed ability to obtain patents and other intellectual property protection, weakened demand for our product candidates, if approved, or our ability to raise additional capital when needed on acceptable terms, if at all. The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. A weak or declining economy also could strain our suppliers, possibly resulting in supply disruption. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn. Risks Related to the Product Development, Regulatory Approval, Manufacturing andCommercialization of Our Program Products and Product Candidates If preclinical studies or clinical studies for our Program Products are unsuccessful or delayed, we will be unable to meet our future development goals. Conducting clinical studies for any product candidates for approval in the United States requires filing an IND and reaching agreement with the FDA on clinical protocols, finding appropriate clinical sites and clinical investigators, securing approvals for such studies from the IRB at each such site, manufacturing clinical quantities of product candidates and supplying drug product or devices to clinical sites. Currently, we do not have an active IND with the FDA in the United States for our Program Products. If our IND is not approved by the FDA, our clinical development timeline may be negatively impacted, and any future clinical programs may be delayed or terminated. Even if the clinical studies are approved by FDA or other regulatory agencies, clinical study is expensive and can take many years to complete, and its outcome is inherently uncertain. A failure of one or more of our clinical studies can occur at any time during the clinical study process. We do not know whether future clinical studies, if any, will begin on time, need to be redesigned, enroll an adequate number of patients on time or be completed on schedule, if at all. Clinical studies can be delayed, suspended or terminated for a variety of reasons, including failure to (i) generate sufficient positive preclinical and clinical data; (ii) recruit CROs, clinical investigators and patients in a timely manner; (iii) manufacture sufficient quantities at the required quality of Program Products for use in clinical studies; (iv) raise sufficient capital to fund a study; (v) comply with all applicable regulatory requirements, whether in the United States or elsewhere, and (vi) obtain successful regulatory approval from regulatory authorities like the FDA. If we experience delays in completing any clinical study of our Program Products or successfully obtaining regulatory approval, the commercial prospects of our Program Products may be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. In addition, any delays in completing our clinical studies will increase our costs, slow down the development and approval process of our Program Products, and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business and financial condition. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates. Drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes, and the results of prior preclinical or clinical studies are not necessarily predictive of our future results. Our clinical studies may fail to adequately demonstrate the safety and efficacy of our Program Products or any future product candidates. We are focused on the development of GEM- ~~SSI, GEM-~~ AKI ~~and~~ **,** GEM- CKD, **and GEM-PSI** which are in pre- clinical development working towards early clinical trials. There is a high failure rate for product candidates proceeding through clinical studies. Failure can occur at any time during the clinical study process. Many companies in the pharmaceutical industry have suffered significant setbacks in late- stage clinical studies even after achieving promising results in preclinical testing and earlier- stage clinical studies. Data obtained from preclinical and clinical activities are subject to varying interpretations, which may delay, limit or prevent regulatory approval. In addition, we may experience regulatory delays

or rejections as a result of many factors, including changes in regulatory policy during the development period of our Program Products. Success in preclinical testing and early clinical studies does not ensure that later clinical studies will generate the same results or otherwise provide adequate data to demonstrate the efficacy and safety of a product candidate. Frequently, product candidates that have shown promising results in early clinical studies have subsequently suffered significant setbacks in later clinical studies. If we are unable to successfully demonstrate the safety and efficacy of our Program Products or other future product candidates and receive the necessary regulatory approvals, our business will be materially harmed. The Clinical Studies of our Program Products' have been and are planned to be conducted outside the United States, and the FDA or comparable foreign regulatory authorities may not accept data from such studies. We currently have not conducted any clinical studies in the United States to date. We have conducted and we plan to conduct additional clinical studies outside the United States, including Europe, Australia, or other foreign jurisdictions. The acceptance of clinical study data by the FDA from clinical studies conducted outside the United States may be subject to certain conditions. In cases where data from clinical studies conducted outside the United States are intended to serve as the sole bases for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practices, (ii) the studies were performed by clinical investigators of recognized competence and (iii) the data may be considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Additionally, the FDA' s clinical study requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions where the studies are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from studies conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional studies, which would be costly and time- consuming and delay aspects of our business plan, and may result in our Program Products' not receiving regulatory approval or clearance for commercialization in the applicable jurisdiction. As an organization, we have never conducted pivotal clinical studies, and we may be unable to do so for any Program Products we may develop. We will need to successfully complete pivotal clinical studies in order to obtain the approval of the FDA, the EMA or other regulatory agencies to market any of our Program Products. Carrying out later- stage clinical studies and the submission to the FDA of a successful NDA is a complicated process. As an organization, we have not previously conducted any later stage or pivotal clinical studies and have limited experience in preparing, submitting and prosecuting regulatory filings. We may be unable to conduct clinical studies at preferred sites, enlist clinical investigators, enroll sufficient numbers of participants or begin or successfully complete clinical studies in a timely fashion, if at all. In addition, the design of a clinical study can determine whether its results will support approval of a product, and flaws in the design of a clinical study may not become apparent until the clinical study is well advanced. Because we have limited experience as a company designing clinical studies, we may be unable to successfully and efficiently execute and complete necessary clinical studies in a way that leads to successful regulatory submission and approval. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical studies, could prevent us from or delay us in commercializing our Program Products. We rely on third parties to conduct certain elements of our preclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our Program Products. **In addition, Congress recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other " pivotal study " of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our product candidates has reached Phase 3 of clinical development, we must submit a diversity action plan to the FDA by the time we submit a Phase 3 trial, or pivotal study, protocol to the agency for review, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 trial for our product candidates or what specific information FDA will expect in such plans. However, initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 trial for our product candidates, and we may experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.** We may find it difficult to enroll patients in our clinical studies, which could delay or prevent us from proceeding with clinical studies. Identifying and qualifying patients to participate in clinical studies of our product candidates is critical to our success. The timing of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing our Program Products, and we may experience delays in our clinical studies if we encounter difficulties in enrollment. Patient enrollment and retention in clinical studies depends on many factors, including the size of the patient population, number and location of the clinical sites, significant adverse events or other side effects observed, if any, the nature of the study protocol, our ability to recruit clinical study investigators with the appropriate competencies and experience, the existing body of safety and efficacy data with respect to the study drug, the number and nature of competing treatments and ongoing clinical studies of competing drugs for the same indication, the proximity of patients to clinical sites, clinicians' and patients' perceptions as to the potential advantages of the Program Products being studied in relation to other available therapies, including any drugs that may be approved for the indications we are investigating, the eligibility criteria for the study, our ability to obtain and maintain patient consents and the risk that patients enrolled in clinical studies will drop out of the studies before completion. In addition, our competitors, some of whom have significantly greater resources than we do, are conducting clinical studies for the same indications and seek to enroll patients in

their studies that may otherwise be eligible for our clinical studies or studies, which could lead to slow recruitment and delays in our clinical programs. Further, since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical studies at the same clinical study sites that some of our competitors use, which could further reduce the number of patients who are available for our clinical studies in these sites. Our inability to enroll sufficient number of patients for our clinical studies would result in significant delays or may require us to abandon one or more clinical studies altogether. If we are unable to enroll sufficient number of patients that will complete clinical testing, we will be unable to seek or gain marketing approval for our Program Products and any future product candidates and our business will be harmed. Even if we are able to enroll a sufficient number of patients in our clinical studies or studies, delays in patient enrollment may result in increased costs or may affect the timing or outcome of our clinical studies, which could prevent completion of these studies and adversely affect our ability to advance the development of our Program Products and any future product candidates. Our Program Products and the administration of our Program Products may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any. The severity and frequency of undesirable side effects caused by our Program Products, could cause us or regulatory authorities to interrupt, delay or halt clinical studies and could result in a more restrictive label, delay or denial of regulatory approval by the FDA or other regulatory agencies. Results of our studies could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our clinical studies could be suspended or terminated, and the FDA or other regulatory agencies could order us to cease further development of or deny or withdraw approval of our product candidates for any or all targeted indications. Moreover, during the conduct of clinical studies, patients report changes in their health, including illnesses, injuries and discomforts, to their study doctor. Often, it is not possible to determine whether or not the product candidate being studied caused these conditions. Drug- related, drug product- related, formulation- related and administration- related side effects could affect patient recruitment, the ability of enrolled patients to complete the clinical study or result in potential product liability claims, which could exceed the insurance coverage. Additionally, if one or more of our Program Products receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result. If we or others identify undesirable or unacceptable side effects caused by our Program Products or any future product candidates or products: • we may be required to modify, suspend or terminate our clinical studies; • we may be required to modify or include additional dosage and administration instructions, warnings and precautions, contraindications, boxed warnings, limitations, restrictions or other statements in the product label for our approved products, or issue field alerts to physicians and pharmacies; • we may be required to conduct costly additional clinical studies; • we may be subject to limitations on how we may promote our approved products; • sales of our approved products may decrease significantly; • regulatory authorities may require us to take our approved products off the market; • we may be subject to regulatory investigations, government enforcement actions, litigation or product liability claims; and • our products may become less competitive, or our reputation may suffer. Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our clinical studies, which are based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or studies. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. In addition, adverse changes between interim data and final data could significantly harm our business and prospects. Additional disclosure of interim data by us or by our competitors in the future could also result in volatility in the price of our common stock after this offering. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our Company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise, appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, drug candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our Program Products or any future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Even if we complete the necessary clinical studies, we cannot predict when, or if, we will obtain regulatory approval to commercialize any of our Program Products, and the approval may be for a more narrow indication than we seek or be subject to other limitations or restrictions that limit its commercial profile. Our Program Products have not received regulatory approval. We do not expect our Program Products or any future product candidate to be commercially available for years, if at all. Our Program Products are, and any future product candidate will be subject to strict regulation by regulatory authorities in the United States and in other countries. We cannot commercialize a product candidate or diagnostic

