Risk Factors Comparison 2024-03-29 to 2023-04-14 Form: 10-K

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Investing in our securities involves a high degree of risk. Before you make a decision to buy our securities, in addition to the risks and uncertainties discussed above under " Special Note Regarding Forward- Looking Statements, " you should carefully consider the risks and uncertainties described below together with all of the other information contained in this ~~Annual Report~~ **Form 10- K**, including our financial statements and related notes included at the end of this ~~Annual Report~~ **Form 10- K** and in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations. " If any of the events or developments described below were to occur, our business, prospects, operating results and financial condition could suffer materially, the trading price of our securities could decline **,** and you could lose all or part of your investment. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. Risk Factors Summary Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. You should carefully consider the full risk factor disclosure outlined in this ~~Annual Report~~ **Form 10- K**, in addition to the other information herein, including the section of this report titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " and our financial statements and related notes. • We are a clinical- stage biopharmaceutical company and have incurred significant losses since ~~our inception~~ **ourinception**. We may incur losses for the foreseeable future and may not be able to generate sufficient revenue to maintain profitability. • The successful development of pharmaceutical products is highly uncertain. • All of our product candidates are in preclinical or clinical development. Clinical drug development is expensive, time consuming and uncertain, and we may ultimately not be able to obtain regulatory approvals for the commercialization of some or all of our product candidates. • Regulatory approval for the genetic modification of animals, including those from which antibodies are isolated for injection into human patients, requires the approval of a New Animal Drug Application, which can be a lengthy and expensive process with uncertain outcomes, delays to which could substantially harm our business. • If we encounter difficulties enrolling patients in clinical trials, clinical trials of our product candidates may be delayed or otherwise adversely affected. • Our business is highly dependent on the success of our product candidates. If we are unable to successfully complete clinical development, obtain regulatory approval for or commercialize one or more of our product candidates, or if we experience delays in doing so, our business will be materially harmed. • **We conduct certain research and development operations through our Australian wholly- owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations could suffer.** • The regulatory approval processes of the FDA ~~is~~ **are** lengthy, time- consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed. • We may never obtain FDA approval for any product candidates in the United States, and even if we do, we may never obtain approval for or commercialize any product candidates in any other jurisdiction, which would limit our ability to realize their full market potential. • If our clinical trials fail to replicate positive results from earlier preclinical studies or clinical trials conducted by us or third parties, we may be unable to successfully develop, obtain regulatory approval for or commercialize our product candidates. • If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed. • Our product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following regulatory approval, if obtained. • Our current and future relationships with customers and third party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. • Regulatory approval for any approved product is limited by the FDA to those specific indications and conditions for which clinical safety and efficacy have been demonstrated. • Current and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize any product candidates we or our collaborators develop and may adversely affect the prices for such product candidates. • We depend upon ~~our~~ senior management and senior scientific staff, and their loss or unavailability could put us at a competitive disadvantage. • We rely on third parties to perform some of our research and preclinical studies **,** and we plan to rely on third parties to conduct our clinical trials. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. • We intend to rely on third parties to produce commercial supplies of our product candidates. • If we fail to successfully operate our animal production facility, it may adversely affect our clinical trials and the commercial viability of our product candidates. • We have not entered into long term manufacturing and supply agreements with any producers. • Cyber- attacks or other failures in our telecommunications or information technology systems, or those of our collaborators, CROs, third- party logistics providers, distributors or other contractors or consultants, could result in information theft, data corruption and significant disruption of our business operations. • Collaborations with third parties may be important to our business. If these collaborations are not successful, our business could be adversely affected. • ~~• We have historically relied on awards from, and contracts with, the U. S. Government to fund our business and operations, and will need to find new and~~

~~alternative sources of funding following the discontinuance of certain such arrangements. ●~~ We are subject to stringent environmental regulation and potentially subject to environmental litigation, proceedings, and investigations. ●• If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business. ~~• ● We may, now or in the future, be required to reimburse our counterparties in connection with costs incurred during performance of our contractual arrangements. ●~~ Our success **may** ~~depends~~ **depend** on our ability to maintain the proprietary nature of our technology. ●• **We may become involved in litigation to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time- consuming. • If patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize our discoveries. •** We have third party collaborators that might claim rights in or to our technology and / or assets. ●• We incur increased costs and demands upon management as a result of complying with the laws and regulations affecting public companies, which could adversely affect our business, financial condition, and results of operations. ●• If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable regulations could be impaired. ●• We have identified a material weakness in our internal control over financial reporting and determined that our disclosure controls and procedures were ineffective as of December 31, ~~2022~~ **2023**. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations, and adversely affect the trading price of our common stock. ●• Our warrants are accounted for as liabilities and changes in value of the warrants could have a material effect on our financial results. ●• The market price of our securities may be volatile, which could cause the value of any investment in our securities to decline. ●• An investment in our common stock is extremely speculative and there can be no assurance of any return on any such investment. ●• There can be no assurance that we will be able to comply with the continued listing standards of Nasdaq. ~~• ● Our failure to meet the continuing listing requirements of Nasdaq could result in a de- listing of our securities. ●~~ Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity plans, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. ●• We have a significant number of **(i)** warrants which are currently exercisable for shares of our common stock **or shares of preferred stock convertible into shares of our common stock, and (ii) shares of preferred stock convertible into shares of common stock**, and the exercise **or conversion** thereof would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders. ~~• ● Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. ●~~ We may be subject to securities litigation, which is expensive and could divert management attention. ~~● Our ability to continue to operate~~ **• Changes in legislation in U. S. and foreign taxation of international business activities or the adoption of other tax reform policies,** as **well as** ~~a going concern depends on our ability to obtain adequate financing in~~ the **application of such** ~~future. ● Changes in tax~~ laws **,** ~~and regulations or exposure to additional tax liabilities~~ could adversely ~~affect~~ **impact** our financial **position and operating** results. Risks Related to Our Business and Operations We are a clinical- stage biopharmaceutical company and have incurred significant losses since our inception. We realized net losses in the fiscal ~~years~~ **year** ended December 31, **2023 and** 2022 ~~and 2021~~, we expect to continue to incur net losses for the foreseeable future, and we may never achieve or maintain profitability in the future. We are a clinical- stage biopharmaceutical company. We expect to experience variability in revenue and expenses which makes it difficult to evaluate our business and prospects. As such, we have incurred and anticipate that we will continue to incur significant operating losses in the foreseeable future. Our historical losses resulted principally from costs incurred in research and development, preclinical testing, clinical development of product candidates as well as costs incurred for research programs and from general and administrative costs associated with these operations. In the future, we intend to continue to conduct research and development, preclinical testing, clinical trials and regulatory compliance activities that, together with anticipated general and administrative expenses, will result in incurring further significant losses for the next several years. We expect that our operating expenses will continue to increase significantly, including as we: ●• continue the research and development of our clinical- and preclinical- stage product candidates and discovery stage programs, including **the** ~~further pre-~~ clinical **trials** ~~and clinical development~~ of ~~SAB- 176, SAB- 195 and~~ SAB- 142; ●• advance our preclinical- stage product candidates into clinical development; ●• invest in our technology and platform; ●• seek to identify, acquire and develop additional product candidates, including through business development efforts to invest in or in- license other technologies or product candidates; ●• seek regulatory approvals for any product candidates that successfully complete clinical trials; ●• market and sell our solutions to existing and new partners; ●• hire additional clinical, quality control, medical, scientific and other technical personnel to support our operations; ●• maintain, expand, enforce, protect, and defend our intellectual property portfolio; ●• create additional infrastructure to support operations; ●• add operational, financial, and management information systems and personnel to support operations as a public company; ~~• ● seek regulatory approvals for any product candidates that successfully complete clinical trials; ●~~ undertake any pre- commercialization activities to establish sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own or jointly with third parties; and ●• experience any delays or encounter issues with any of the above. Biopharmaceutical product development entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by companies in clinical development, especially clinical- stage biopharmaceutical companies such as ours. Any predictions you make about our future success or viability may not be as

accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. Our expenses could increase beyond expectations for a variety of reasons, including **due to** ~~as a result of~~ our growth strategy and the increase in the scope and complexity of our operations. In executing our strategy and plans to invest in enhancing and scaling our business, we will need to generate significant additional revenue to achieve and maintain future profitability. We may not be able to generate sufficient revenue to achieve profitability and our recent and historical growth should not be considered indicative of future performance **.** Our limited operating history makes future forecasting difficult. We commenced operations in April 2014 and became a public company in October 2021. As a result of our limited operating history, it is difficult to accurately forecast revenues or to predict operating expenses. Our current and future expense estimates are based, in large part, on our estimates of future revenue and on our research, development and commercialization plans. In particular, we plan to increase operating expenses significantly in order to expand our research, development and sales and marketing operations. To the extent that these expenses precede increased revenue, our business, results of operations and financial condition would be materially adversely affected. We may be unable to, or may elect not to, adjust spending quickly enough to offset any unexpected revenue shortfall. Therefore, any significant shortfall in revenue in relation to our expectations would also have a material adverse effect on our business, results of operations and financial condition. We currently have no products approved for sale and are investing substantially all of our efforts and financial resources in the development of our ~~DiversitAb~~ **immunotherapy** platform and clinical development of our current lead programs. The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of therapeutic biological product candidates. We will need to raise sufficient funds for, and successfully complete, our preclinical development programs and future clinical trials of product candidates for our lead programs. There is no guarantee that any product candidate we develop will proceed into and through clinical development or achieve regulatory approval to allow such products to be commercialized. Successful development of therapeutic biological products is highly uncertain and is dependent on numerous factors, many of which are beyond our control. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including: ~~•~~ preclinical study results may show the product candidate to be less effective than desired or to have harmful side effects; ~~•~~ clinical trial results may show the product candidate to be less effective than expected (e. g., a clinical trial could fail to meet its primary or key secondary endpoint (s) or have an unacceptable safety or tolerability profile); ~~•~~ failure to receive the necessary regulatory approvals or a delay in receiving such approvals; and ~~•~~ post- marketing approval requirements. In addition, the length of time necessary to complete clinical trials and submit an application for marketing approval for a final decision by a regulatory authority varies significantly among product candidates, and any delay in receipt of marketing approval for a product candidate could negatively impact market acceptance of any resulting product. Even if we are successful in obtaining marketing approval, commercial success of any approved products will also depend in large part on the availability of coverage and adequate reimbursement from third- party payors, including government payors such as the Medicare and Medicaid programs and managed care organizations in the United States or country specific governmental organizations in foreign countries, which may be affected by existing and future healthcare reform measures designed to reduce the cost of healthcare. Third- party payors could require us to conduct additional studies, including post- marketing studies related to the cost effectiveness of a product, to qualify for reimbursement, which could be costly and divert our resources. If government and other healthcare payors were not to provide coverage and adequate reimbursement for our products once approved, market acceptance and commercial success would be reduced. In addition, if any of our product candidates receive marketing approval, we will be subject to significant regulatory obligations regarding the submission of safety and other post- marketing information and reports and registration, and will need to continue to comply (ensure that our third- party providers comply) with current Good Manufacturing Practices (cGMPs), and good clinical practices (GCPs), for any clinical trials that we conduct post- approval. In addition, there is always the risk that we, a regulatory authority or a third party might identify previously unknown problems with a product post- approval, such as adverse events of unanticipated severity or frequency. Compliance with these requirements is costly, and any failure to comply or other issues with our product candidates post- approval could adversely affect our business, financial condition and results of operations. The research, testing, manufacturing, labeling, approval, selling, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities, which regulations differ from country to country. Our product candidates are in various stages of development and are subject to the risks of failure typical of drug development. The development and approval process is expensive and can take many years to complete, and its outcome is inherently uncertain. We have not submitted an application for **,** or received **,** marketing approval for any of our product candidates. We have limited experience in conducting and managing the later- stage clinical trials necessary to obtain regulatory approvals, including approval by the FDA. To receive regulatory approval, we must, among other things, demonstrate with substantial evidence from clinical trials that the product candidate is safe and effective for each indication for which approval is sought, and failure can occur in any stage of development. Satisfaction of the approval requirements typically takes several years **,** and the time needed to satisfy them may vary substantially, based on the type, complexity and novelty of the pharmaceutical product. We cannot predict if or when we might receive regulatory approvals for any of our product candidates currently under development. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have a beneficial

effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue. The FDA and foreign regulatory authorities also have substantial discretion in the drug approval process. The number and types of preclinical studies and clinical trials that the FDA will require to establish substantial evidence of safety and effectiveness for regulatory approval varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. Approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among countries and regulatory authorities, and there may be varying interpretations of data obtained from preclinical studies or clinical trials, either of which may cause delays or limitations in the approval or the decision not to approve an application. Regulatory agencies can delay, limit or deny approval of a product candidate for many reasons, including: the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials; the results of clinical trials may not meet the level of statistical or clinical significance required by the FDA or comparable foreign regulatory authorities for approval; the clinical trial results may not confirm the positive results from earlier preclinical studies or clinical trials; the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials; the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; regulatory agencies might not approve or might require changes to our manufacturing processes or facilities; and regulatory agencies may change their approval policies, clinical development guidelines and recommendations, or adopt new regulations in a manner rendering our clinical data insufficient for approval. This lengthy approval process, as well as the unpredictability of future clinical trial results, may result in our failing to obtain regulatory approval to market our product candidates, which would significantly harm our business, results of operations and prospects. The FDA or a comparable foreign regulatory authority may require more information, including additional preclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or which we may lead us to decide to abandon the development program. In addition, even if we were to obtain marketing approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request (including failing to approve the most commercially promising indications), may require a REMS that restricts prescribing or distribution of our therapeutic biological product candidates, may grant approval contingent on the performance of costly post- marketing clinical studies, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Regulatory approval for the genetic modification of animals, including those from which antibodies are isolated for injection into human patients, requires the approval of a New Animal Drug Application (NADA), which can be a lengthy and expensive process with uncertain outcomes, delays to which could substantially harm our business. We cannot commercialize our therapeutic biological product candidates in the United States without first obtaining a regulatory approval for our animal drug candidates, i. e., the genomic modifications to our Tc Bovine, in the form of a NADA. The requirements governing development and approval of a new animal drug are largely analogous to those for new human drugs, requiring a demonstration of the safety and efficacy of the drug for the target indication, a demonstration that the manufacturing facilities, processes and controls are adequate with respect to such product candidate to assure safety, purity and potency, and a review of potential environmental impacts from the altered genomic DNA and the transgenic animals pursuant to the requirements of the National Environmental Policy Act (NEPA). The time required to obtain approval for a NADA by the FDA and comparable foreign regulatory authorities is unpredictable. Approval policies, regulations, or the type and amount of data necessary to gain approval is dependent on the specific product candidate and may change during the course of the product candidate' s preclinical and clinical development. Furthermore, we have not obtained regulatory approval for an animal drug , and it is possible that none of our existing animal drug candidates, or any future animal drug candidates, will ever obtain regulatory approval. The reasons our animal drug candidates could fail to receive regulatory approvals are generally the same as the reasons that human drug product candidates may fail to obtain approval. Our failure to obtain a regulatory approval for our animal drug candidates could significantly harm our business, the results of our operations and our prospects. Requests for additional information from a regulatory authority could delay or prevent approval , or result in our decision to abandon the development program entirely. If we do receive regulatory approval of our animal drug candidates, then we will have ongoing responsibilities including registration, recordkeeping, filing supplements, and periodic reporting, which could reveal additional complications and threaten the ongoing approval of our animal drug candidates. Further, as our polyclonal antibody product candidates are regulated as biological products, such product candidates will also require the submission and approval of a BLA prior to marketing. In general, to commercialize any of our product candidates, we must obtain marketing authorization for both the therapeutic antibody product and the altered animal genomic DNA that enables production of the polyclonal antibodies. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price. We are not permitted to market our product candidates in the United States until we receive approval of a NADA and BLA from the FDA or in other countries until we receive similar marketing authorization from applicable regulatory authorities outside the United States. We are also not permitted to promote our product candidates as safe and effective therapies until after receiving approval. Obtaining approval of a NADA or BLA can

be a lengthy, expensive and uncertain process. If we fail to obtain FDA approval to market our product candidates, we will be unable to sell our product candidates in the United States, which will significantly impair our ability to generate any revenue. In addition, failure to comply with FDA and non- U. S. regulatory requirements may, either before or after product approval, if any, subject our company to administrative or judicially imposed sanctions, including: • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • restrictions on the products' marketing, promotion, distribution or manufacturing processes; • warning letters or untitled letters alleging violations; • civil and criminal penalties; • injunctions; • suspension or withdrawal of regulatory approvals; • product seizures, detentions or import bans; • voluntary or mandatory product recalls and publicity requirements; • imposition of restrictions on operations, including costly new manufacturing requirements; • suspension of substantive review of pending applications, such as NADAs, BLAs, INADs, or INDs, pending data validation; and • refusal to approve pending NADAs or BLAs or supplements to approved NADAs or BLAs. Even if we do receive regulatory approval to market a product candidate, any such approval may be subject to limitations on the indicated uses for which we may market the product. It is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain the appropriate regulatory approvals necessary for us to commence product sales. Any delay in obtaining, or an inability to obtain, applicable regulatory approvals would prevent us from commercializing our product candidates, generating revenue and achieving and sustaining profitability. We may not be able to initiate or continue clinical trials for any product candidate we develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until conclusion. We may experience difficulties in patient enrollment in clinical trials for a variety of reasons, including: • the size and nature of the patient population; • the design of the trial, including the patient eligibility criteria defined in the protocol; • the size of the study population required for analysis of the trial' s primary endpoints; • the proximity of patients to trial sites; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • competing clinical trials for similar therapies or other new therapeutics; • clinicians' and patients' perceptions as to the potential advantages and side effects of the drug candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating; **• our ability to obtain and maintain patient consents;** • travel restrictions and other potential limitations by federal, state, or local governments affecting the workforce or ~~affective~~ **affecting** clinical research **site** policies implemented in response to ~~the COVID- 19 pandemic or similar~~ public health emergencies that may arise in the future ~~;~~ **;** • delays in or temporary suspension of the enrollment of patients in our anticipated clinical trials due to the ~~COVID- 19 pandemic or similar~~ public health emergencies that may arise in the future ~~;~~ **;** • proximity and availability of clinical trial sites for prospective patients ~~;~~ **;** • the risk that patients enrolled in clinical trials will not complete a clinical trial ~~;~~ **;** and • the availability of approved therapies that are similar in mechanism to our product candidates. If we experience delays or difficulties in the enrollment of subjects in our anticipated clinical trials, such clinical trials may be delayed or terminated. Even if we are able to enroll a sufficient number of subjects in our future clinical trials, if the pace of enrollment is slower than we expect, the development costs for our product candidates may increase and the completion of such trials may be delayed, or the trials could become too expensive to complete. Our failure to timely complete our current and planned clinical trials would delay the approval and commercialization of our product candidates, impair the commercial performance of our product candidates, may decrease the period of commercial exclusivity and consequently harm our business and results of operations. Our preclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could prevent, delay or limit the scope of regulatory approval of our product candidates, limit their commercialization, increase costs or necessitate the abandonment or limitation of the development of some of our product candidates. To obtain the requisite regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that such product candidates are safe, pure and potent for use in each target indication. These trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. Preclinical studies and clinical trials often fail to demonstrate safety or efficacy of the product candidate studied for the target indication, and most product candidates that begin clinical trials are never approved. Success in preclinical studies does not ensure that later clinical trials will generate adequate data to demonstrate the efficacy and safety of any product candidate we may develop. Likewise, a number of companies in the pharmaceutical and biotechnology industries, including those with greater resources and experience than us, have suffered significant setbacks in clinical trials, even after seeing promising results in earlier preclinical studies or clinical trials. Despite the results reported in preclinical studies for our product candidates to date, results may not be replicated in subsequent studies, and we do not know whether the clinical trials we may conduct will demonstrate adequate efficacy and safety to support regulatory approval of any current or future product candidate we develop. Moreover, later audits of earlier preclinical data may reveal inaccuracies or deviations impacting the integrity of those data. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that believed their product candidates performed satisfactorily in such studies or trials nonetheless failed to obtain FDA or other necessary regulatory agency approval. We may fail to demonstrate with substantial evidence from adequate and well- controlled trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that our product candidates are safe and potent for their intended uses. If any future late- stage clinical trials we may conduct do not produce favorable results, our ability to achieve regulatory approval for any of our product candidates may be adversely impacted. Even if we believe that we have adequate data to support an application for regulatory approval to market any of our product candidates, the FDA or other regulatory authorities may not agree with our interpretation of the relevant data and may require that we conduct additional preclinical studies or clinical trials to support the regulatory

approval of any product candidate that we develop. If we fail to obtain results in our planned and future preclinical and clinical activities and studies sufficient to meet the requirements of the relevant regulatory agencies, the development timeline and regulatory approval and commercialization prospects for any potential product candidate, and, correspondingly, our business and financial prospects, would be materially adversely affected. We have not completed the development of any product candidates. Our future success and ability to generate revenue from our product candidates, which we do not expect will occur for several years, if ever, is dependent on our ability to successfully develop, obtain regulatory approval for and commercialize one or more of our product candidates. ~~Our~~ **All of our product candidates, including our** lead product candidate ~~,~~ SAB- ~~176~~ **142** , **are** ~~was evaluated~~ in ~~a Phase 2a challenge study~~ **early stages of development and require substantial additional investment for clinical development, regulatory review and approval** in ~~healthy volunteers that were challenged with~~ **one or more jurisdictions. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or** ~~the~~ **other problems** ~~2009 pandemic H1N1 influenza A strain and showed significant reduction of viral load~~ , **our development plans** ~~reduction of influenza systems at day 4 post challenge~~ and **business would** ~~a shorter period of viral shedding in SAB- 176 treated patients compared to placebo controls. There is no guarantee that similar results will~~ be **materially harmed** ~~seen in naturally infected patients with high risk of developing severe influenza symptoms in future anticipated Phase 2b or Phase 3 clinical trials or that the company will have sufficient financial resources to conduct these trials~~ . All of our other product candidates are in earlier stages of development and will require substantial additional investment for clinical development, regulatory review and approval in one or more jurisdictions. If any of our product candidates encounters safety or efficacy problems, development delays or regulatory issues or other problems, our development plans and business would be materially harmed. We may not have the financial resources to continue development of our product candidates if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, our product candidates, including: ● our inability to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective; ● insufficiency of our financial and other resources to complete the necessary clinical trials and preclinical studies; ● negative or inconclusive results from our clinical trials, preclinical studies or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional clinical trials or preclinical studies or abandon a program; ● product- related adverse events experienced by subjects in our clinical trials, including unexpected toxicity results, or by individuals using drugs or therapeutic biologics similar to our product candidates; ● delays in submitting an INAD or IND or comparable foreign applications or delays or failure in obtaining the necessary approvals from regulators to commence a clinical trial or a suspension or termination, or hold, of a clinical trial once commenced; ● conditions imposed by the FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials; ● poor effectiveness of our product candidates during clinical trials; ● delays in enrolling subjects in our clinical trials; ● higher than anticipated clinical trial or manufacturing costs; ● failure of our third- party contractors or investigators to comply with regulatory requirements or the clinical trial protocol or otherwise meet their contractual obligations in a timely manner, or at all; and ● delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our therapies in particular. **Our wholly- owned Australian subsidiary, SAB Australia, was formed to conduct various preclinical and clinical activities for SAB- 142 and other future drug candidates in Australia. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop and commercialize our lead products in Australia, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidates in Australia will be accepted by the FDA or applicable foreign authorities. In addition, current Australian tax regulations provide for a refundable research and development tax credit equal to 39. 5 % of qualified expenditures. Although we have previously claimed a refundable research and development tax credit there is a possibility that we may not be able to claim such credit, or we might qualify for a lesser credit. If we lose our ability to operate SAB Australia, or if in the future we are ineligible or unable to receive the research and development tax credit or are required to refund any research and development tax credit previously received or have to reserve for such credit in our financial statements, or if the Australian government significantly reduces or eliminates the tax credit, our business and results of operation may be adversely affected.** We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions. To date, we have not submitted a NADA or BLA to the FDA or similar drug or biological product approval submissions to comparable foreign regulatory authorities for any product candidate ~~. With respect to our lead product, SAB- 185, we must complete additional clinical trials to demonstrate the safety and efficacy of SAB- 185 before we will be able to obtain these approvals~~ . In addition to regulations in the United States, to market and sell our product candidates in the European Union, many Asian countries and other jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements, both from a clinical and manufacturing perspective. The approval procedure for complex therapeutic biological product candidates such as ours varies among countries and can involve additional testing and validation and additional administrative review periods. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The regulatory approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. Clinical trials accepted in one country may not be accepted by regulatory authorities in other countries. In addition, many countries outside the United States require that a product be approved for reimbursement before it can be approved for sale in that country. A product candidate that has