device until the appropriate regulatory authorities have reviewed and approved such product candidate or diagnostic device. Even if our current or future Program Products meet safety and efficacy endpoints in pivotal clinical studies, the regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non- approval or restrictions on approval. This may include approval of a product candidate for more limited indications than requested or they may impose significant limitations in the form of warnings. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical studies and the review process. Our business depends on the success of our Program Products, including obtaining regulatory approval to market our product candidates in the United States and / or other major foreign markets such as the EU. We are focusing our time and financial resources in the clinical development of GEM- ~~SSI, GEM-~~ AKI ~~and~~ **,** GEM- CKD **, and GEM- PSI** . If we cannot successfully develop, obtain regulatory approval for, and commercialize our Program Products, we may not be able to continue our operations. The future regulatory approval and commercial success of our Program Products are subject to a number of risks, including the following: • we may not have sufficient financial and other resources to complete the necessary clinical studies for our Program Products, including, but not limited to, the clinical studies needed to obtain regulatory approval for commercialization; • we may not be able to obtain regulatory authorization to proceed with various clinical studies in the United States, and even if we are able to proceed with clinical studies, the regulatory authorities may limit, delay, or put our clinical studies on hold; • we may not be able to obtain adequate evidence from our clinical studies for our Program Products; • the results of our clinical studies may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for marketing approval; • we cannot be certain of the number of types of clinical studies and non- clinical studies that the regulatory agencies will require in order to approve our Program Products; • the data from clinical studies conducted outside of the United States may not be accepted by the FDA or other regulatory authorities; • patients in our clinical studies may suffer serious adverse events for reasons that may or may not be related to our Program Products, which could delay or prevent further clinical development; • the regulatory agencies may find deficiencies without manufacturing processes or facilities; • the CROs, that we retain to conduct our clinical studies may take actions outside of our control that materially adversely impact our clinical studies; • the regulatory agencies may not approve the formulation, labeling or specifications of GEM- ~~SSI, GEM-~~ AKI, GEM- CKD **, GEM- PSI,** or other future product candidates; • the regulatory agencies may change their approval policies or adopt new regulations; • if approved, our Program Products will likely compete with products that may reach approval for the same indication or use prior to our Program Products, products that are currently approved and the products that are currently marketed products; and • we may not be able to obtain, maintain or enforce our patents and other intellectual property rights. Of the large number of drugs and devices in development in the pharmaceutical industry, only a small percentage results in the submission of a marketing authorization to the FDA or comparable foreign regulatory authorities and even fewer are approved for commercialization. Furthermore, even if we do receive regulatory approval to market our Program Products, any such approval may be subject to limitations on the indicated uses or patient populations for which we may market the products. Accordingly, even if we are able to obtain the requisite financing to continue to fund our development programs, we may be unable to successfully develop or commercialize our Program Products. If we or any of our future development collaborators are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our Program Products, we may not be able to generate sufficient revenue to continue our business. Disruptions at the FDA and other national and foreign government authorities caused by funding shortages or global health concerns, such as COVID- 19, could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA' s and foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s and comparable foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and comparable foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government authorities that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other national and foreign authorities also may slow the time necessary for new biologics or modifications to approved biologics to be reviewed and / or approved by necessary government authorities, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U. S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on- site inspections of domestic manufacturing facilities subject to a risk- based prioritization system. The FDA utilized this risk- based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA began conducting voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities in circumstances where the FDA determines that such remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities. Since that time, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID- 19 pandemic. Regulatory authorities outside the United States have adopted similar restrictions

or other policy measures in response to the COVID- 19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Even if we obtain regulatory approval for a product candidate, our products and business will remain subject to ongoing regulatory obligations and review. Even if our Program Products are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, distribution, promotion, sampling, record- keeping, conduct of post- marketing studies and submission of safety, efficacy and other post- market information, including both federal and state requirements in the United States and comparable requirements outside of the United States. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, quality of product or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring recall or withdrawal of the product from the market. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP, regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with applicable regulatory requirements, or undesirable side effects caused by such products are identified, a regulatory agency may: • issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings about such product; • mandate modification to promotional materials or require us to provide corrective information to healthcare practitioners; • require that we conduct post- marketing studies; • require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific action and penalties for noncompliance; • seek an injunction or impose civil or criminal penalties or monetary fines; • suspend marketing of, withdraw regulatory approval of or recall such product; • suspend any ongoing clinical studies; • refuse to approve pending applications or supplements to applications filed by us; • suspend or impose restrictions on operations, including costly new manufacturing requirements; or • seize or detain products, refuse to import or export products or require us to initiate a product recall. The occurrence of any event or penalty described above may inhibit our ability to commercialize our products and generate product revenue. If one or more of our Program Products is approved for marketing in the United States or other countries, we may be subject, directly or indirectly, to United States or other countries equivalent federal and state healthcare fraud and abuse laws, false claims laws, physician payment transparency laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties. Even if we obtain FDA or other comparable regulatory agencies approval for any of our Program Products and begin commercializing those products in the United States or other countries, our operations may be directly or indirectly through our relationships with physicians, patients, third- party payors and customers, subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business or financial arrangements and relationships through which we research, market, sell and distribute our Program Products. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, among others, the United States Anti-Kickback Statute, the False Claims Act, the United States Health Insurance Portability and Accountability Act of 1996, and the Sunshine Act and analogous state laws. Ensuring that our internal operations and business arrangements with third parties comply with all applicable healthcare laws and regulations will likely be costly. Legislative or regulatory healthcare reforms in the United States or other countries may make it more difficult and costly for us to obtain regulatory clearance or approval of our Program Products and to produce, market and distribute our Program Products after clearance or approval is obtained. From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulatory clearance or approval, manufacture and marketing of regulated products or the reimbursement thereof. In addition, FDA or other comparable regulatory agencies regulations and guidance are often revised or reinterpreted by the FDA or other comparable regulatory agencies in ways that may significantly affect our business and our products. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of our Program Products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. We face intense competition in an environment of rapid technological change and the possibility that our competitors may develop products and drug delivery systems that are similar, more advanced or more effective than ours, which may adversely affect our financial condition and our ability to successfully market or commercialize our Program Products. The pharmaceutical industry in which we operate is intensely competitive and subject to rapid and significant technological change. We are currently aware of various existing therapies in the market and in development that may in the future compete with our Program Products. Even if approved, we will compete with currently approved therapies and therapies further along in development. Our competitors both in the United States and abroad include large, well- established pharmaceutical and generic companies with significantly greater name recognition and an established market share. Our competitors may be able to charge lower prices than we can, which may adversely affect our market acceptance. Many of these competitors have greater resources than we do, including financial, product development, marketing, personnel and other resources. If our competitors market products that are more effective, safer or cheaper than our products or that reach the market sooner than our products, we may not achieve commercial success. In addition, the biopharmaceutical industry is characterized by rapid technological change. Because our research approach integrates many

technologies, it may be difficult for us to stay abreast of the rapid changes in other technologies. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or products developed by our competitors may render our technologies, products or product candidates obsolete, less competitive or not economical. Many of our competitors have substantially greater financial, technical, human and other resources than we do and may be better equipped to develop, manufacture and market technologically superior products. In addition, many of these competitors have significantly longer operating histories and greater experience than we have in undertaking ~~nonclinical~~ **preclinical** studies and human clinical studies of new pharmaceutical products and in obtaining regulatory approvals of human therapeutic products. Many of our competitors have established distribution channels for the commercialization of their products, whereas we have no such channel or capabilities. In addition, many competitors have greater name recognition and more extensive collaborative relationships. As a result, our competitors may obtain regulatory approval of their products more rapidly than we do or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidate or any future product candidates. Our competitors may also develop and succeed in obtaining approval for drugs that are more effective, more convenient, more widely used and less costly or have a better safety profile than our products and these competitors may also be more successful than we are in manufacturing and marketing their products. If we are unable to compete effectively against these companies, then we may not be able to commercialize our product candidate or any future product candidates or achieve a competitive position in the market. This would adversely affect our ability to generate revenue. Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, establishing clinical study sites and enrolling patients for clinical studies, as well as in acquiring technologies complementary to, or necessary for, our programs. Our inability to compete effectively in any of these aspects of our business could harm our business, financial condition, results of operations and prospects. Risks Related to our Reliance on Third Parties We currently rely on, and expect to continue to rely on, third parties, such as CROs, clinical data management organizations, medical institutions, consultants and clinical investigators, to conduct our clinical studies and certain aspects of our research and preclinical testing. Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it will delay our product development activities and such alternative arrangements may not be available on terms acceptable to us. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical studies are conducted in accordance with the general investigational plan and protocols for the study. Moreover, the FDA and other regulatory agencies requires us to comply with standards, commonly referred to as current Good Clinical Practices or equivalent, for conducting, recording and reporting the results of clinical studies to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of study participants are protected. We also are required to register ongoing clinical studies and post the results of completed clinical. We rely on third parties to manufacture the raw materials, including the active pharmaceutical ingredients that we use to create our therapeutic product candidate, and to manufacture the diagnostic devices, including the antibodies used for testing. Our business could be harmed if existing and prospective third parties fail to provide us with sufficient quantities of these materials and products or fail to do so at acceptable quality levels or prices. We rely on third party suppliers for certain raw materials necessary to manufacture our product candidates for our preclinical studies and clinical studies and to manufacture our diagnostic tests for our clinical studies. Some of these raw materials and test components are difficult to source. Because there are a limited number of suppliers for these raw materials and components, we may need to engage alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our Program Products for our clinical studies, and if approved, ultimately for commercial sale. In particular, there is only one supplier for PHAD ®, Avanti Polar Lipids, Inc. Although we have secured enough material through a purchase order for our planned clinical trials, we do not have a long- term supply agreement with Avanti Polar Lipids, Inc. We do not have any control over the availability of raw materials and components. If we or our manufacturers are unable to purchase these raw materials or components on acceptable terms, at sufficient quality levels, or in adequate quantities, if at all, the development and commercialization of our product candidates or any future product candidates, would be delayed or there would be a shortage in supply, which would impair our ability to meet our development objectives for our Program Products or generate revenues from the sale of any approved products. Until such time, if ever, as we establish a manufacturing facility that has been properly validated to comply with FDA or other comparable regulatory agencies cGMP requirements, we will not be able to independently manufacture Program Products for our planned preclinical and clinical programs. We currently rely on a third- party manufacturer for the production of our clinical study materials., GEM- ~~SSI, GEM-~~ AKI ~~and~~ **,** GEM- CKD **, and GEM- PSI** have been and for the near- term will be manufactured by a single third- party manufacturer. This manufacturer may not be able to scale production to the larger quantities required for large clinical studies and to commercialize GEM- ~~SSI, GEM-~~ AKI ~~and~~ **,** GEM- CKD **, and GEM- PSI** , if approved. Also, the third- party manufacturers may not be able to produce Program Products that meet the quality requirements. In the event that this third- party manufacturer does not successfully carry out its contractual duties, meet expected deadlines or manufacture our products in accordance with regulatory requirements or if there are disagreements between us and this third- party manufacturer, we will not be able to complete, or may be delayed in completing, the clinical studies required. In such instances, we may need to locate an appropriate replacement third- party relationship, which may not be readily available or on acceptable terms, which would cause additional delay or increased expense and would thereby have a material adverse effect on our business, financial condition, results of operations and prospects. We do not have a long- term supply agreement with any third- party manufacturer. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufacture product candidates or products ourselves. For example, if we do not maintain our key manufacturing relationships, we may fail to find replacement manufacturers or develop our own manufacturing capabilities in a timely manner or at all, which could delay or impair our ability to obtain regulatory approval for our products and substantially increase our costs or deplete profit margins, if any. If we