been approved for sale in a particular country may not receive reimbursement approval in that country. We may not be able to obtain approvals from regulatory authorities or payor authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory or payor authorities in other countries or jurisdictions, and approval by one regulatory or payor authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may not be able to file for future regulatory approvals and may not receive necessary approvals to commercialize our products in any market. If we are unable to obtain approval of any of our product candidates by regulatory or payor authorities in the European Union, Asia or elsewhere, the commercial prospects of that product candidate may be significantly diminished. We do not have any product candidates approved for sale in any jurisdiction, including in the United States or in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our products will be unrealized. The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates. The general approach for FDA approval of a new drug is dispositive data from two or more well- controlled Phase 3 clinical trials of the product candidate in the relevant patient population. Phase 3 clinical trials typically involve a large number of patients, have significant costs and take years to complete. In addition, there is no assurance that the endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following: ● the FDA or comparable foreign regulatory authorities may not file or accept our NADA, BLA or other marketing applications for substantive review; ● the FDA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials; ● we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications; ● the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval; ● we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks; ● the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a NADA, BLA or other comparable submissions in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere; ● the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and ● the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. The results observed from preclinical studies or early- stage clinical trials of our product candidates may not necessarily be predictive of the results of later- stage clinical trials that we conduct. Similarly, positive results from such preclinical studies or early- stage clinical trials may not be replicated in our subsequent preclinical studies or clinical trials. There can be no assurance that any of our clinical trials will ultimately be successful or support further clinical development of any of our product candidates. There is a high failure rate for drugs proceeding through clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late- stage clinical trials after achieving positive results in early- stage development, and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. To obtain the requisite regulatory approvals to commercialize any of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an INAD or IND, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. We may also experience numerous unforeseen events during our clinical trials that could delay or prevent our ability to receive marketing approval or commercialize the product candidates we develop, including: ● regulators, institutional review boards ("IRBs "), or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site; ● we may not reach agreement on acceptable terms with prospective contract research organizations ("CROs "), and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● we may experience challenges or delays in recruiting principal investigators or study sites to lead our clinical trials; ● the number of subjects or patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be insufficient or slower than we anticipate, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate; ● our third- party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; ● we may have to amend clinical trial protocols submitted to regulatory authorities or conduct additional studies to reflect changes in regulatory requirements or guidance; ● regulators or other reviewing bodies may find deficiencies with, fail to approve or subsequently find fault with the manufacturing processes or facilities of third- party manufacturers with which we enter into agreements for clinical and commercial supplies, or the supply or quality of any product candidate or other materials necessary to conduct

clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply; and ● the potential for approval policies or regulations of the FDA or the applicable foreign regulatory agencies to significantly change in a manner rendering our clinical data insufficient for approval. Regulators or IRBs of the institutions in which clinical trials are being conducted may suspend, limit or terminate a clinical trial, or data monitoring committees may recommend that we suspend or terminate a clinical trial, due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using an investigational product, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. We do not know whether any clinical trials that we conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates for the indications that we are pursuing. If later- stage clinical trials do not produce favorable results, our ability to obtain regulatory approval for our product candidates will be adversely impacted. Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process for product candidates is expensive, time- consuming and uncertain, and may prevent us from obtaining approvals for the commercialization of our product candidates. Any product candidate we develop , and the activities associated with its development and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, and distribution, are subject to comprehensive regulation by the FDA and other regulatory authorities in the United States and by comparable authorities in other countries. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in a given jurisdiction. We have not received approval to market any product candidates from regulatory authorities in any jurisdiction and it is possible that none of the product candidates we are developing or may seek to develop in the future will ever obtain regulatory approval. We have no experience in submitting and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs or regulatory consultants to assist us in this process. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to the various regulatory authorities for each therapeutic indication to establish the product candidate' s safety and efficacy. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and successful inspection of manufacturing facilities by, the relevant regulatory authority. Any product candidates we develop may not be effective, may be only moderately effective, or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude its obtaining marketing approval or prevent or limit commercial use. The process of obtaining marketing approvals, both in the United States and abroad, is expensive, may take many years if additional clinical trials are required, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity, and novelty of the product candidates involved. Changes in marketing approval policies during the development period, changes in or the enactment of additional statutes or regulations, or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. The FDA and comparable authorities in other countries have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit, or prevent marketing approval of a product candidate. Any marketing approval that we may ultimately obtain could be limited or subject to restrictions or post- approval commitments that render the approved product not commercially viable. If we experience delays in obtaining approval or if we fail to obtain approval of any product candidates we may develop, the commercial prospects for those product candidates may be harmed, and our ability to generate revenues will be materially impaired. Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data becomes available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publish interim, topline or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or 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, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects. For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including: ● our available capital resources or capital constraints we experience; ● the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators; ● our ability to identify and enroll patients who meet clinical trial eligibility criteria; ● our receipt of approvals by the FDA and other regulatory authorities and the timing thereof; ● other actions, decisions or rules issued by regulators; ● our ability to access sufficient, reliable and affordable supplies of materials used to manufacture of our product candidates; ● the efforts of our collaborators with respect to the

commercialization of our product candidates; and • the securing of costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities. If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delays. As product candidates proceed through preclinical studies to late- stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay or prevent completion of clinical trials, require conducting bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay or prevent approval of our product candidates and jeopardize our ability to commence sales and generate revenue. Undesirable side effects caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities or a more restrictive label for any of our product candidates that may receive regulatory approval. In our planned and future clinical trials of our product candidates, we may observe a more unfavorable safety and tolerability profile than was observed in earlier- stage testing of these candidates. If unacceptable side effects arise in the development of our product candidates, we, the FDA or comparable foreign regulatory authorities, the IRBs, or independent ethics committees at the institutions in which our trials are conducted, could suspend, limit or terminate our clinical trials, or the independent safety monitoring committee could recommend that we suspend, limit or terminate our trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment- emergent side effects that are deemed to be related to administration of our product candidates could delay recruitment of clinical trial subjects or may cause subjects that enroll in our clinical trials to discontinue participation in our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Additionally, during the course of our product development programs, FDA or comparable foreign regulatory authority review teams may change, and new agency personnel may view the risk- benefit profile of any product candidates we may develop differently than prior agency review teams. Any negative views as to the risk- benefit profile of the product candidates we are developing for our lead programs or any product candidates we may develop in the future could lead FDA or comparable foreign regulatory authorities to require that we conduct additional clinical trials or could require more onerous clinical trial designs for any then- ongoing or future clinical trials. The product- related side effects also could result in potential product liability claims being asserted against us. Furthermore, we or others may later identify undesirable side effects caused by our products, including during any long- term follow- up observation period. If any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused or risks exacerbated by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient; a REMS may include, among other things, a communication plan to healthcare practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the biopharmaceutical industry. Other potentially significant negative consequences include that: • we may be forced to suspend marketing of that product, or decide to recall the product or remove it from the marketplace; • regulatory authorities may withdraw or limit their approvals of that product; • regulatory authorities may require additional statements, specific warnings or contraindications on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment; • we may be required to conduct additional clinical trials or costly post- marketing testing and surveillance to monitor the safety and efficacy of the product; • we may be required to change the way the product is distributed or administered; • we may be subject to regulatory investigations and government enforcement actions; • we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to sued and held liable for harm caused to subjects or patients; and • the product may become less competitive, and our reputation may suffer. Any of these occurrences could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities, and may adversely affect our business, financial condition and prospects significantly. The future commercial success of our product candidates will depend on the degree of market acceptance of our potential products among physicians, patients, healthcare payers, and the medical community. When available on the market, our products may not achieve an adequate level of acceptance by physicians, patients and the medical community, which may result in us failing to achieve profitability. In addition, efforts to educate the medical community and third- party payers on the benefits of our products may require significant resources and may never be successful, which would prevent us from generating significant revenues or becoming profitable. Failure to successfully identify, develop and commercialize additional products or product candidates could impair our ability to grow. Although a substantial amount of our efforts will focus on the continued preclinical and clinical testing and potential approval of product candidates in our current pipeline, a key element of long- term growth strategy is to develop and market additional products and product candidates. Because we have limited financial and managerial resources, research programs to identify product candidates will require substantial additional technical, financial and human resources, whether or

not any product candidates are ultimately identified. The success of this strategy depends partly upon our ability to identify, select and develop promising product candidates and products. Our technology platforms may fail to discover and to generate additional product candidates that are suitable for further development. All product candidates are prone to risks of failure typical of pharmaceutical product development, including the possibility that a product candidate may not be suitable for clinical development as a result of its harmful side effects, limited efficacy or other characteristics that indicate that it is unlikely to be a product that will receive approval by the FDA and other comparable foreign regulatory authorities and achieve market acceptance. If we do not successfully develop and commercialize product candidates based upon its technological approach, we may not be able to obtain product or collaboration revenues in future periods, which would adversely affect our business, prospects, financial condition and results of operations. Our long- term growth strategy to develop and market additional products and product candidates is heavily dependent on precise, accurate and reliable scientific data to identify, select and develop promising pharmaceutical product candidates and products. Our business decisions may therefore be adversely influenced by improper or fraudulent scientific data sourced from third parties. Any irregularities in the scientific data used by us to determine our focus in research and development of product candidates and products could have a material adverse effect on our business, prospects, financial condition and results of operations. If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates. We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize ~~SAB176~~ **SAB- 142,** and our other product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of SAB ~~176 -~~ **142,** and our other product candidates and other future product candidates. Factors that may inhibit our efforts to commercialize our product candidates on our own include: ● our inability to recruit and retain adequate numbers of effective sales and marketing personnel; ● our inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products; ● the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer, and we may incur significant additional losses. 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 product candidates. Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates. We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients **,** and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in: ● decreased demand for any of our future approved products; ● injury to our reputation; ● withdrawal of clinical trial participants; ● termination of clinical trial sites or entire trial programs; ● significant litigation costs; ● substantial monetary awards to, or costly settlements with, patients or other claimants; ● product recalls or a change in the indications for which they may be used; ● loss of revenue; ● diversion of management and scientific resources from our business operations; and ● the inability to commercialize our product candidates. Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies. Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of our product

candidates, which could harm our business, financial condition, results of operations and prospects. Our current and future relationships with customers and third- party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti- kickback, fraud and abuse, false claims, transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings. Healthcare providers, physicians and third- party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our future arrangements with third party payors, distributors, retailers, marketers and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti- Kickback Statute, the federal False Claims Act, and similar state or foreign laws which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any product candidates for which we obtain marketing approval. In addition, we may be subject to transparency laws and patient privacy regulation by U. S. federal and state governments and by governments in foreign jurisdictions in which we conduct our business. The applicable federal, state and foreign healthcare laws and regulations that may affect our ability to operate include, but are not necessarily limited to: ● the federal Anti- Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid; ● federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, which impose criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent, making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, or the knowing retention of an overpayment from government health care programs; **the federal Health Insurance Portability and Accountability Act of 1996, or** HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose obligations on covered healthcare providers, health plans, and healthcare clearinghouses, as well as their business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● the federal Physician Payments Sunshine Act, which requires manufacturers of certain drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to " payments or other transfers of value " made to physicians, which is defined to include doctors, dentists, optometrists, podiatrists and chiropractors, and certain teaching hospitals and applicable manufacturers to report annually to CMS ownership and investment interests held by the physicians and their immediate family members. **Certain** ~~Beginning in 2022, applicable~~ manufacturers also **are** ~~will be~~ required to report such information regarding payments and transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists and certified nurse- midwives; and ● analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non- governmental third party payors, including private insurers; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; 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 often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could have a material adverse effect on our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including our collaborators, is found not to be in compliance with applicable laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government healthcare programs, which could also materially affect our business. Any regulatory approval is limited to those specific diseases and indications for which a product is deemed to be safe and effective by the FDA. In addition to the FDA approval required for new formulations, any new indication for an approved product also requires FDA approval. If we are not able to obtain FDA approval for any desired future indications for our products, our ability to effectively market and sell our products may be reduced and our business may be adversely affected. While our ability to promote the products is limited to those indications that are specifically approved by the FDA, physicians may choose to prescribe drugs for uses that are not described in the product' s approved labeling and for uses that differ from those tested in clinical studies and approved by the regulatory authorities. These " off- label " uses are common across medical specialties and may constitute an appropriate treatment for some patients in varied circumstances. Regulatory authorities in the United States

generally do not regulate a physician' s use of professional judgment in prescribing treatments for patients. Regulatory authorities do, however, restrict communications by pharmaceutical companies on the subject of off- label use or off- label information. If our promotional activities fail to comply with these regulations or guidelines, we may be subject to warnings from, or enforcement action by, these authorities. In addition, our failure to follow FDA rules and guidelines relating to promotion and advertising may cause the FDA to suspend or withdraw an approved product from the market, require a recall or corrective advertising, institute fines, or could result in disgorgement of money, operating restrictions, injunctions or civil or criminal prosecution by the government, any of which could harm our reputation and business. In the United States and certain non- U. S. jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities and affect our or our collaborators' ability to profitably sell any product candidates that obtain marketing approval. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively the Affordable Care Act, was enacted in the United States. ~~Among the provisions of the Affordable Care Act of importance to our product candidates, the Affordable Care Act established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program, extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations, expanded eligibility criteria for Medicaid programs, expanded the entities eligible for discounts under the Public Health program, 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, created a new Medicare Part D coverage gap discount program, in which manufacturers must now 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, and created a licensure framework for follow- on biologic products.~~ Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the Affordable Care Act. However, following several years of litigation in the federal courts, in June 2021, the U. S. Supreme Court upheld the ACA when it dismissed a legal challenge to the ACA' s constitutionality. Further legislative and regulatory changes under the ACA remain possible, but it is unknown what form any such changes or any law would take or how or whether such changes may affect the biopharmaceutical industry as a whole or our business in the future. In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, included reductions to Medicare payments to providers of 2 % per fiscal year, which went into effect on April 1, 2013 ~~,~~ and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 ~~, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021~~ , 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, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, there has been heightened governmental scrutiny recently over pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies, rebates and price negotiation for pharmaceutical products. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and medical devices to purchase **,** and which suppliers will be included in their prescription drug and other healthcare programs. We expect that other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria, new payment methodologies and in additional downward pressure on the price that we or our collaborators may receive for any approved or cleared product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we or our collaborators are slow or unable to adapt to new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, any of our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business. Even if we obtain regulatory approval for a product ~~candidate~~ **candidates** , our products will remain subject to regulatory scrutiny. Even if we obtain regulatory approval in a jurisdiction for our product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, recordkeeping, and submission of safety and other post- market information. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post- marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product. For example, the holder of an approved BLA is obligated to monitor and report adverse events and any failure of a product to meet the specifications in the BLA. The holder of an approved BLA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. Advertising and promotional materials and claims must be consistent with approved labeling and be in compliance with FDA regulations as well as other potentially applicable federal and state laws. In addition, biological product advertising and promotional materials intended to be

used during the first 120 days after approval must be submitted to the FDA during the BLA review period. After approval, advertising and promotional materials must be submitted to the FDA 30 days prior to their intended use. In addition, product manufacturers are subject to payment of program fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with GMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we or a regulatory agency discovers 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 or with the integrity or sufficiency of data, records, or documentation, or disagrees with the promotion, marketing or labeling of that product, a regulatory agency may impose restrictions relative to that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. If we or a regulatory agency later discovers previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, or if we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may: ● issue a warning letter asserting that we are in violation of the law; ● seek an injunction or impose civil or criminal penalties or monetary fines; ● suspend or withdraw regulatory approval; ● suspend any ongoing clinical trials; ● refuse to approve a pending BLA or comparable foreign marketing application (any supplements thereto) submitted by us or our strategic partners; ● restrict the marketing or labeling of the product; ● restrict manufacturing of the product, the approved manufacturers or the manufacturing process; ● restrict product distribution or use; ● demand a recall; ● seize or detain product or otherwise require the withdrawal of product from the market; ● impose fines, restitution or disgorgement of profits or revenues; ● impose consent decrees, injunctions or the imposition of civil or criminal penalties; ● refuse to permit the import or export of products; or ● refuse to allow us to enter into supply contracts, including government contracts. Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue. Advertising and promotion of any human therapeutic biological product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U. S. Federal Trade Commission, the Department of Justice (DOJ), the Office of Inspector General of the Department of Health and Human Services (HHS), state attorneys general, members of the U. S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off- label uses, are subject to enforcement letters, inquiries and investigations, and civil and criminal sanctions by the FDA, other U. S. governmental authorities, or comparable foreign bodies. Any actual or alleged failure to comply with labeling and promotion requirements may result in fines, warning letters, mandates to issue corrective information to healthcare practitioners and / or the general public, injunctions, or civil or criminal penalties. In addition, the FDA' s policies may change, and additional government laws may be enacted and implementing regulations promulgated, which could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, the FDA' s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA' s ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to approved biologics to be reviewed and / or approved by necessary government agencies, 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 agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. **Since** ~~Separately, in response to the COVID- 19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products. Subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on- site inspections of domestic manufacturing facilities subject to a risk- based prioritization system. The FDA intends to use this risk- based assessment system to identify the categories of regulatory activity~~ that ~~can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in- person inspection would not be prioritized, deemed mission- critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. As of early 2022, the FDA has resumed inspections of domestic and foreign facilities to ensure timely~~ -- **time** ~~reviews of applications for all products lines. However~~ , ~~the FDA may not be able to continue its current pace and review timelines could be extended, including where~~ **there have been several threatened " shutdowns "** ~~a pre- approval inspection or an inspection~~ of ~~clinical sites is required. On January 30, 2023,~~ the **U** ~~Biden administration~~

~~announced that it will end the public health emergency declarations related to COVID- 19 on May 11, 2023~~ . **S.** ~~On January 31, 2023, the FDA indicated that it would soon issue a Federal~~ **federal government** ~~Register notice describing how the termination of the public health emergency will impact the agency' s COVID- 19 related guidance. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the pandemic related to COVID- 19 and its variants~~ . 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. We **must** ~~need to~~ attract and retain highly skilled personnel and strategic partners, and we may be unable to effectively manage our growth with our limited resources. We have limited human resources and our future success **depends and** will depend in part on our ability to attract, train, retain and motivate highly skilled executive level management, research and development, and sales personnel and to establish and maintain effective strategic alliances with key companies in our industry. Competition is intense for many of these types of personnel from other companies, consulting firms and more established organizations, many of which have significantly larger operations and greater financial, marketing, human, and other resources. We may not be successful in attracting and retaining qualified personnel on a timely basis, on competitive terms or at all. If we are not successful in attracting and retaining these personnel, our business, prospects, financial condition and results of operations may be materially adversely affected. We anticipate adding new employees and we will have to integrate such new employees into our operations. Our officers and directors may not possess all of the skills or experience necessary to successfully implement our business plan. Further, we anticipate hiring new employees. Failure to fully integrate new employees into our operations could have a material adverse effect on our business, prospects, financial condition and results of operations **. We depend on our senior management and senior scientific staff, and their loss or unavailability could put us at a competitive disadvantage** . Our success depends largely on the skills, experience and reputation of certain key management and personnel, in particular our directors, executive officers and senior scientific staff. The loss or unavailability of any of these individuals for any significant period of time could have a material adverse effect on our business, prospects, financial condition and results of operations. Our employees and independent contractors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could negatively impact our business, prospects, financial condition and operating results. We are exposed to the risk that our employees, independent contractors, consultants, commercial partners, suppliers and distributors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the rules and regulations of the FDA and other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities 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 be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, imprisonment, additional integrity reporting and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could harm our business, financial condition and results of operations. We ~~rely on third parties to perform some of our research and preclinical studies, and we plan to rely on third parties to conduct our clinical trials. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects. We~~ do not have the ability to conduct all aspects of our preclinical studies or future clinical trials ourselves. As a result, we are, and expect to remain, dependent on third parties to perform some of our research and preclinical studies and any future clinical trials of our product candidates, including but not limited to governmental agencies and university laboratories, contract manufacturers, **contract research organizations (** CROs **)** , distribution and supply (logistics) services organizations, contract testing organizations (CTOs), consultants or consultant organization with specialized knowledge based expertise. The timing of the initiation and completion of our current and planned preclinical studies and clinical trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators, and consultants to play a significant role in the conduct of future clinical trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, as the sponsor of the INADs, INDs and clinical protocols governing our future clinical trials, we will be responsible for ensuring that each of our trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on

the CROs, CTOs, and other third parties does not relieve us of our regulatory responsibilities. We, our CROs, CTOs, and clinical sites will be required to comply with GLP requirements for preclinical studies, as well as GCP requirements for clinical trials involving human subjects, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area, and comparable foreign regulatory authorities, for all of our current product candidates and any future product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of trial sponsors, testing laboratories, clinical trial investigators, and clinical trial sites. If we or any of our CROs, CTOs, or clinical trial sites fail to adhere to our clinical trial protocols or to comply with applicable GLP or GCP requirements, as applicable, the data generated in our future preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before accepting for review or approving our marketing applications. In addition, our clinical trials must be conducted with product candidates produced under GMP regulations. Our failure to comply with these regulations may require us to stop and / or repeat clinical trials, which would delay the marketing approval process. Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial results or data. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of our product candidates. There is no guarantee that any such CROs, CTOs, clinical trial investigators or other third parties on which we plan to rely will devote adequate time and resources to our development activities or perform as contractually required. Further, the performance of our third parties on which we rely may be interrupted by the ongoing COVID- 19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID- 19 or prioritization of resources toward the pandemic (similar public health emergencies that may arise in the future). If any of these third parties fails to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our future clinical trial sites terminates for any reason, we may experience the loss of follow- up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. We are limited in our ability to manufacture pharmaceutical products. To be successful, our products and the products of our partners must be manufactured in commercial quantities in compliance with regulatory requirements and at a commercially acceptable cost. We have not commercialized any pharmaceutical products, nor have we demonstrated an ability to manufacture commercial quantities of our or our partners' product candidates in accordance with regulatory requirements. If we are unable to produce suitable quantities of our or our partners' products, or contract third parties to do so, in accordance with regulatory standards at a commercially acceptable cost, our ability or the ability of our partners to conduct clinical trials, obtain regulatory approvals and market such products may be adversely affected, which could adversely affect our competitive position and our chances of achieving profitability. There can be no assurance that such products can be manufactured by us or any other party at a cost or in quantities which are commercially viable. We intend to rely on third- party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. We do not yet have a commercial supply agreement for commercial quantities of drug substance or drug product. If we are not able to meet market demand for any approved product, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business and financial condition. Further, our reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including: ● inability to meet our product specifications and quality requirements consistently; ● delay or inability to procure or expand sufficient manufacturing capacity; ● issues related to scale- up of manufacturing; ● costs and validation of new equipment and facilities required for scale- up; ● our third- party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately; ● our third- party manufacturers may fail to comply with cGMP requirements and other inspections by the FDA or other comparable regulatory authorities; ● our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all; ● breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us; ● reliance on single sources for drug components; ● lack of qualified backup suppliers for those components that are currently purchased from a sole or single- source supplier; ● our third- party manufacturers may not devote sufficient resources to our product candidates; ● we may not own, or may have to share, the intellectual property rights to any improvements made by our third- party manufacturers in the manufacturing process for our product candidates; ● operations of our third- party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and ● carrier disruptions or increased costs that are beyond our control. In addition, if we enter into a strategic collaboration with a third party for the commercialization of our current or any future product candidates, we will not be able to control the amount of time or resources that they devote to such efforts. If any strategic collaborator does not commit adequate resources to the marketing and distribution of our product candidates, it could limit our potential revenues. Any of these events could lead to clinical trial delays or failure to obtain regulatory approval , or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, or total or partial suspension of production. We operate our own animal production facility, where we produce