do find replacement manufacturers, we may not be able to enter into agreements with them on terms and conditions favorable to us, and there could be a substantial delay before new facilities could be qualified and registered with the FDA and other comparable foreign regulatory authorities. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • the possible failure of the third party to manufacture product candidates according to our schedule, or at all, including if our third- party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them; • the possible breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to manufacture product candidates in accordance with our product specifications); • the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified; • the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical study interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; • the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; and • reliance on the third party for regulatory compliance, quality assurance and safety and pharmacovigilance reporting. Certain raw materials necessary for the manufacture of our Program Products, such as our ~~API~~ **active pharmaceutical ingredient**, are available only from a single supplier. Any significant delay in the acquisition or decrease in the availability of these raw materials from our supplier could considerably delay their manufacture, which could adversely impact the timing of any planned studies or the regulatory approvals. The FDA and other comparable foreign regulatory authorities require manufacturers to register manufacturing facilities. The FDA and other comparable foreign regulatory authorities also inspect these facilities to confirm compliance with cGMP. Contract manufacturers may face manufacturing or quality control problems causing drug substance, drug product, diagnostic test kit production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. We may have little to no control regarding the occurrence of third- party manufacturer incidents. Any failure to comply with cGMP requirements or other FDA or comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our Program Products or any future product candidates and market our Program Products following approval. If our Program Products or any future product candidates are approved by the FDA or other comparable foreign regulatory authorities for commercial sale, we may need to manufacture such product candidate in larger quantities. We intend to use third- party manufacturers for commercial quantities of our Program Products to the extent we advance this product candidate and other product candidates. Our manufacturers may not be able to successfully increase the manufacturing capacity for any of our product candidates in a timely or efficient manner, or at all. If we are unable to successfully increase the manufacturing capacity for a product candidate, the regulatory approval or commercial launch of that product candidate may be delayed or there may be a shortage in the supply of the product candidate. In addition, the operations of our third- party manufacturers may be subject to earthquakes, power shortages, telecommunications failures, failures or breaches of information technology systems, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man- made disasters or business interruptions. Damage or extended periods of interruption to our facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. Our current and anticipated future dependence upon others for the manufacture of our product candidates may adversely affect our future profit margins and our ability to develop our product candidates and commercialize any products that receive regulatory approval on a timely basis. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer, we may have difficulty transferring such skills or technology to another third party and a feasible alternative many not exist. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third party manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer, if we are able to identify an alternative source, could negatively affect our ability to develop product candidates in a timely manner or within budget. We may not be able to obtain and maintain the third- party relationships that are necessary to develop, commercialize and manufacture some or all of our product candidates. We expect to depend on collaborators, partners, licensees, clinical investigators, CROs, manufacturers and other third parties to support our discovery efforts, to formulate product candidates, to conduct clinical studies for some or all of our Program Products, to manufacture clinical and commercial scale quantities of our drug substance, drug product, diagnostic test and to market, sell and distribute any products we successfully develop. Any problems we experience with any of these third parties could delay the development, commercialization and manufacturing of our product candidates, which could harm our results of operations. We cannot guarantee that we will be able to successfully negotiate agreements for, or maintain relationships with, collaborators, partners, licensees, clinical investigators, CROs, manufacturers and other third parties on favorable terms, if at all. If we are unable to obtain or maintain these agreements, we may not be able to clinically develop, formulate, manufacture, obtain regulatory approvals for or commercialize our Program Products and any future product candidates, which will in turn adversely affect our business. We expect to expend substantial management time and effort to enter into relationships with third parties and, if we successfully enter into such relationships, to manage these relationships. In addition, substantial amounts will be paid to third parties in these relationships. However, we cannot control the amount or timing of resources our future contract partners will devote to our research and development programs, product candidates or potential product candidates, and we cannot guarantee that these parties will fulfill their obligations to us under these arrangements in a timely fashion, if at all. In addition,

while we manage the relationships with third parties, we cannot control all of the operations of, and any outsourcing used by such third parties. We rely on third parties' knowledge regarding specific local laws and regulatory requirements in foreign jurisdictions, where applicable. We depend on our information technology systems and those of our third- party collaborators, service providers, contractors or consultants. Our internal computer systems, or those of our third- party collaborators, service providers, contractors or consultants, may fail or suffer security breaches, disruptions, or incidents, which could result in a material disruption of our development programs or loss of data or compromise the privacy, security, integrity or confidentiality of sensitive information related to our business and have a material adverse effect on our reputation, business, financial condition or results of operations. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. Our internal technology systems and infrastructure, and those of our current or future third- party collaborators, service providers, contractors and consultants are vulnerable to damage from computer viruses, unauthorized access or use resulting from malware, natural disasters, terrorism, war and telecommunication and electrical failures, denial- of- service attacks, cyber- attacks or cyber- intrusions over the Internet, hacking, phishing and other social engineering attacks, persons inside our organizations (including employees or contractors), loss or theft, or persons with access to systems inside our organization. Attacks on information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and they are being conducted by increasingly sophisticated and organized foreign governments, groups and individuals with a wide range of motives and expertise. In addition to extracting or accessing sensitive information, such attacks could include the deployment of harmful malware, ransomware, denial- of- service attacks, social engineering and other means to affect service reliability and threaten the security, confidentiality, integrity and availability of information. The prevalent use of mobile devices that access sensitive information also increases the risk of data security incidents which could lead to the loss of confidential information or other intellectual property. While to our knowledge we have not experienced any material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations or the operations of third- party collaborators, service providers, contractors and consultants, it could result in a material disruption of our development programs and significant reputational, financial, legal, regulatory, business or operational harm. The costs to us to mitigate, investigate and respond to potential security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. For example, the loss of clinical study data from completed, ongoing or planned clinical studies for our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any real or perceived security breach affects our systems (or those of our third- party collaborators, service providers, contractors or consultants), or results in the loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information or damage to our data or applications or other data or applications relating to our technology or product candidates, or inappropriate disclosure of confidential or proprietary information, we could incur liabilities and the further development of our product candidates could be delayed. Such a breach may require notification to governmental agencies, the media or individuals pursuant to various foreign, domestic (federal and state) privacy and security laws, if applicable, including HIPAA, as amended by HITECH, and its implementing rules and regulations, as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related incidents. Any failure or perceived failure by us or any third- party collaborators, service providers, contractors or consultants to comply with our privacy, confidentiality, data security or similar obligations, or any data security incidents or other security breaches that result in the accidental, unlawful or unauthorized access to, use of, release of, processing of, or transfer of sensitive information, including personally identifiable information, may result in negative publicity, harm to our reputation, governmental investigations, enforcement actions, regulatory fines, litigation or public statements against us, could cause third parties to lose trust in us or could result in claims by third parties, including those that assert that we have breached our privacy, confidentiality, data security or similar obligations, any of which could have a material adverse effect on our reputation, business, financial condition or results of operations. To the extent we maintain individually identifiable health information, we could be subject to fines and penalties (including civil and criminal) under HIPAA for any failure by us or our business associates to comply with HIPAA' s requirements. Moreover, data security incidents and other security breaches can be difficult to detect, and any delay in identifying them may lead to increased harm. While we have implemented data security measures intended to protect our information, data, information technology systems, applications and infrastructure, there can be no assurance that such measures will successfully prevent service interruptions or data security incidents. Risks Related to Our Intellectual Property If we are unable to obtain and maintain effective patent rights for our product candidates or any future product candidates, we may not be able to compete effectively in our markets. If we are unable to protect the confidentiality of our trade secrets or know- how, such proprietary information may be used by others to compete against us. Our success will depend in significant part on our and our future licensors', licensees' or collaborators' ability to establish and maintain adequate protection of our owned and licensed intellectual property covering the product candidates we plan to develop, and the ability to develop these product candidates and commercialize the products resulting therefrom, without infringing the intellectual property rights of others. Our Program Products have been developed in- house and are not subject to any third- party license. In addition to taking other steps to protect our intellectual property, we file patent applications to protect inventions we have developed, seeking to protect compositions, methods of use, manufacturing methods, and other aspects of our technology. There can be no assurance that any of these patent applications will issue as patents or, for those applications that do mature into patents, that the claims of these patents will exclude others from making, using or selling our product

candidates or products that compete with or are similar to our product candidates. With respect to patent rights, we cannot be certain whether any of the technology described in our patent applications for any of our product candidates will remain relevant to our future commercial products, whether any of our patent applications will issue as patents, whether any patents that may be issued to us will effectively protect our commercial processes and product candidates, or whether any patents that may be issued to us will effectively prevent others from competing with our products. In countries where we have not sought and do not seek patent protection, third parties may be able to manufacture and sell our product candidates without our permission, and we may not be able to stop them from doing so. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing or in some cases not at all, until they are issued as a patent. Therefore, we cannot be certain that we or future licensors, licensees or collaborators were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we or future licensors, licensees or collaborators were the first to file for patent protection of such inventions. Any changes we make to our Program Products or any future product candidates to cause them to have what we view as more advantageous properties may fall outside the coverage of our existing patent applications, and we may need to file new patent applications and / or seek other forms of protection for any such altered product candidates. The patent landscape surrounding the technology underlying our product candidates is crowded, and there can be no assurance that we will be able to secure patent protection that would adequately cover such altered Program Products or any future product candidates. The patent prosecution process is expensive and time- consuming, and we and our future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our future licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection for them. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from or license to third parties and may be reliant on our current or future licensors, licensees or collaborators to perform these activities, which means that these patent applications may not be prosecuted, and these patents may not be enforced or maintained, in a manner consistent with the best interests of our business. If our future licensors, licensees or collaborators fail to establish, maintain, protect or enforce such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future licensors, licensees or collaborators are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. Similar to the patent rights of other biotechnology companies, the scope, validity and enforceability of our owned and licensed patent rights generally are highly uncertain and involve complex legal and factual questions. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. In recent years, these areas have been the subject of much litigation in the industry. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our future licensors', licensees' or collaborators' future patent applications may not result in patents being issued that protect our technology or product candidates, or that effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our future licensors, licensees or collaborators to narrow the scope of the claims of our patent applications, which would limit the scope of patent protection that is obtained, if any. Our and our future licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology that is currently claimed in such applications unless and until a patent issues from such applications, and then only to the extent the claims that issue are broad enough to cover the technology being practiced by those third parties. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, enforcing and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and we may not protect our intellectual property in some countries outside the United States to the same extent as in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and certain state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we do not have patent protection, or where we do have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our Program Products or any future product candidates and our patents or other intellectual property rights may not effectively prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals. This could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being revoked, invalidated or interpreted narrowly, and could provoke third parties to assert claims against us or our collaborator. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not adequately compensate us for the harm to our business. Different countries impose different requirements for patentability and certain countries have heightened requirements for patentability, requiring more disclosure in the patent application or disfavoring the issuance of broad claims. In addition, certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In such countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our

potential revenue opportunities. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. We may not have sufficient patent lifespan to effectively protect our products and business. All of our patents are in early stages. Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its priority date. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after the resulting products are commercialized. As a result, our owned and future in- licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We expect to seek extensions of patent terms for our issued patents, where available. This includes in the United States under the Hatch- Waxman Act, which permits a patent term extension of up to five years beyond the original expiration date of the patent as compensation for regulatory delays. However, such a patent term extension cannot lengthen the remaining term of a patent beyond a total of 14 years from the product' s approval date. Only one patent applicable to an approved drug is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent. During the period of patent term extension, the claims of a patent are not enforceable for their full scope but are instead limited to the scope of the approved product. In addition, the applicable authorities, including the FDA in the United States, and any comparable foreign regulatory authorities, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. In addition, we may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to the expiration of relevant patents or otherwise failing to satisfy applicable requirements. If this occurs, any period during which we have the right to exclusively market our product will be shorter than we would otherwise have expected, and our competitors may obtain approval of and launch products earlier than might otherwise have been the case. If we are unable to maintain effective proprietary rights for our Program Products or any future product candidates, we may not be able to compete effectively in our markets. In addition to the protection afforded by any patents that may be granted, we rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect. We protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We also seek to preserve the integrity and confidentiality of our data, trade secrets and intellectual property by maintaining the physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets and intellectual property may otherwise become known or be independently discovered by competitors. Additionally, our reliance on third parties, including CROs and outside consultants, requires us to share our trade secrets and intellectual property, which increases the possibility that a competitor will discover them or that our trade secrets and intellectual property will be misappropriated or publicly disclosed. The steps that we have already taken to protect our intellectual property may not be sufficient or effective, and our confidentiality, non- disclosure, or invention assignment agreements with employees, consultants, partners, or other parties may be breached and may otherwise not be effective in establishing our rights in intellectual property and in controlling access to our proprietary information. Even if we do detect violations, we may need to engage in litigation to enforce our rights, and such litigation, even if successful, may not restore our proprietary rights or adequately compensate us for the damage to our rights or our business. We may be involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time- consuming and unsuccessful. Third parties may infringe our patents or misappropriate or otherwise violate our intellectual property rights. In the future, we may initiate legal proceedings to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity or scope of intellectual property rights we own or control. Also, third parties may initiate legal proceedings against us to challenge the validity or scope of intellectual property rights we own, control or license. For example, generic or biosimilar drug manufacturers or other competitors or third parties may challenge the scope, validity or enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or other proceedings. These proceedings can be expensive and time- consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating intellectual property rights we own, control or license, particularly in countries where the laws may not protect those rights as fully as in the United States. Litigation could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, if we initiated legal proceedings against a third party to enforce a patent covering a product candidate, the defendant could assert that such patent is invalid or unenforceable, or does not cover their product candidate. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. In an infringement or declaratory judgment proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable or may refuse to stop the other party from using the subject matter alleged to be infringing on the grounds that our patents do not cover that subject matter. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated, narrowed, held unenforceable or interpreted in such a manner that would allow third parties to enter the market with competing products. Third- party pre- issuance submission of prior art to the USPTO, or opposition, derivation, revocation, reexamination, inter parties review, post- grant review or interference

proceedings, or other patent office proceedings or litigation in the United States or other jurisdictions provoked by third parties or brought by us, may be necessary to determine the inventorship, priority, patentability or validity of inventions with respect to our patents or patent applications. An unfavorable outcome could leave our technology or product candidates without patent protection, could allow third parties to commercialize our technology or product candidates and compete directly with us, or without payment to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Even if we successfully defend such litigation or proceeding, we may incur substantial costs and our defense may distract our management and other employees. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, many foreign jurisdictions have rules of discovery that are different than those in the United States and that may make defending or enforcing our patents extremely difficult. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. We may infringe the intellectual property rights of others, which could increase our costs and delay or prevent our development efforts. Our commercial success depends upon our ability to develop, manufacture, market and sell our Program Products and any future product candidates that we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. Third parties may initiate legal proceedings against us alleging that we infringe their intellectual property rights, or we may initiate legal proceedings against third parties to challenge the validity or scope of intellectual property rights controlled by third parties, including in oppositions, interferences, revocations, reexaminations, inter parties review, post- grant review or derivation proceedings before the USPTO or its counterparts in other jurisdictions. These proceedings can be expensive and time-consuming and many of our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. We could be found liable for monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent of a third party. A finding of infringement could prevent us from commercializing our Program Products or any future product candidates or force us to cease some of our business operations, which could materially harm our business. We may not be aware of all third- party intellectual property rights potentially relating to our Program Products or any future product candidates. As to pending third- party applications, we cannot predict with any certainty which claims will issue, if any, or the scope of any claims that may issue. Even if we believe third-party intellectual property claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that these third- party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize any product candidates we may develop and any other product candidates covered by the asserted third- party patents. In order to successfully challenge the validity of any such U. S. patent in federal court, we would need to overcome a presumption of validity. As this burden is a high one requiring us to present clear and convincing evidence as to the invalidity of any such U. S. patent claim, there is no assurance that a court of competent jurisdiction would invalidate the claims of any such U. S. patent. If any third- party patents were successfully asserted against us or our commercialization partners and we were unable to successfully challenge the scope, validity or enforceability of any such asserted patents, then we and our commercialization partners may be prevented from commercializing our product candidates, or may be required to pay significant damages, including treble damages and attorneys' fees if we are found to willfully infringe the asserted patents, or obtain a license to such patents, which may not be available on commercially reasonable terms, or at all. Even if we were able to obtain a license, it could be non- exclusive, thereby giving our competitors and other third parties' access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. Any of the foregoing would have a material adverse effect on our business, financial condition and operating results. Although we have reviewed certain third- party patents and patent filings that we believe may be relevant to our therapeutic candidates or products, we have not conducted a freedom- to-operate search or analysis for any of our therapeutic candidates or products, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our therapeutic candidates or products. Thus, we cannot guarantee that our therapeutic candidates or products, or our commercialization thereof, do not and will not infringe any third party' s intellectual property. Changes in United States and international patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biotechnology companies, our success is heavily dependent on IP, particularly patents. Obtaining and enforcing patents in the biotechnology industry involve both technological and legal complexity, and therefore obtaining and enforcing biotechnology patents is costly, time- consuming and inherently uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations, which may diminish our ability to obtain and enforce patents for our inventions. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Furthermore, depending on the Supreme Court' s review of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the " Affordable Care Act "), or legislation to repeal or amend the Affordable Care Act, the twelve years of regulatory exclusivity currently provided to certain biologic products in the United States may be reduced or eliminated. Any such reduction or elimination could impair the length of exclusivity against similar products. Our inability to protect our trade secrets would harm our business and competitive position. In addition to seeking patents for some of our technology and product candidates, we also rely substantially on trade secrets, including unpatented know- how, technology and other proprietary