supplies of our product candidates for our preclinical and clinical studies, and such facility is currently subject to certain regulatory requirements and inspections, including by the USDA to ensure compliance with the Animal Welfare Act and other regulations relating to the care and welfare of laboratory and research animals. Before approving any of our product candidates for commercialization, the FDA must conduct a pre- approval inspection of our animal production and manufacturing facilities to determine whether the manufacturing processes and facilities comply with GMPs. If and when we obtain regulatory approval for any of our product candidates, we would need to register our animal production and manufacturing facilities with the FDA and list all licensed biological products manufactured at such facilities. Even if the FDA determines that our facilities are in substantial compliance with applicable regulations and standards, we would be subject to ongoing periodic unannounced inspection by the FDA, the USDA, corresponding state agencies and potentially third- party collaborators to ensure strict compliance with GMPs, animal welfare requirements, and other applicable laws and government regulations. Our license to manufacture such future approved product candidates will be subject to continued regulatory review. In addition, our animal production facility maintains detailed standard operating procedures and other documentation necessary to comply with the Animal Welfare Act and applicable regulations for the humane treatment of the pigs and piglets in our custody. We also maintain an Institutional Animal Care and Use Committee (IACUC) to provide ongoing oversight and to conduct assessments of the care and use of the animals in our research and development programs. If the USDA determines that our current equipment, facilities, or processes relating to donor animal production do not comply with applicable Animal Welfare Act standards, it may issue an inspection report documenting the deficiencies and setting deadlines for any required corrective actions. For continued noncompliance, the USDA may impose fines, suspend, or revoke animal research licenses or confiscate research animals. There can be no assurance that we will not encounter difficulties in scaling up our manufacturing processes. Significant scale- up of manufacturing may result in unanticipated technical challenges and may require additional inspections, permits, or other authorizations by the FDA, the USDA, or corresponding state agencies. We may encounter difficulties in scaling up production, including problems involving raw material suppliers, production yields, technical difficulties, scaled- up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. The actual cost to manufacture and process our product candidates could also be greater than we expect and could materially and adversely affect the commercial viability of any product candidates that we develop. Any of these difficulties, if they occur and are not resolved to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the future development or commercial program for such product candidate. These risks become more acute as we scale- up for commercial quantities, where a reliable source of product becomes critical to commercial success. The commercial viability of any of our product candidates, if approved, will depend on our ability to produce our product candidates at a large scale. Failure to achieve this level of supply could jeopardize the successful commercialization of our therapeutic product candidates, should any be approved for marketing. The manufacture of polyclonal antibodies from transgenic animals is complex and requires significant expertise, including the development of advanced manufacturing techniques and process controls. Manufacturers of polyclonal antibody products often encounter difficulties in production, particularly in scaling out up and validating initial production and ensuring the absence of contamination. These problems include difficulties with production costs and yields, quality control, including stability of the product candidate, quality assurance testing, operator error, shortages of qualified personnel, shortages of raw materials, as well as compliance with strictly enforced federal, state and foreign regulations. Furthermore, if contaminants are discovered in our animal production facility, it may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot ensure provide assurance that any stability or other issues relating to the manufacture of our product candidates will not occur in the future. Our manufacturing capabilities could be affected by cost- overruns, resource constraints, unexpected delays, equipment failures, labor shortages or disputes, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy, jeopardize our ability to produce our product candidates, and have a material adverse effect on our business, financial condition, results of operations and prospects. Our product candidates are uniquely manufactured, and we may encounter difficulties in production, particularly with respect to scaling our manufacturing capabilities. The manufacturing process used to produce Tc Bovine is novel and has not been validated for commercial production. There is a risk that of we may experience manufacturing issues associated with the differences in donor starting materials, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, and variability in product characteristics. Even minor deviations from our normal manufacturing processes could result in reduced production yields, lot failures, product defects, product delays, product recalls, product liability claims and other supply disruptions. Further, as product candidates advance through preclinical to later- stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered in an effort to optimize processes and results. We may not achieve our intended objectives and any of these changes could cause our product candidates to perform differently than we expect, potentially affecting the results of future clinical trials. Although we continually attempt to optimize our manufacturing process, doing so is a difficult and uncertain task and there are risks associated with scaling to the level required for future initial clinical trials, advanced late- stage clinical trials or commercialization, including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, lot consistency and timely availability of reagents or raw materials. If we are unable to adequately validate or scale- up our manufacturing processes, we may encounter lengthy delays in commercializing our product candidates. The manufacturing process for any products candidates that we may develop is subject to the FDA and foreign regulatory authority approval processes and, if we choose to outsource our commercial production, we will need to contract with third- party manufacturers who we believe can meet applicable FDA, USDA, and foreign regulatory authority requirements on an ongoing basis. If we are unable to reliably produce any product candidate to specifications acceptable to the FDA, the

USDA, or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize our products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or any third- party manufacturers we may contract with in the future will be able to manufacture the approved product to specifications and under GMPs acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of future clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects. Our future success depends on our ability to manufacture our product candidates on a timely basis with acceptable manufacturing costs, while at the same time maintaining good quality control and complying with applicable regulatory requirements. Our inability to do so could have a material adverse effect on our business, financial condition, prospects and results of operations. In addition, we could incur higher manufacturing costs if manufacturing processes or standards change and we could need to replace, modify, design or build and install equipment, all of which would require additional capital expenditures. ~~We have not entered into definitive long term manufacturing and supply agreements with any producers.~~ On October 26, 2022, we entered into a Manufacturing Option Agreement (the " Emergent Manufacturing Agreement ") and Right of First Refusal Agreement (the " Emergent RoFR Agreement, " and together with the Emergent Manufacturing Agreement, the " Emergent Agreements ") with Emergent BioSolutions Canada, Inc., a wholly- owned subsidiary of Emergent BioSolutions Inc. (" Emergent "). The Emergent Agreements contemplate that we will enter into one or more binding Master Manufacturing Services Agreements, whereby Emergent will provide contract development and manufacturing services to produce our fully- human polyclonal antibody products. Under the Emergent Manufacturing Agreement, we granted Emergent an exclusive option for the exclusive commercial manufacture of commercial stage product utilizing our humanized polyclonal antibodies. Pursuant to the terms of our arrangement, we will notify Emergent in advance of our first commercial manufacturing needs for any product and each additional product, and Emergent may then exercise the exclusive manufacturing option with respect to such product. Under the Emergent RoFR Agreement, we granted Emergent an exclusive right of first refusal to license and develop our products, developed using humanized polyclonal antibodies based on our platform to treat (i) botulism anti- toxin, (ii) pandemic influenza, or (iii) anti- fungal diseases. Any definitive manufacturing arrangement will be determined at the time any Master Manufacturing Services Agreement is entered into with Emergent, and there is no guarantee we will do so. We intend to pursue agreements with contract manufacturers to produce the components and drug products that we will use in the future for the commercialization of products that make using of our technology, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. Components of our product candidates are currently manufactured for us in small quantities for use in our preclinical and clinical studies. We will require significantly greater quantities to commercialize any given product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from our existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of our product candidates may be delayed. If we are unable to obtain sufficient compounds and labeling services on acceptable terms, or if we should encounter delays or difficulties in our relationships with our current and future suppliers or if our current and future suppliers of each component do not comply with applicable regulations for the manufacturing and production of drugs, our business, financial condition, and results of operations may be materially harmed. We are subject to manufacturing risks that could substantially increase the costs and limit supply of product candidates or prevent us from achieving a commercially viable production process. The process of manufacturing our product candidates is complex, highly regulated and subject to several risks, including: • we do not have experience in manufacturing our product candidates at commercial scale. • we plan to develop a larger scale manufacturing process for our product candidates. • we may not succeed in scaling up the process. • we may need a larger scale manufacturing process for certain product candidates than what has been planned. Any changes in our manufacturing processes as a result of scaling up may result in the need to obtain additional regulatory approvals. Difficulties in achieving commercial-scale production or the need for additional regulatory approvals as a result of scaling up could delay the development and regulatory approval of our product candidates and ultimately affect our success. We may not achieve the manufacturing productivity (" yield ") required to achieve a commercially viable cost of goods. Low productivities may result in a cost of goods which is too high to allow profitable commercialization , or give rise to the need for additional manufacturing process optimization which would require additional funding and time. Additionally, the process of manufacturing biologics, such as our product candidates, is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We and our contract manufacturers are subject to significant regulatory oversight with respect to manufacturing our products. The manufacturing facilities on which we rely may not continue to meet regulatory requirements and may have limited capacity. All parties involved in the preparation of therapeutics for clinical trial or commercial sale are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical trials must be manufactured in accordance with GMP requirements. These regulations govern manufacturing processes and procedures (including recordkeeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. In addition, due to our use of transgenic animals to manufacture our product candidates, we, and potentially our third- party manufacturers, are subject to animal welfare requirements as part of our production process. The FDA, the

USDA, and comparable foreign regulatory agencies may also implement new standards at any time, or change their interpretations and enforcement of existing standards, including for the manufacture, packaging or testing of biological products or for the care and welfare of research animals. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing. We or our contract manufacturers must supply all necessary documentation in support of a NADA and BLA on a timely basis and must adhere to the FDA' s GMP requirements and USDA animal welfare requirements enforced by each agency through its respective facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our third- party contractors must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of our product candidates. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre- approval plant inspection, FDA approval of the products will not be granted. The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our third- party manufacturers. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and / or time- consuming for us or our third- party manufacturers to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a manufacturing facility. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business. If we or any of our third- party manufacturers or testing contractors fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions. Such an occurrence may cause our business, financial condition and results of operations to be materially harmed. The manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors. We presently manufacture our product candidates at our lab facilities in South Dakota. If our lab facilities were to be damaged or destroyed by fire, flood, other natural disaster or other occurrences of any kind, it would have a material adverse effect on our ability to produce product candidates and on our business, financial condition and results of operations. We must comply with applicable **current Good Manufacturing Practice, or** cGMP, regulations and guidelines. We may encounter difficulties in achieving quality control and quality assurance and may experience shortages in qualified personnel. We are subject to inspections by regulatory authorities to confirm compliance with applicable regulatory requirements. Any failure to follow cGMP or other regulatory requirements or delay, interruption or other issues that arise in the manufacture, fill- finish, packaging, or storage of our product candidates as a result of a failure of our facilities or the facilities or operations of third parties to comply with regulatory requirements or pass any regulatory authority inspection could significantly impair our ability to develop and commercialize our product candidates, leading to significant delays in the availability of therapeutic product for clinical studies or the termination or hold on a clinical study, or the delay or prevention of a filing or approval of marketing applications for our product candidates. Significant noncompliance could also result in the imposition of sanctions, including fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation. If we are not able to achieve and maintain regulatory compliance, we may not be permitted to market our product candidates and / or may be subject to product recalls, seizures, injunctions, or criminal prosecution. Any adverse developments affecting manufacturing operations for our product candidates, if any are approved, may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of product candidates. We may also have to take inventory write- offs and incur other charges and expenses for products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Our product candidates that have been produced and are stored for later use may degrade, become contaminated or suffer other quality defects, which may cause the affected product candidates to no longer be suitable for their intended use in clinical studies or other development activities. If the defective product candidates cannot be replaced in a timely fashion, we may incur significant delays in our development programs that could adversely affect the value of such product candidates. Outbreaks of livestock diseases and other events affecting the health of our bovine herd can adversely impact our ability to conduct our operations and production of our product candidates. Our product candidates are based on materials produced by genetically engineered bovines. We maintain a herd of approximately ~~200~~ **80** genetically engineered production animals at a single location in South Dakota and a larger herd of recipient animals at other locations. Our ability to produce product candidates is dependent on the continued health and productivity of these animals. The supply of our product candidates can be adversely impacted by outbreaks of livestock diseases, which can have a significant adverse impact on our financial condition. Our animals produced by the recipient herd do not typically become productive until ~~15-~~18 months from the start of gestation. If all or a material number of the productive herd were to become diseased, injured or die as a result of bacterial, fungal or viral infections, such as foot and mouth disease, or natural disaster or other occurrences of any kind, it would have a material adverse effect on our ability to produce product candidates and on our business, financial condition and results of operations **.** Extreme factors or forces beyond our control could negatively impact our business. Natural disasters, fire, bioterrorism or other acts of terrorism or vandalism, animal activist activity or adverse public perception or media coverage or other public relations issues, pandemics or extreme weather, including droughts, floods, excessive cold or heat, hurricanes or other storms, could impair the health or growth of livestock or interfere with our operations due to power outages, fuel shortages, feed shortages, decrease in availability of water, damage to our production and manufacturing facilities or disruption