materials and information, to maintain our competitive position. We protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. However, these steps may be inadequate, we may fail to enter into agreements with all such parties or any of these parties may breach the agreements and disclose our trade secrets and there may be no adequate remedy available for such breach of an agreement. We cannot assure you that our trade secrets will not be disclosed or that we can meaningfully protect our trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts both within and outside the United States may be less willing, or unwilling, to protect trade secrets. If a competitor lawfully obtained or independently developed any technology or information that we protect as trade secret, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to our Program Products and any future product candidates we may develop but that are not covered by the claims of the patents that we may own or license in the future; • we, or our future collaborators, might not have been the first to make the inventions covered by the issued patents and pending patent applications that we may own or license in the future; • we, or our future collaborators, might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights; • it is possible that our pending patent applications or those that we may file in the future will not result in issued patents; • patents that we may own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the resulting information to develop competitive products for sale in major commercial markets in which we do not have sufficient patent rights to stop such sales; • we may not develop additional proprietary technologies that are patentable; • third- party patents may be asserted against our product candidates and technologies in a manner that threatens or harms our business; and • we may choose not to file a patent application in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such trade secrets or know- how. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects. If our trademarks and trade names are not maintained and adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected. Failure to obtain trademark registrations in the future could limit our ability to protect and enforce our trademarks and impede our marketing efforts in the countries in which we intend to operate. We may not be able to protect our rights to trademarks and trade names which we may need to build name recognition with potential partners or customers in our markets of interest. As a means to enforce any future trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be time- consuming and expensive and may strain the financial resources of a company of our size, and we may not ultimately be successful in enforcing our trademark rights. In addition, our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. Future trademark applications in the United States and in other foreign jurisdictions where we may file may not be allowed or may subsequently be opposed. Even if these applications result in registration of trademarks, third parties may challenge our use or registration of these trademarks in the future. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Risks Related to Our Business Operations Our future success depends in part on our ability to retain our senior management team, directors and other key employees and to attract, retain and motivate other qualified personnel. We may not be able to attract or retain qualified directors, personnel and consultants due to the intense competition for such individuals among in the biotechnology and pharmaceutical industries. If we are not able to attract and retain necessary personnel and consultants to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. Our industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the development, regulatory, commercialization and business development expertise of the members of our executive team, as well as other key employees and consultants. If we lose one or more of our executive officers or other key employees or consultants, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or other key employees or consultants may terminate their employment or consultancy arrangements with us at any time and replacing such individuals may be difficult and time- consuming because of the limited number of individuals in our industry with the necessary breadth of skills and experience. Competition to hire and retain employees and consultants from this limited pool is intense, and we may be unable to hire, train, retain or motivate such individuals. Additionally, we do not currently maintain “ key person ” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not receive adequate compensation for the loss of the services of these individuals. If we are unable to continue to attract and retain high- quality personnel, the rate and success with which we can discover and develop product candidates and our business will be limited. We will need to expand our organization, and we may experience difficulties in managing this growth, which could disrupt our operations. We are in the early stages of building the full management team and employee base that we anticipate we will need to complete the development of our Program Products and other future product candidates. As of March ~~18~~ **3**, ~~2024~~ **2025**, we had ~~10~~ **9** employees. As we advance our preclinical and clinical development programs for our product candidates, seek regulatory approval in the United States and elsewhere and increase the number of ongoing product development programs, we anticipate that we will need to increase our product

development, scientific and administrative headcount. We will also need to establish commercial capabilities in order to commercialize any product candidates that may be approved. Such an evolution may impact our strategic focus and our deployment and allocation of resources. Our management, personnel and systems may experience difficulty in adjusting to our growth and strategic focus. Our ability to manage our operations and growth effectively depends upon the continual improvement of our procedures, reporting systems and operational, financial and management controls. We may not be able to implement administrative and operational improvements in an efficient or timely manner and may discover deficiencies in existing systems and controls. If we do not meet these challenges, we may be unable to execute our business strategies and may be forced to expend more resources than anticipated addressing these issues. We may acquire additional technology and complementary businesses in the future. Acquisitions involve many risks, any of which could materially harm our business, including the diversion of management' s attention from core business concerns, failure to effectively exploit acquired technologies, failure to successfully integrate the acquired business or realize expected synergies or the loss of key employees from either our business or the acquired businesses. In addition, in order to continue to meet our obligations as a public company and to support our anticipated long- term growth, we will need to increase our general and administrative capabilities. Our management, personnel and systems may not be adequate to support this future growth. If we are unable to successfully manage our growth and the increased complexity of our operations, our business, financial position, results of operations and prospects may be materially and adversely affected. We may not be successful in our efforts to identify, discover or license additional product candidates. Although a substantial amount of our effort will focus on the continued clinical testing, potential approval and commercialization of our lead Program Products, the success of our business also depends upon our ability to identify, discover or license additional product candidates. Our research programs or licensing efforts may fail to yield additional product candidates for clinical development for a number of reasons, including (i) lack of financial or personnel resources to acquire or discover additional product candidates; (ii) product candidates may not succeed in preclinical or clinical testing; (iii) product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval; (iv) competitors may develop alternatives that render our product candidates obsolete or less attractive; (v) the market for a product candidate may change during our development program so that such product may become unprofitable to continue to develop; (vi) product candidates may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and (vii) product candidates may not be accepted as safe and effective by patients, the medical community, or third- party payors. We may be forced to abandon our development efforts for a program or programs that are unsuccessful, or we may not be able to identify, license, or discover additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Further, research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. Our research, development and manufacturing activities and our third- party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third- party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages, such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Ongoing healthcare legislative and regulatory reform measures may adversely affect our business, results of operations and financial condition. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (1) changes to our manufacturing arrangements; (2) additions or modifications to product labeling; (3) the recall or discontinuation of our products; (4) post-marketing approvals or compliance programs or (5) additional record- keeping requirements. If any such changes were to be imposed, they could adversely affect our business, results of operations and financial condition. In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, was passed by Congress, which substantially changes the way health care is financed by both governmental and private insurers, and significantly impacts the U. S. pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower- cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70 % point- of- sale discounts off negotiated prices of applicable brand drugs to

eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D. Since its enactment, certain provisions the ACA have been subject to executive, judicial and congressional challenges. On June 17, 2021, the U. S. Supreme Court dismissed the most recent challenge to the ACA on procedural grounds that argued the ACA is unconstitutional in its entirety because the " individual mandate " was repealed by Congress. Thus, the ACA will remain in effect in its current form. Further, prior to the U. S. Supreme Court ruling, President Biden issued an executive order that initiated a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental authorities 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, or 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 is unclear how other healthcare reform measures of the Biden administration, if any, will impact our business. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things included aggregate reductions of Medicare payments to providers of 2 % per fiscal year. These reductions went into effect on April 1, 2013, and, due to subsequent legislative amendments, will stay in effect through 2032 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. Further, the IRA, among other things, (1) directs HHS to negotiate the price of certain single- source drugs and biologics covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. 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 it is likely to have a significant effect on the pharmaceutical industry. Further, in response to the Biden administration' s October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services, or CMS, Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Risks Related to Commercialization of Our Program Products and Product Candidates As we evolve from a company that is primarily involved in clinical development to a company that is also involved in commercialization, we may encounter difficulties in expanding our operations successfully. As we advance our Program Products through clinical studies, we will need to expand our development, regulatory, manufacturing, and marketing and sales capabilities and may need to further contract with third parties to provide these capabilities, such as collaborators, distributors, marketers and additional suppliers. We currently have no experience as a Company in or infrastructure for sales, marketing and distribution, and our operations are currently limited to clinical development activities and as our operations expand, we likely will need to manage additional relationships with such third parties. If our Program Products or any future product candidate is approved, we intend either to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize our Program Products or any future product candidate or to outsource such functions to one or more third parties. Either of these options would be expensive and time-consuming. Some or all of these costs may be incurred in advance of any approval of our Program Products or any future product candidate. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely affect the commercialization of our Program Products and other future product candidates. Maintaining third- party relationships for these purposes will impose significant added responsibilities on members of our management and other personnel. We must be able to effectively manage our development efforts, recruit and train sales and marketing personnel, effectively manage our participation in the clinical studies in which our product candidates are involved and improve our managerial, development, operational and finance systems, all of which may impose a strain on our administrative and operational infrastructure. If we enter into arrangements with third parties to perform sales, marketing or distribution services, any product revenues that we receive, or the profitability of these product revenues to us, are likely to be lower than if we were to market and sell any products that we develop without the involvement of these third parties. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or in doing so on terms that are favorable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products. We may seek to establish commercial collaborations for our Program Products and future product candidates, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development plans. Our drug development programs, and the potential commercialization of our product candidates will require substantial additional cash to