of transportation channels which would delay the development, regulatory approval and manufacture of our product candidates and ultimately affect our success. Any of these factors could have an adverse effect on our financial condition and ability to operate. We, along with our collaborators, CROs, third- party logistics providers, distributors and other contractors and consultants, utilize information technology, or IT, systems and networks to process, transmit and store electronic information in connection with our business activities. As use of digital technologies has increased, cyber incidents, including third parties gaining access to employee accounts using stolen or inferred credentials, computer malware, viruses, spamming, phishing attacks or other means, and deliberate attacks and attempts to gain unauthorized access to computer systems and networks, have increased in frequency and sophistication. These threats pose a risk to the security of our, our collaborators', CROs', third- party logistics providers', distributors' and other contractors' and consultants' systems and networks, and the confidentiality, availability and integrity of our data. There can be no assurance that we will be successful in preventing cyber- attacks or successfully mitigating their effects. Like other companies, we have on occasion experienced, and will continue to experience, threats to our data and systems, including malicious codes and viruses, phishing, business email compromise attacks or other cyber- attacks. There can be no assurance that our collaborators, CROs, third- party logistics providers, distributors and other contractors and consultants will be successful in protecting our clinical and other data that is stored on their systems. Any cyber-attack, data breach or destruction or loss of data could result in a violation of applicable U. S. and international privacy, data protection and other laws and subject us to litigation and governmental investigations and proceedings by federal, state and local regulatory entities in the United States and by international regulatory entities, resulting in exposure to material civil and / or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed, which could have a material adverse effect on our business and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber- attacks or other data security breaches and may incur significant additional expense to implement further data protection measures. **See Item 1C. " Cybersecurity ", of this Annual Report on Form 10- K for more information.** In addition to our current collaborations, we may in the future seek third- party collaborators for the development and commercialization of product candidates. If we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from any future collaboration or license agreement will depend on the collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any collaborators may have the right to abandon research or development projects and terminate applicable agreements, including any funding obligations, prior to or upon the expiration of the agreed upon terms. Any collaboration that we enter into in the future may pose a number of risks, including the following: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators may not perform their obligations as expected; • collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities; • collaborators may decide not to continue the development of collaboration products and could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • a collaborator with marketing, distribution and commercialization rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of any such product candidate; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development of any product candidates, might cause delays or termination of the research, development or commercialization of such product candidates, might lead to additional responsibilities for us with respect to such product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborations may be terminated at the convenience of the collaborator or for a material breach by either party, and, if a collaboration is terminated, we could be required to make payments to the collaborator or have our potential payments under the collaboration reduced; and • in the event of the termination of a collaboration, we could be required to raise additional capital to pursue further development or commercialization of the product candidates returned to us by our former collaborator. Additionally, subject to its contractual obligations to us, if one of our collaborators is involved in a business combination, the collaborator might deemphasize or terminate the development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our perception in the business and financial communities could be adversely affected ~~. We have historically relied on awards from, and contracts with, the U. S. Government to fund our business and operations, but we have recently mutually agreed with the U. S. federal Government (USG) to discontinue Project Agreement No. 01; MCDC1902- 007, an award agreement which represented a substantial majority of our revenues. We therefore need to secure new and alternative sources of funding for our projects. There is no guarantee that we will find such other sources of funding on favorable terms or at all, which could have a direct adverse effect on our financial condition and ability to operate~~ . We operate in a highly competitive industry. We are engaged in highly competitive industries. We compete with many public and private companies, including pharmaceutical companies, chemical companies, specialized biotechnology companies and academic institutions. Many of our competitors have substantially greater financial, scientific and technical resources, and manufacturing and marketing experience and capabilities than us. In addition, many of our competitors have significantly greater experience conducting preclinical studies and clinical trials of new pharmaceutical products, and in obtaining regulatory approvals for pharmaceutical products. Our competitors and competitors of our collaborators may develop and commercialize such products more rapidly than we and our collaborators do. Competition may increase further as a result of potential advances from the

study of pharmaceutical products, and greater availability of capital for investment in this field. There can be no assurance that our competitors will not succeed in developing technologies and products that are more effective than any being developed by us or that would render our technology and products obsolete or noncompetitive. There can be no assurance that these and other efforts by potential competitors will not be successful, or that other methods will not be developed to compete with our technology. There are specific products and technologies that compete with our current product pipeline and that may outperform or be more competitive than our products. For example, there are multiple products that may be competitive with SAB- 142 for T1D such as animal- derived polyclonal biologics ~~Thymoglobulin~~ **ThymoglobulinTM** (Sanofi ~~Genzyme~~) **,** and ~~Atgam~~ **AtgamTM** (Pfizer), and monoclonal ~~antibody~~ **antibodies** ~~treatments~~ such as ~~teplizumab~~ **TzieldTM** (~~Tzield~~ **Sanofi**) ~~,~~ ~~Alefacept,~~ **. Competition may increase further as a result of advances in the commercial applicability of technologies** and ~~Orencia;~~ **greater availability of capital for investment in** ~~there~~ **these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, drug products that** are ~~other antibody~~ **more effective, safer or less costly than any product candidate that we may develop. Our existing competitors and new market entrants may respond more quickly to or integrate new or emerging** technologies ~~that may compete with our anti- influenza product, SAB- 176~~ such as **artificial intelligence** ~~VIR- 2482 (Vir), DAS- 181 (Ansun)~~ and ~~FLU- IVIG (Emergent Biosolutions)~~ **machine learning, undertake more extensive marketing campaigns, have greater access to clinical information to support ongoing product position in the market, have greater financial, marketing** and ~~with~~ **other resources** ~~our~~ **or be more successful in attracting potential customers, employees and strategic partners** ~~SAB- 195 (anti- C. diff) such as bezlotoxumab (Zinplava)~~ . We have no sales and marketing experience. We have no experience in sales, marketing or distribution. Before we can market any of our product candidates directly, we must develop a substantial marketing and sales force with technical expertise and supporting distribution capability. Alternatively, we may obtain the assistance of a pharmaceutical company with a large distribution system and a large direct sales force. We do not have any existing distribution arrangements with any pharmaceutical company for our products. There can be no assurance that we will be able to establish sales and distribution capabilities or be successful in gaining market acceptance for our products. Our business operations and use of real property are subject to stringent federal, state, and local environmental laws and regulations pertaining to safe working conditions, ethical experimental use of animals, the discharge of materials into the environment, and the handling and disposition of wastes (including solid and hazardous wastes) or otherwise relating to protection of the environment. These laws include the Occupational Safety and Health Act, the Toxic Test Substances Control Act and the Resource Conservation and Recovery Act. Compliance with these laws and regulations, and the ability to comply with any modifications to these laws and regulations, is material to our business. New matters or sites may be identified in the future that will require additional investigation, assessment, or expenditures. In addition, some of our facilities have been in operation for some time and, over time, we and any other prior operators of these facilities may have generated and disposed of wastes that now may be considered hazardous. Future discovery of contamination of property underlying or in the vicinity of our present or former properties or manufacturing facilities and / or waste disposal sites could require us to incur additional expenses. In addition, claimants may sue us for injury or contamination that results from our use of or our handling of contaminants, and our liability may exceed our total assets. Compliance with environmental laws and regulations may be expensive, and current or future environmental regulations may impair our research, development or production efforts. The occurrence of any of these events, the implementation of new laws and regulations, or stricter interpretation of existing laws or regulations, could adversely affect our financial condition and ability to operate. We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, 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 and 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. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination. ~~On August 3, 2022, we received notice from the DoD to terminate the Department of Defense, Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense Enabling Biotechnologies (" JPEO ") Rapid Response contract, dated as of August 7, 2019 with the DoD most recently amended as of September 14, 2021, relating to a prototype research and development of a Rapid Response Antibody Program and advanced clinical development through licensure and commercial manufacturing for SAB- 185 (the" JPEO Rapid Response Contract Termination"). A termination and settlement proposal (the "~~

~~TSP ") was submitted the DoD on September 9, 2022; we submitted a final invoice on December 15, 2022; and received payment from the DoD on or about January 12, 2023. The terms of the arrangement provide for a cost- reimbursable structure, and state that the parties will work in good faith equitable reimbursement for work performed toward accomplishment of the tasks provided in the agreement. At this time, other than certain deferred obligations potentially payable to the DoD solely due to subsequent negotiations with our third- party vendors, we believe and have been advised there is a reasonable, good faith basis for the position that no present or future obligations exist by us in favor of our counterparties. However, if an alternative determination is made, we may become liable for costs incurred during the termination of the JPEO Rapid Response contract, which could have an adverse effect on our business and results of operations.~~ Risks Related to Our Intellectual Property **Our success depends on our ability to maintain the proprietary nature of our technology.** Our success in large part depends on our ability to maintain the proprietary nature of our technology and other trade secrets. To do so, we must prosecute and maintain existing patents, obtain new patents and pursue trade secret and other intellectual property protection. We also must operate without infringing the proprietary rights of third- parties or allowing third - parties to infringe our rights. Patent issues relating to pharmaceuticals and biologics involve complex legal, scientific and factual questions. To date, no consistent policy has emerged regarding the breadth of biotechnology patent claims that are granted by the U. S. Patent and Trademark Office (" USPTO ") or enforced by the federal courts. Therefore, we do not know whether any particular patent applications will result in the issuance of patents, or that any patents issued to us will provide us with any competitive advantage. We also cannot be sure that we will develop additional proprietary products that are patentable. Furthermore, there is a risk that others will independently develop or duplicate similar technology or products or circumvent the patents issued to us. Third parties may claim we infringe their intellectual property rights. Our research, development and commercialization activities may be found to infringe patents owned by third - parties from whom we do not hold licenses or other rights to use their intellectual properties. There may be rights we are not aware of, including applications that have been filed, but not published that, when issued, could be asserted against us. These third - parties could bring claims against us, and that may cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages. Further, if a patent infringement suit were brought against us, we could be forced to stop or delay research, development, manufacturing or sales of the product or product candidate that is the subject of the suit. As a result of potential patent infringement claims, or in order to avoid potential claims, we may choose or be required to seek a license from the third- party. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be non- exclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. All of the issues described above could also impact our collaborators, which would also impact the success of the collaboration and therefore us ~~. We may become involved in litigation to protect or enforce our patents or the patents of our collaborators or licensors, which could be expensive and time- consuming~~ . Competitors may infringe our patents or the patents of our collaborators or licensors. As a result, we may be required to file suit to counter infringement for unauthorized use. This can be expensive, particularly for a company of our size, and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover our technology. An adverse determination of any litigation or defense proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at the risk of not issuing. Even if we are successful, litigation may result in substantial costs and distraction to our management. Even with a broad portfolio, we may not be able, alone or with our collaborators and licensors, to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect such rights as fully as in the U. S. 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, during the course of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If investors perceive these results to be negative, the market price for our common stock could be significantly harmed ~~. If patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize our discoveries~~ . Important legal issues remain to be resolved as to the extent and scope of available patent protection for biopharmaceutical products and processes in the U. S. and other important markets outside the U. S., such as Europe and Japan. In addition, foreign markets may not provide the same level of patent protection as provided under the U. S. patent system. Litigation or administrative proceedings may be necessary to determine the validity and scope of certain of our and others' proprietary rights. Any such litigation or proceeding may result in a significant commitment of resources in the future and could force us to do one or more of the following: cease selling or using any of our products that incorporate the challenged intellectual property, which would adversely affect our revenue; obtain a license from the holder of the intellectual property right alleged to have been infringed, which license may not be available on reasonable terms, if at all; and redesign our products to avoid infringing the intellectual property rights of third- parties, which may be time- consuming or impossible to do. In addition, changes in, or different interpretations of, patent laws in the U. S. and other countries may result in patent laws that allow others to use our discoveries or develop and commercialize our products. We cannot provide assurance that the patents we obtain or the unpatented technology we hold will afford us significant commercial protection. We have extensive experience collaborating with multiple parties in Government and industry, and has agreements and collaborations that allow potential claims and actual rights, such as shared publication rights, shared inventions, access to assets, potential claims of co-inventorship, limited rights to data, general purpose rights to data, and other claims that may affect our business operations, intellectual property portfolio, interruption of operating assets or our ability to protect our own rights. There can be no assurance that our competitors, suppliers, service providers, collaborators or other parties will not succeed in asserting rights that are or

become contrary to our interests. Changes in patent law in the United States and in ex- U. S. jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological and legal complexity, and is therefore costly, time- consuming and inherently uncertain. In addition, the United States has recently enacted and is currently implementing and proposing wide-ranging patent reform legislation. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents, particularly those directed to pharmaceutical and biopharmaceutical products and uses could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. We cannot predict how these decisions or any future decisions by the U. S. Congress, the federal courts or the USPTO may impact the value of our patents. Similarly, any adverse changes in the patent laws of other jurisdictions could have a material adverse effect on our business and financial condition. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on product candidates in all countries throughout the world is expensive. While many of our licensed patents, including the patents covering our lead product candidates, have been issued in major markets and other countries, our intellectual property rights in some countries outside the United States can be less extensive than those 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 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 where we have issued patents, or from selling or importing products made using our inventions in other jurisdictions. Competitors may also use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we do not have patent protection or where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products , and our patents or other intellectual property rights may not be effective or sufficient to prevent such competition. 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, trade secrets and other intellectual property protection, particularly those relating to pharmaceutical and biopharmaceutical products, which could make it difficult for us or our licensors to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings for infringement by third parties or by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could also result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and any related patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors. We may not prevail in any lawsuits that we initiate or are initiated against us, and the damages or other remedies awarded in lawsuits that we initiate, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or Hatch-Waxman Amendments. The Hatch- Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent per eligible drug may be extended and only those claims covering the approved drug, an approved method for using it or a method for manufacturing it may be extended. Patent term extensions tied to marketing approval in foreign jurisdictions may also be available for our patents. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. Risks Related to Being a Public Company As a public company, we are and will continue to be subject to the reporting requirements of the Exchange Act, the listing standards of 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, financial condition, and results of operations, although we have already hired additional employees to assist us in complying with these requirements, we may need to hire more employees in the future or engage outside consultants, which will increase our operating expenses. In addition, changing laws, regulations, and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs, and making some activities more time- consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest substantial resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from business operations to compliance activities. If our efforts to comply with new laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. We also expect that being a public company and these new rules and regulations will make it increasingly expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors **(the " Board ")**, particularly to serve on our ~~audit~~ **Audit** ~~committee~~ **Committee of the Board (the " Audit Committee ")** and compensation committee **of the Board (the " Compensation Committee ")**, and qualified executive officers. As a result of disclosure of information in filings required of a public company, our business and financial condition are more visible, which may result in an increased risk of threatened or actual litigation, including by competitors and other third parties. If such claims are successful, our business, financial condition, and results of operations could be harmed, and even if the claims do not result in litigation or are resolved in our favor, these claims, and the time and resources necessary to resolve them, could divert the resources of our management and harm our business, financial condition, and results of operations. We are an " emerging growth company, " ~~as well as a" smaller reporting company,"~~ and our election to comply with the reduced disclosure requirements as a public company may make our common stock less attractive to investors. For so long as we remain an " emerging growth company " as defined in **Section 2 (a) of** the **Securities** ~~Tax Cuts and Jobs~~ Act **, as modified by the Jumpstart our Business Startups Act** of ~~2017~~ **2012 ,** (the ~~"~~ **"** JOBS Act ~~"~~ **")**, we may take advantage of certain exemptions from various requirements that are applicable to public companies that are not " emerging growth companies, " including not being required to comply with the independent auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 (**the "** Sarbanes- Oxley ~~-~~Act **"**), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, being required to provide fewer years of audited financial statements, and exemptions from the requirements of holding a non- binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved **.** We may lose our emerging growth company status and become subject to the ~~SEC~~ **U.S.Securities and Exchange Commission** ' s **(the " SEC ")** internal control over financial reporting management and auditor attestation requirements.If we are unable to certify the effectiveness of our internal controls,or if our internal controls have a material weakness,we could be subject to regulatory scrutiny and a loss of confidence by stockholders,which could harm our business and adversely affect the market price of our common stock.We will cease to be an " emerging growth company " upon the earliest to occur of:(i) the last day of the fiscal year in which we have more than $ 1.235 billion in annual revenue;(ii) the date we qualify as a large accelerated filer,with at least $ 700 million of equity securities held by non- affiliates;(iii) the date on which we have,in any three- year period,issued more than $ 1.0 billion in non- convertible debt securities;and (iv) December 31,2026 (the last day of the fiscal year following the fifth anniversary of becoming a public company) ~~.We are also a " smaller reporting company " as defined under the~~ . As an emerging growth company, we may choose to take advantage of some but not all of these reduced reporting burdens. Accordingly, the information we provide to our stockholders may be different than the information you receive from other public companies in which you hold stock. In addition, the JOBS Act also provides that an " emerging growth company " can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected to take advantage of this extended transition period under the JOBS Act. As a result, our operating results and financial statements may not be comparable to the operating results and financial statements of other companies who have adopted the new or revised accounting standards. It is possible that some investors will find our common stock less attractive as a result, which may result in a less active trading market for our common stock and higher volatility in our stock price. We may lose our emerging growth company..... our independent registered public accounting firm. Investors may 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 and may decline. As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes- Oxley Act and the rules and regulations of the applicable listing standards of Nasdaq. 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. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the ~~U. S. Securities and Exchange Commission (" SEC ")~~ is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. We are also continuing to improve our internal control over financial reporting, which includes hiring additional accounting and financial personnel to implement such processes and controls. In order to maintain and improve the

effectiveness of our disclosure controls and procedures and internal control over financial reporting, we have expended, and anticipate that we will continue to expend, significant resources, including accounting- related costs and significant management oversight. If any of these new or improved controls and systems do not perform as expected, we may experience material weaknesses in our controls. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business. Further, weaknesses in our disclosure controls and internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls or any difficulties encountered in their implementation or improvement could harm our results of operations or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting also could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the trading price of our common stock. In addition, if we are unable to continue to meet these requirements, we may not be able to remain listed on Nasdaq. **We are not currently required to comply with the SEC rules that implement Section 404 of the Sarbanes- Oxley Act and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. As a public company, we are required to provide an annual management report on the effectiveness of our internal control over financial reporting commencing with our Form 10- K.** Our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal control over financial reporting until after we are no longer an " emerging growth company " as defined in the JOBS Act. At such time, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could have an adverse effect on our business and results of operations and could cause a decline in the price of our common stock. ~~We have identified a material weakness in our internal control over financial reporting and determined that our disclosure controls and procedures were ineffective as of December 31, 2022. In the future, we may identify additional material weaknesses or otherwise fail to maintain an effective system of internal control over financial reporting or adequate disclosure controls and procedures, which may result in material errors in our financial statements or cause us to fail to meet our period reporting obligations, and adversely affect the trading price of our common stock.~~ Under the supervision and with participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, ~~2022~~ **2023** , and we have concluded that our internal controls over financial reporting were not effective as of December 31, ~~2022~~ **2023** , due to the existence of material weaknesses in such controls. We have also concluded that our disclosure controls and procedures were not effective as of December 31, ~~2022~~ **2023** , all as described in Item 9A, " Controls and Procedures, " of this Annual Report on Form 10- K. Management is actively engaged in the planning for, and implementation of, remediation efforts to address our material weaknesses. Continuing costs to remedy these material weaknesses and to address inquiries from regulators may be significant and may require significant attention from our management and other personnel, and we cannot assure you that we will be able to remedy the material weaknesses. The incurrence of significant additional expense, or the requirement that management and other personnel devote significant time to these matters could reduce the time available to execute on our business strategies and could have a material adverse effect on our business, financial condition and results of operations. We also cannot assure you that additional material weaknesses in our internal control over financial reporting will not arise or be identified in the future. If our remediation efforts are insufficient to address the identified deficiencies, or if additional deficiencies in our internal control over financial reporting are discovered or occur in the future, our ~~consolidated~~ **Consolidated** financial statements may contain material misstatements and we could be required to restate our financial results and may be unable to make our filings with the SEC on a timely basis. Moreover, because of the inherent limitations of any control system, material misstatements due to error or fraud may not be prevented or detected on a timely basis, or at all. If we are unable to provide reliable and timely financial reports in the future, our business and reputation may be further harmed. Failures in internal controls may negatively affect investor confidence in our management and the accuracy of our financial statements and disclosures or result in adverse publicity and concerns from investors and commercial customers, any of which could have a negative effect on the price of our shares, subject us to regulatory investigations and penalties and / or shareholder litigation, and materially adversely impact our business and financial condition **. In October 2021, the Company consummated the business combination contemplated by the agreement and plan of merger, dated as of June 21, 2021, as amended on August 12, 2021, made by and among Big Cypress Acquisition Corp., a Delaware corporation (" BCYP "), Big Cypress Merger Sub Inc., a Delaware corporation (" Merger Sub "), the Company, and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the representative, agent and attorney- in- fact of the SAB Stockholders (the " Business Combination ")** . Prior to the Business Combination, on April 12, 2021, the staff of the SEC issued a Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (" SPACs ") (the " SEC Staff Statement "). The SEC Staff Statement focused on certain accounting and reporting considerations related to warrants of a kind similar to warrants that we issued prior to the Business Combination at the time of our initial public offering and the exercises by the underwriters of their over- allotment options in January 2021. In response to the SEC Staff Statement **,** we determined to classify the warrants as derivative liabilities measured at fair value, with the initial valuation occurring on October 22, 2021, the **"** **"** Closing Date **"** **"** of the Business Combination, with changes in fair value each period reported in earnings **. On September 29, 2023, the Company entered into a securities purchase agreement with certain accredited investors (the " September 2023**