fund expenses. We may decide to collaborate with other pharmaceutical and biotechnology companies for the development and potential commercialization of our product candidates. For example, we have recently licensed a patent from Vanderbilt University which is the basis of GEM- ~~SSI~~ **PSI** . We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical studies, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products and the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborators may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue. We currently have no Program Products approved for marketing. We do not have a marketing and sales organization. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our Program Products, we may be unable to generate any product revenue. We have no experience selling and marketing our Program Products, and we currently have no marketing or sales organization. To successfully commercialize any product candidates that may result from our development programs, we will need to develop these capabilities, either on our own or with others. If our product candidates receive regulatory approval, we intend to establish a sales and marketing organization independently or by utilizing experienced third parties with technical expertise and supporting distribution capabilities to commercialize our Program Products in major markets, all of which will be expensive, difficult and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact our ability to commercialize our Program Products. Our efforts to educate the medical community, including physicians, hospital pharmacists and third- party payors on the benefits of our Program Products may require significant resources and may never be successful. If any of our Program Products are approved but fail to achieve market acceptance among physicians, patients or third- party payors, we will not be able to generate significant revenues from such product, which could have a material adverse effect on our business, financial condition, results of operations and prospects. It may be difficult for us to profitably sell our Program Products, if and when approved, if coverage and reimbursement for these Program Products are limited by government authorities and / or third- party payor policies. In addition to any healthcare reform measures which may affect reimbursement, market acceptance and sales of our Program Products, if approved, will depend on, in part, the extent to which the procedures utilizing our Program Products, performed by health care providers, will be covered by third party payors, such as government health care programs, commercial insurance and managed care organizations. In the event health care providers and patients accept our Program Products as medically useful, cost effective and safe, there is uncertainty regarding whether our Program Products will be directly reimbursed, reimbursed through a bundled payment or if the product candidates will be included in another type of value- based reimbursement program. Third party payors determine the extent to which new products will be covered as a benefit under their plans and the level of reimbursement for any covered product or procedure which may utilize a covered product. It is difficult to predict at this time what third party payors will decide with respect to the coverage and reimbursement for our Program Products. Obtaining coverage and reimbursement approval for a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of our products to the payor. Additionally, we may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. We cannot be sure that coverage or adequate reimbursement will be available for our product candidates, if approved. Also, we cannot be sure that reimbursement amounts will not reduce the demand for, or the price of, our future products. If reimbursement is not available, or is available only to limited levels, we may not be able to commercialize our product candidates, or achieve profitably at all, even if approved. Our business entails a significant risk of clinical study and / or product liability and our ability to obtain sufficient insurance coverage could have a material effect on our business, financial condition, results of operations or prospects. Our business exposes us to significant clinical study and / or product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Clinical study liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, product liability claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management' s time and our resources, substantial monetary awards to study participants or patients and a decline in our Company valuation. We currently carry insurance coverage to the limit required by clinical sites for our clinical study. We do not anticipate carrying product liability insurance until such time we have a

commercially available product. Our current insurance coverage or any other insurance coverage that we may obtain in the future may not provide sufficient coverage against potential liabilities. Furthermore, clinical study and product liability insurance are becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by clinical study and product liability claims that could have a material adverse effect on our business. Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical studies and will face an even greater risk if we commercialize any resulting products. Product liability claims may be brought against us by subjects enrolled in our clinical studies, patients, or others using our products. If we cannot successfully defend ourselves against claims that our product candidates or products that we may develop caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidates or products that we may develop; • product recalls or a change in the indications for which products may be used; • termination of clinical study sites or entire study programs; • injury to our reputation and significant negative media attention; • withdrawal of clinical study participants; • significant costs to defend the related litigation; • substantial monetary awards to study subjects or patients; • loss of revenue; • diversion of management and scientific resources from our business operations; and • the inability to commercialize any products that we may develop. Our clinical study liability insurance coverage may not adequately cover all liabilities that we may incur. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our inability to obtain product liability insurance at an acceptable cost or to otherwise protect against potential product liability claims could prevent or delay the commercialization of any products or product candidates that we develop. We intend to expand our insurance coverage for products to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. Large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. If we are sued for any injury caused by our products, product candidates or processes, our liability could exceed our product liability insurance coverage and our total assets. Claims against us, regardless of their merit or potential outcome, may also generate negative publicity or hurt our ability to obtain physician endorsement of our products or expand our business. Our employees, contractors, vendors, principal investigators, consultants and future partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, contractors, vendors, principal investigators, consultants or future partners. Misconduct by these parties could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data timely, completely or accurately, or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Third-party misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. Although we have adopted a Code of Business Conduct and Ethics, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us resulting from this misconduct and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. If we or our future partners market products in a manner that violates fraud and abuse and other healthcare laws, or if we or our future partners violate government price reporting laws, we or our future partners may be subject to administrative civil and / or criminal penalties, among other sanctions. Pharmaceutical and other healthcare companies have been prosecuted under these laws for a variety of promotional and marketing activities, such as: providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers; reporting to pricing services inflated average wholesale prices that were then used by federal programs to set reimbursement rates; engaging in off- label promotion; and submitting inflated best price information to the Medicaid Rebate Program to reduce liability for Medicaid rebates. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. Our business operations and relationships with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers are subject to broadly applicable healthcare regulatory laws, which could expose us to penalties. Healthcare providers, physicians and third- party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain regulatory approval. Our current and future arrangements may expose us to broadly applicable fraud and abuse and other healthcare laws that may constrain the business or financial arrangements and relationships through which we would market, sell and distribute our products. Even though we will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, federal and state healthcare laws pertaining to fraud and abuse are and will be applicable to our business. Such laws include, but are not limited to, the following: • Federal false claims, false statements and civil monetary penalties laws, including the federal civil FCA, which can be enforced through civil whistleblower or qui tam actions, prohibit, among others, any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. • The federal Anti- Kickback Statute prohibits, among other things, knowingly and willfully offering, paying,

soliciting or receiving remuneration to induce, or in return for, purchasing, leasing, ordering or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid or other federally financed healthcare programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers, on the one hand, and prescribers, purchasers and formulary managers, on the other. Although there are several statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution, the exceptions and safe harbors are drawn narrowly, and practices that involve remuneration intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. In addition, the intent standard under the federal Anti- Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Moreover, the government may assert that a claim including items or services resulting from violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. • The federal HIPAA, which prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme or artifice to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private), willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. • Patient data privacy and security regulation, including, in the United States, HIPAA, as amended by the Health Information Technology for Clinical Health Act of 2009 (“ HITECH ”), and their respective implementing regulations, which impose specified requirements on “ covered entities, ” including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective “ business associates ” that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information. • The federal transparency requirements under the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, that require applicable manufacturers of covered 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 track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in the applicable manufacturer, and disclosure of such information will be made by CMS on a publicly available website. • Analogous state, local or foreign laws, such as state anti-kickback and false claims laws, which may apply to items or services reimbursed by any third- party payor, including commercial insurers; state and local marketing and / or transparency laws applicable to manufacturers that may be broader in scope than the federal requirements; state laws that require biopharmaceutical companies to comply with the biopharmaceutical industry’ s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state and local laws that require licensure or registration by sales and marketing agents of a pharmaceutical company; state laws that require disclosure of information related to drug pricing; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect as HIPAA. The global data protection landscape is rapidly evolving, and we may be affected by or subject to new, amended or existing laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. Several foreign jurisdictions, including the EU, its member states, the United Kingdom, Japan and Australia, among others, have adopted legislation and regulations that increase or change the requirements governing the collection, use, disclosure and transfer of the personal information of individuals in these jurisdictions. Additionally, certain countries have passed or are considering passing laws that require local data residency and / or restrict the international transfer of data. These laws have the potential to increase costs of compliance, risks of noncompliance and penalties for noncompliance. 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, disgorgement, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, additional oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, that person or entity may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Data collection is governed by restrictive regulations governing the collection, use, processing and cross- border transfer of personal information. We have completed a Phase 2 clinical study in Europe and we will continue to collect, process, use or transfer personal information from individuals located in the **European Economic Area (“** EEA **”)** in connection with our business, including in connection with conducting clinical studies in the EEA. Additionally, if any of our product candidates are approved, we may seek to commercialize those products in the EEA. The collection and use of personal health data in the EEA is governed by the provisions of the **General Data Protection Regulation ((EU) 2016 / 679) (“** GDPR **”)** , along with other European Union and country- specific laws and regulations. The United Kingdom and Switzerland have also adopted data protection laws and regulations. These legislative acts (together with regulations and guidelines) impose requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such data outside of the EEA, including to the United States, providing details to those individuals regarding the processing of their personal data, keeping personal data secure, having data processing agreements with third parties who process personal data, responding to individuals’ requests to exercise their rights in respect of their personal data, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers or corporate representatives, conducting data protection impact

assessments and record- keeping. The GDPR imposes additional responsibilities and liabilities in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. Failure to comply with the requirements of the GDPR and related national data protection laws of the member states of the EEA and other states in the EEA may result in substantial fines, other administrative penalties and civil claims being brought against us, which could have a material adverse effect on our business, financial condition and results of operations. European data protection authorities may interpret the GDPR and national laws differently and may impose additional requirements, which adds to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices are often updated or otherwise revised. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. In addition, in 2018 California enacted the California Consumer Privacy Act (“ CCPA ”), which created new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide new disclosure to consumers about such companies’ data collection, use and sharing practices, provide such consumers new ways to opt- out of certain sales or transfers of personal information, and provide consumers with additional causes of action. The CCPA went into effect on January 1, 2020, and the California Attorney General commenced enforcement actions for violations on July 1, 2020. Moreover, the California Privacy Rights Act, or CPRA, which was passed in November 2020 and will go into effect on January 1, 2023, with a “ look- back ” period to January 1, 2022. The CPRA significantly modified the CCPA, resulting in further uncertainty and requiring us to incur additional costs and expenses in an effort to comply. The CCPA and the CPRA, may impact our business activities and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data and protected health information. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Any actual or alleged failure to comply with U. S. or international laws and regulations relating to privacy, data protection, and data security could result in governmental investigations, proceedings and enforcement actions (which could include civil or criminal penalties), private litigation or adverse publicity, harm to our reputation, and could negatively affect our operating results and business. Moreover, clinical study subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information or impose other obligations or restrictions in connection with our use, retention and other processing of information, and we may otherwise face contractual restrictions applicable to our use, retention, and other processing of information. Claims that we have violated individuals’ privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business. Unstable market and economic conditions may have serious adverse consequences on our business and financial condition. Global credit and financial markets have experienced extreme disruptions at various points over the last few decades, characterized by diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If another such disruption in credit and financial markets and deterioration of confidence in economic conditions occurs, our business may be adversely affected. If the equity and credit markets were to deteriorate significantly in the future, it may make any necessary debt or equity financing more difficult to complete, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and share price and could require us to delay or abandon development or commercialization plans. In addition, there is a risk that one or more of our service providers, manufacturers or other partners would not survive or be able to meet their commitments to us under such circumstances, which could directly affect our ability to attain our operating goals on schedule and on budget. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business. We are 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, the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti-money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical studies, and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. Changes in our effective income tax rate could adversely affect our results of operations. We are subject to income taxes in the United States. Various factors may have favorable or unfavorable effects on our effective income tax rate. These factors include, but are not limited to, interpretations of existing tax laws, changes in tax laws and rates, the accounting for stock options and

other stock- based compensation, changes in accounting standards, future levels of research and development spending, changes in the mix and level of pre- tax earnings in different jurisdictions, the outcome of audits or other examinations by the U. S. Internal Revenue Service and tax regulators in other jurisdictions, the accuracy of our estimates for unrecognized tax benefits, the realization of deferred tax assets and changes to our ownership or capital structure. The impact of the above- mentioned factors and others on our effective income tax rate may be significant and could adversely affect our results of operations. Our future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets for which we may rely on collaboration with third parties. We are evaluating the opportunities for the development and commercialization of our product candidates in foreign markets. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approvals in other countries, we may be required to comply with numerous and varying regulatory requirements of such countries regarding the safety and efficacy of our product candidates and governing, among other things, clinical studies and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. We may not obtain foreign regulatory approvals on a timely basis, if at all. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including: • our customers' ability to obtain reimbursement for our product candidates in foreign markets; • our inability to directly control commercial activities if we are relying on third parties; the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements; • different medical practices and customs in foreign countries affecting acceptance in the marketplace; • import or export licensing requirements; • longer accounts receivable collection times; • our ability to supply our product candidates on a timely and large- scale basis in local markets; • longer lead times for shipping which may necessitate local manufacture of our product candidates; • language barriers for technical training and the need for language translations; • reduced protection of patent and other intellectual property rights in some foreign countries; • the existence of additional potentially relevant third- party intellectual property rights; • foreign currency exchange rate fluctuations; and • the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute. Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. If any of our product candidates is approved for commercialization, we may selectively partner with third parties to market it in certain jurisdictions outside the United States. We expect that we will be subject to additional risks related to international pharmaceutical operations, including: • different regulatory requirements for drug approvals and rules governing drug commercialization in foreign countries, including requirements specific to biologics or cell therapy products; • reduced protection for patent and other intellectual property rights; • foreign reimbursement, pricing and insurance regimes; • 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; and • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad. We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by both the EU and many of the individual countries in Europe with which we will need to comply. Many U. S.- based biotechnology companies have found the process of marketing their own products in Europe to be very challenging. Certain legal and political risks are also inherent in foreign operations. There is a risk that foreign governments may nationalize private enterprises in certain countries where we may operate. In certain countries or regions, terrorist activities and the response to such activities may threaten our operations more than in the United States. Social and cultural norms in certain countries may not support compliance with our corporate policies, including those that require compliance with substantive laws and regulations. Also, changes in general economic and political conditions in countries where we may operate are a risk to our financial performance and future growth. Additionally, the need to identify financially and commercially strong partners for commercialization outside the United States who will comply with the high manufacturing and legal and regulatory compliance standards we require is a risk to our financial performance. As we operate our business globally, our success will depend, in part, on our ability to anticipate and effectively manage these and other related risks. There can be no assurance that the consequences of these and other factors relating to our international operations will not have an adverse effect on our business, financial condition or results of operations. In some countries, particularly in Europe, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we may be required to conduct clinical studies that compare the cost- effectiveness of our product candidates to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. We face the risk of product liability claims and may not be able to obtain insurance. Our business exposes us to the risk of product liability claims that are inherent in the development of drugs and diagnostic devices. We may be subject to costly and damaging product liability claims brought against us by clinical study participants, consumers, health care providers, pharmaceutical companies or others selling our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. While we currently carry clinical study insurance and product liability insurance, the amount of insurance coverage we hold now may not be adequate to cover all liabilities we might incur. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. 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 Program 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. Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities. We carry insurance for most categories of risk that our business may encounter; however, we may not have adequate levels of coverage. We currently maintain general liability, property, workers' compensation, clinical study, products liability and directors' and officers' insurance, along with an umbrella policy. We may not be able to maintain existing insurance at current or adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations. We have no current plans to pay dividends on our shares of common stock. We do not anticipate paying any cash dividends in the foreseeable future. If we incur indebtedness in the future to fund our future growth, our ability to pay dividends may be further restricted by the terms of such indebtedness. **Loss** ~~If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views~~ of **Emerging Grown Company Status We** ~~us and, as a result, the value of our common stock. When and if we are a " large accelerated filer " or an " accelerated filer " and~~ are no longer an ~~"~~ emerging growth company **(" EGC** ~~"~~ **) as defined in the Jumpstart Our Business Startup Act of 2012, as amended. As a result, we are now subject to additional regulatory and compliance obligations, which may increase** ~~or~~ **our** ~~"~~ **costs, divert management' s attention, and adversely affect our financial condition. These obligations include: • Enhanced disclosures: We must provide expanded executive compensation disclosures and comply with new or revised accounting standards on the same timeline as non- EGC public companies. • Reduced flexibility: We can no longer use EGC exemptions for test- the- waters communications or scaled executive compensation disclosures. Our transition from EGC status became effective on December 31, 2024, as we exceeded the five- year anniversary of our initial public offering. However, we continue to qualify as a** smaller reporting company ~~," each~~ **under SEC rules and** as defined in the **Securities** Exchange Act ~~, our independent registered public accounting firm will be required to attest to the effectiveness~~ of **1934** ~~our internal control over financial reporting. However~~ , ~~for so long~~ as **amended (** ~~we remain an emerging growth company or smaller reporting company, we intend to take advantage of an exemption available to emerging growth companies and smaller reporting companies from these~~ -- **the "** ~~auditor attestation requirements. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. To comply with the requirements of being a reporting company under the~~ Exchange Act **")** , ~~we will need to upgrade~~ **which permits certain scaled disclosures but does not alleviate all obligations triggered by the loss of EGC status. Compliance with these requirements may strain** our ~~systems including information technology; implement additional~~ financial and **operational resources** ~~management controls, reporting systems, and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting, and the trading price of our common stock may decline. We are an~~ **and could** ~~emerging growth company, and the reduced reporting requirements applicable to emerging growth companies may~~ make **us** ~~our common stock~~ less attractive to investors **accustomed** ~~. We are an emerging growth company and are eligible~~ to **EGC** ~~take advantage of certain exemptions from various~~ reporting ~~requirements that are applicable to other public companies that are not emerging growth companies, including, but not limited to, only two years of audited financial statements in addition to any required unaudited interim financial statements with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, exemptions from the requirements of holding non- binding advisory votes on executive compensation and seeking stockholder approval of any golden parachute payments not previously approved and not being required to adopt certain accounting~~ standards ~~until those standards would otherwise apply to private companies. We could be an emerging growth company until the last day of the fiscal year following the fifth anniversary of Petra' s IPO, although circumstances could cause us to lose that status earlier, including if we become a large accelerated filer (in which case we will cease to be an emerging company as of the date we become a large accelerated filer, which, generally, would occur if, at the end of a fiscal year, among other things, the market value of our common stock that is held by non- affiliates exceeds $ 700 million as of the last business day of our most recently completed second fiscal quarter), if we have total annual gross revenue of $ 1. 07 billion or more during any fiscal year (in which cases we would no longer be an emerging growth company as of March 31 of such fiscal year), or if we issue more than $ 1. 0 billion in non- convertible debt during any three year period before that time (in which case we would cease to be an emerging growth company immediately). Even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to take advantage of many of the same exemptions from disclosure requirements including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may 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 our stock price may be more volatile~~ . Our common stock price may be volatile and as a result you could lose all or part of your investment. In addition to volatility associated with equity securities in general, the value of your investment could decline due to the impact of any of the following factors upon the market price of our shares of common stock: • disappointing results from our development efforts; • decline in demand for our shares of common stock; • downward revisions in securities analysts' estimates or changes in general market conditions; • technological innovations by competitors or in competing products; • investor perception of our industry or our prospects; and • general economic trends. Stock markets in general have experienced extreme price and volume

fluctuations, and the market prices of securities have been highly volatile. These fluctuations are often unrelated to operating performance and may adversely affect the market price of our shares of common stock. Potential future sales pursuant to registration rights granted by the Company and under Rule 144 may depress the market price for our shares of common stock. The Company has granted a number of its stockholders' registration rights with respect to their shares of common stock. See the section titled " Registration Rights. " Such future sales of our shares of common stock by our existing stockholders, pursuant to and in accordance with the provisions of any registration statement, may have a depressive effect on the market price of our shares of common stock. Further, in general, under Rule 144 under the Securities Act **of 1933, as amended (the " Securities Act ")** , a person who has satisfied a minimum holding period of between six months and one- year and any other applicable requirements of Rule 144, may thereafter sell such shares publicly. A significant number of our currently issued and outstanding shares of common stock held by existing stockholders, including officers and directors and other principal stockholders are currently eligible for resale pursuant to and in accordance with the provisions of Rule 144. The possible future sale of our shares by our existing stockholders, pursuant to and in accordance with the provisions of Rule 144, may have a depressive effect on the price of our shares of common stock in the applicable trading marketplace. FINRA has adopted sales practice requirements, which may also limit a stockholder' s ability to buy and sell our common stock. **The Financial Industry Regulatory Authority (" FINRA ")** has adopted rules that require that in recommending an investment to a customer, a broker- dealer must have reasonable grounds for believing that the investment is suitable for that customer. Prior to recommending speculative low- priced securities to their non- institutional customers, broker- dealers must make reasonable efforts to obtain information about the customer' s financial status, tax status, investment objectives and other information. Under interpretations of these rules, FINRA believes that there is a high probability that speculative low- priced securities will not be suitable for at least some customers. FINRA requirements make it more difficult for broker- dealers to recommend that their customers buy our shares of common stock, which may limit your ability to buy and sell our stock and have an adverse effect on the market for our shares of common stock. We face risks related to compliance with corporate governance laws and financial reporting standards. The Sarbanes- Oxley Act, as well as related new rules and regulations implemented by the SEC and the Public Company Accounting Oversight Board, require changes in the corporate governance practices and financial reporting standards for public companies. These laws, rules and regulations, including compliance with Section 404 of the Sarbanes- Oxley Act relating to internal control over financial reporting, referred to as Section 404, materially increased our legal and financial compliance costs and made some activities more time- consuming and more burdensome ~~,~~ **.** Anti- takeover provisions contained in our Charter and bylaws, as well as provisions of Delaware law, could impair a takeover attempt. Our Charter contains provisions that may discourage unsolicited takeover proposals that stockholders may consider to be in their best interests. We are also subject to anti- takeover provisions under Delaware law, which could delay or prevent a change of control. Together, these provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions will include: • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • a classified board of directors with three- year staggered terms, which could delay the ability of stockholders to change the membership of a majority of the Board; • the right of our Board to elect a director to fill a vacancy created by the expansion of our Board or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our Board; and • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders. Our Charter provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our Charter provides that, subject to limited exceptions, any (i) derivative action or proceeding brought on our behalf of under Delaware law, (ii) any action asserting a claim of breach of a fiduciary duty owed by any current or former director, officer or other employee of Revelation to its stockholders, (iii) any action asserting a claim against Revelation or any of its directors, officers or other employees arising pursuant to any provision of the **Delaware General Corporation Law (" DGCL ")** , the Charter or the Bylaws of Revelation (in each case, as may be amended from time to time), (iv) any action asserting a claim against Revelation or any of its directors, officers or other employees governed by the internal affairs doctrine of the State of Delaware or (v) any other action asserting an " internal corporate claim, " as defined in Section 115 of the DGCL, in all cases subject to the court' s having personal jurisdiction over all indispensable parties named as defendants shall, to the fullest extent permitted by law, be exclusively brought in the Court of Chancery of the State of Delaware or, if such court does not have subject matter jurisdiction thereof, another state or federal court located within the State of Delaware. The Charter also provides that unless a majority of the Board of Revelation, acting on behalf of Revelation, consents in writing to the selection of an alternative forum (which consent may be given at any time, including during the pendency of litigation), the federal district courts of the United States of America, to the fullest extent permitted by law, will be the sole and exclusive forum for the resolution of any action asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in shares of Revelation' s capital stock shall be deemed to have notice of and to have consented to the provisions of Revelation' s certificate of incorporation described above. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. As a result, the exclusive forum provision will not apply to suits brought to enforce any duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Section 22 of the Securities Act creates concurrent jurisdiction for state and federal courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. This choice of forum provision may limit a stockholders ability to bring a claim in a judicial forum that it finds favorable for disputes with Revelation or its directors, officers, or other employees, which, along with potential increased costs of litigating the courts provided by the choice of forum provision, may discourage such

lawsuits against Revelation and its directors, officers, and employees. Alternatively, if a court were to find these provisions of Revelation' s Charter inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, Revelation may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect Revelation' s business and financial condition. If Revelation is not able to comply with the applicable continued listing requirements or standards of Nasdaq, Nasdaq could delist our common stock. Revelation' s common stock and Public Warrants are listed on the Nasdaq Capital Market **listing tier (" Nasdaq Capital Market ")** under the symbols " REVB " and " REVBW, " respectively. If Nasdaq delists the Revelation common stock and Public Warrants from trading on its exchange for failure to meet the listing standards such as the minimum public stockholders equity requirement, minimum bid price, for failure to hold an annual stockholders meeting, or any other listing standards, we and our stockholders could face significant material adverse consequences including: • limited availability of market quotations for our securities; • reduced liquidity for Revelation' s securities; • a determination that the Revelation common stock is a " penny stock " which will require brokers trading in the Revelation common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for Revelation' s securities; • a limited amount of news and analyst coverage; and • a decreased ability to issue additional securities or obtain additional financing in the future. Revelation will continue to incur significant increased expenses and administrative burdens as a public company, which could negatively impact its business, financial condition and results of operations. As a public company, we are subject to the reporting requirements of the Exchange Act, the listing standards of the Nasdaq, and other applicable securities rules and regulations. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting, and financial compliance costs, make some activities more difficult, time- consuming and costly, and place significant strain on our personnel, systems, and resources. For example, the Exchange Act requires, among other things, that we file annual, quarterly, and current reports with respect to our business and results of operations. As a result of the complexity involved in complying with the rules and regulations applicable to public companies, our management' s attention may be diverted from other business concerns, which could harm our business, results of operations, and financial condition. Revelation' s business and operations could be negatively affected if it becomes subject to any securities litigation or stockholder activism, which could cause Revelation to incur significant expense, hinder execution of business and growth strategy and impact its stock price. In the past, following periods of volatility in the market price of a company' s securities, securities class action litigation has often been brought against that company. Stockholder activism, which could take many forms or arise in a variety of situations, has been increasing recently. Volatility in the stock price of Revelation common stock or other reasons may in the future cause it to become the target of securities litigation or stockholder activism. Securities litigation and stockholder activism, including potential proxy contests, could result in substantial costs and divert management' s and board of directors' attention and resources from the Revelation' s business. Additionally, such securities litigation and stockholder activism could give rise to perceived uncertainties as to the Combined Entity' s future, adversely affect its relationships with service providers and make it more difficult to attract and retain qualified personnel. Also, Revelation may be required to incur significant legal fees and other expenses related to any securities litigation and activist stockholder matters. Further, its stock price could be subject to significant fluctuation or otherwise be adversely affected by the events, risks and uncertainties of any securities litigation and stockholder activism. Our common stock warrants may be accounted for as warrant liabilities and the changes in value of our warrants could have a material effect on our financial results. Historically, warrants were reflected on a company' s balance as a component of equity as opposed to liabilities on the balance sheet and the statements of operations did not include subsequent non- cash changes in estimated fair value of the warrants, based on the prevailing application of **the** Financial Accounting Standards ~~Board~~ **Boar** (" FASB ") Accounting Standards Codification (" ASC ") **including** ASC 480, Distinguishing Liabilities from Equity (" ASC 480 ") and ASC 815, Derivatives and Hedging (" ASC 815 "). Based upon the provisions of ASC 480 and ASC 815, the Company accounts for certain types of common stock warrants as current liabilities if the warrant fails the equity classification criteria. Common stock warrants classified as liabilities are initially recorded at fair value on the grant date (based ~~up~~ **upon** option pricing models since in most cases there is no public market for the warrants) and remeasured at each balance sheet date with the offsetting adjustments recorded in change in fair value of warrant liabilities within the consolidated statements of operations. One result of this accounting treatment is that as the market price of the Company' s common stock increases, the value of the warrant liability increases, resulting in a non- cash charge to earnings in the quarter in which the revaluation took place. Conversely, if the common stock price declines, the warrant liability is reduced and the Company recognizes income in the quarter in the amount of the reduction in the liability. Due to specific provisions within the warrant agreement for the Class C Common Stock Warrants **(defined below)** and the Company' s application of ASC 480 and ASC 815 to the warrant agreement, we assessed our accounting for the Class C Common Stock Warrants **(defined below)** as a warrant liability. Future issuances of warrants may be accounted for on the same basis. ~~Our financial condition will be adversely affected if we are unsuccessful in our defense in our litigation with LifeSci Capital LLC The investment banking firm for the SPAC into which we merged has brought suit against us for unpaid investment banking fees relating to the merger and deferred underwriting commissions, which claims damages of $ 5. 3 million. See " Legal Proceedings. " While we have defenses which we believe are meritorious, if we were to be unsuccessful in the proceeding it would have a material adverse effect on our financial condition and reduce the available funds to advance our product development. 72~~