Purchase Agreement "), pursuant to which the Company agreed to issue and sell shares of preferred stock and warrants, in a private placement. See Note 12, Warrants for further information about the private placement offering . As a result, included on our balance sheet are derivative liabilities related to embedded features contained within the warrants. Financial Accounting Standards Board (" FASB ") Accounting Standards Codification (" ASC ") 815- 40, Derivatives and Hedging — Contracts in Entity' s Own Equity provides for the remeasurement of the fair value of such derivatives at each balance sheet date, with a resulting non- cash gain or loss related to the change in the fair value being recognized in earnings in the statement of income. As a result of the recurring fair value measurement, our financial statements and results of operations may fluctuate quarterly based on factors which are outside of our control. Due to the recurring fair value measurement, we expect that we will recognize non- cash gains or losses on the warrants each reporting period and that the amount of such gains or losses could be material. Our business, financial condition, and results of operations may fluctuate on a quarterly and annual basis, which may result in a decline in our stock price if such fluctuations result in a failure to meet the expectations of securities analysts or investors. Our operating results have in the past and could in the future vary significantly from quarter- to- quarter and year- to- year and may fail to match our past performance, our projections or the expectations of securities analysts because of a variety of factors, many of which are outside of our control and, as a result, should not be relied upon as an indicator of future performance. As a result, we may not be able to accurately forecast our operating results and growth rate. Any of these events could cause the market price of our common stock to fluctuate. Factors that may contribute to the variability of our operating results include, but are not limited to: our ability to attract new clients and partners, retain existing clients and partners and maximize engagement and enrollment with existing and future clients; changes in our sales and implementation cycles, especially in the case of our large clients; new solution introductions and expansions, or challenges with such introductions; changes in our pricing or fee policies or those of our competitors; the timing and success of new solution introductions by us or our competitors or announcements by competitors or other third parties of significant new products or acquisitions or entrance into certain markets; any other change in the competitive landscape of our industry, including consolidation among our competitors; increases in operating expenses that we may incur to grow and expand our operations and to remain competitive; our ability to successfully expand our business, whether domestically or internationally; breaches of security or privacy; changes in stock- based compensation expenses; the amount and timing of operating costs and capital expenditures related to the expansion of our business; adverse litigation judgments, settlements, or other litigation- related costs; changes in the legislative or regulatory environment, including with respect to privacy or data protection, or enforcement by government regulators, including fines, orders, or consent decrees; the cost and potential outcomes of ongoing or future regulatory investigations or examinations, or of future litigation; changes in our effective tax rate; our ability to make accurate accounting estimates and appropriately recognize revenue for our solutions for which there are no relevant comparable products; changes in accounting standards, policies, guidance, interpretations, or principles; instability in the financial markets; general economic conditions, both domestic and international; volatility in the global financial markets; political, economic, and social instability, including terrorist activities and health epidemics (including the recent outbreak of COVID- 19), and any disruption these events may cause to the global economy; and changes in business or macroeconomic conditions. The impact of one or more of the foregoing or other factors may cause our operating results to vary significantly. Changes in accounting principles may cause previously unanticipated fluctuations in our financial results, and the implementation of such changes may impact our ability to meet our financial reporting obligations. We prepare our financial statements in conformity with accounting principles generally accepted in the U. S. (" U. S. GAAP "), which are subject to interpretation or changes by the FASB, the SEC, and other various bodies formed to promulgate and interpret appropriate accounting principles. New accounting pronouncements and changes in accounting principles have occurred in the past and are expected to occur in the future which may have a significant effect on our financial results. Furthermore, any difficulties in implementation of changes in accounting principles, including the ability to modify our accounting systems, could cause us to fail to meet our financial reporting obligations, which could result in regulatory discipline and harm investors' confidence in us. If our estimates or judgments relating to our critical accounting policies prove to be incorrect, our business, financial condition, and results of operations could be adversely affected. The preparation of financial statements in conformity with U. S. GAAP and our key metrics require management to make estimates and assumptions that affect the amounts reported in the ~~consolidated~~ **Consolidated** financial statements and accompanying notes and amounts reported in our key metrics. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances, as provided in the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations " The results of these estimates form the basis for making judgments about the carrying values of assets, liabilities, and equity and the amount of revenue and expenses that are not readily apparent from other sources. Significant assumptions and estimates used in preparing our ~~consolidated~~ **Consolidated** financial statements include those related to allowance for doubtful accounts, assessment of the useful life and recoverability of long- lived assets, fair value of guarantees included in revenue arrangements and fair values of stock- based awards, warrants, contingent consideration, and income taxes. Our results of operations may be adversely affected if our assumptions change or if actual circumstances differ from those in our assumptions, which could cause our results of operations to fall below the expectations of securities analysts and investors, resulting in a decline in the trading price of our common stock. Risks Related to our Common Stock Anti- takeover provisions contained in our certificate of incorporation as well as provisions of Delaware law, could impair a takeover attempt. Our certificate of incorporation 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 include: ~~•~~ • the right of our ~~board~~ **Board** ~~of directors~~ to issue shares of preferred stock and to fix the terms of such shares; ~~•~~ • no cumulative voting in the election of directors, which limits the ability of minority

stockholders to elect director candidates; ~~•~~ • a classified ~~board~~ **Board** ~~of directors~~ with three- year staggered terms, which could delay the ability of stockholders to change the membership of a majority of our ~~board~~ **Board** ~~of directors~~ ; ~~•~~ • the right of our ~~board~~ **Board** ~~of directors~~ to elect a director to fill a vacancy created by the expansion of our ~~board~~ **Board** ~~of directors~~ or the resignation, death or removal of a director in certain circumstances, which prevents stockholders from being able to fill vacancies on our ~~board~~ **Board** ~~of directors~~ ; ~~•~~ • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; and ~~•~~ • requirement that a meeting of stockholders may only be called by members of our ~~board~~ **Board** ~~of directors~~ and the ability of our stockholders to call a special meeting is specifically denied, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors. These provisions, alone or together, could delay hostile takeovers and changes in control or changes in our ~~board~~ **Board** ~~of directors~~ and management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the DGCL, which prevents some stockholders holding more than 15 % of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our common stock. Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of common stock and could also affect the price that some investors are willing to pay for our common stock. The price of our securities may fluctuate significantly due to general market and economic conditions. An active trading market for our securities may not develop or, if developed, it may not be sustained. In addition, fluctuations in the price of our securities could contribute to the loss of all or part of your investment. Even if an active market for our securities develops and continues, the trading price of our securities could be volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. Any of the factors listed below could have a material adverse effect on an investment in our securities and our securities may trade at prices significantly below the price paid for them. In such circumstances, the trading price of our securities may not recover and may experience a further decline. Factors affecting the trading price of our securities may include, but are not solely limited to, the risk factors identified herein. The stock market in general, and Nasdaq and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results, or financial condition ~~. In addition, our Business Combination resulted in our merging with a special purpose acquisition company, which can cause additional volatility in the price of our common stock and warrants. There has also been increased focus by government agencies on transactions such as our Business Combination in the last year, and we expect that increased focus to continue, and we may be subject to increased scrutiny by the SEC, other government agencies and holders of our securities, as a result~~ . These market and industry factors may materially reduce the market price of our common stock and warrants regardless of our operating performance. An investment in our common stock is extremely speculative and there is no assurance that investors will obtain any return on their investment. Investors will be subject to substantial risks involved in an investment in us, including the risk of losing their entire investment. ~~On~~ **If Nasdaq delists our securities from trading on its exchange for failure to meet their continued listing standards, we and our stockholders could face significant negative consequences including: • Limited availability of market quotations for our securities; • A determination that our common stock is a " penny stock " which will require brokers trading in our securities to adhere to more stringent rules; • Possibly resulting in a reduced level of trading activity in the secondary trading market for shares of our common stock; • A limited amount of analyst coverage; and • A decreased ability to issue additional securities or obtain additional financing in the future. Nasdaq previously notified the Company that, due to the average closing price of our common stock, it was below the trading price criteria of the exchange. In order to regain compliance, we effected a reverse stock split of our common stock at a ratio of 1- for- 10, in** January ~~23, 2023~~ **2024** ~~, we received a written notification~~ (the " ~~Notice Letter~~ **Reverse Stock Split** ") **. We are** ~~from Nasdaq indicating that we were not~~ **no longer considered below** ~~in compliance with Nasdaq Listing Rule 5450 (a) (1), as~~ the ~~closing bid~~ **minimum share** price ~~for~~ **continued listing criterion. The Reverse Stock Split may adversely affect the liquidity of the shares of** our common stock **given** ~~was below~~ the **reduced number of** ~~$ 1. 00 per share~~ **shares** ~~requirement for~~ **outstanding following** the **reverse split** ~~last 30 consecutive business days. The Notice Letter stated that we have 180 calendar days~~ , **especially if** ~~or until July 24, 2023 (~~ the **reverse split- adjusted market** ~~" Initial Compliance Period "), to regain compliance with the minimum bid~~ price ~~requirement. In the event that we do not regain compliance with Listing Rule 5450 (a) (1) prior to the expiration~~ of ~~the Initial Compliance Period (or additional compliance period, if applicable), we will receive written notification that our securities are subject to delisting. If we fail to satisfy the continuing listing requirements of Nasdaq, such as minimum closing bid price requirements, as discussed above, the corporate governance, or stockholders' equity or minimum closing bid price requirements, Nasdaq may take steps to delist~~ our common stock **does not generate greater investor interest** . **Furthermore,** ~~Such a delisting would likely have a negative effect on the~~ **there** ~~price of our common stock and would impair our stockholders' ability to sell or purchase our common stock. In the event of a delisting, we would likely take actions to restore our compliance with Nasdaq' s listing requirements, but we~~ can ~~provide~~ **be** no assurance that ~~any~~ such **reverse split will continue** ~~action taken by us would allow our common stock~~ to **be sufficient to satisfy** ~~become listed again, stabilize~~ the ~~market price or improve the liquidity of our securities, prevent our common stock from dropping below the Nasdaq~~ minimum ~~bid~~ **share** price requirement ~~or prevent future non- compliance with Nasdaq' s listing requirements~~ . Because we have no current plans to pay cash dividends on our common stock for the foreseeable future, investors may not receive any return on their investment unless they sell their common stock for a price greater than the price paid. We may retain future earnings, if any, for future operations, expansion and debt

repayment and have no current plans to pay any cash dividends for the foreseeable future. Any decision to declare and pay dividends as a public company in the future will be made at the discretion of our ~~board~~ **Board** ~~of directors~~ and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that our ~~board~~ **Board** ~~of directors~~ may deem relevant. As a result, investors may not receive any return on an investment in our common stock unless they sell the common stock for a price greater than the price paid. Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock. Sales of significant number of shares of our common stock may make it more difficult for us to sell equity or equity- related securities in the future at a time and price that it deems reasonable or appropriate and make it more difficult for you to sell shares of our common stock. Certain holders of our securities are entitled to rights with respect to the registration of the shares of our common stock under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner it determines from time to time. We may also sell our common stock as part of entering into strategic alliances, creating joint ventures or collaborations or entering into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts. If we ~~sell~~ **raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our** common stock ~~, convertible securities~~ **. Any debt financing secured by us in the future could involve restrictive covenants relating to** ~~or~~ **our capital raising activities and** other ~~equity securities~~ **financial and operational matters. In addition** , ~~investors~~ **we** may **not** be **able** ~~materially diluted by subsequent sales. Such sales may also result in material dilution~~ to ~~existing stockholders~~ **obtain additional financing on terms favorable to us** , **if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to support our business growth** and ~~new investors~~ **to respond to business challenges** could ~~gain rights~~ **be significantly limited. On January 26** , ~~preferences and privileges senior to~~ **2024, we entered into a Controlled Equity Offering ℠ Sales Agreement (** the ~~holders~~ **" Sales Agreement ") with Cantor Fitzgerald & Co. (" Cantor "), relating to shares** of our common stock. **In accordance** ~~On December 7, 2022, we consummated a private placement~~ with ~~certain institutional and accredited investors~~ **the terms of the Sales Agreement** , ~~whereby~~ we ~~issued~~ **may offer and sell shares of our common stock having** an aggregate **offering price** of ~~7~~ **up to $ 20** , ~~363~~ **000** , ~~377~~ **000 from time to time through Cantor, acting as our sales agent. As of the date hereof, we have not offered or sold any** shares of common stock **pursuant** ~~and warrants~~ to ~~purchase up to 7, 363, 377 shares of common stock (~~the **Sales Agreement** ~~" PIPE Warrants "), each share and PIPE Warrant sold at a combined purchase price of $ 1. 08. The PIPE Warrants become exercisable on the six- month anniversary of the date of grant for a price of $ 1. 08 per share and are exercisable for five years from the date of issuance. We also issued our placement agent, Brookline Capital Markets, PIPE Placement Agent Warrants to purchase up to an aggregate of 210, 913 shares of Common Stock (the " PIPE Placement Agent Warrants "). The Placement Agent Warrants have an exercise price equal to $ 1. 35 per share and are exercisable six months from the date of issuance and expires five years from the date of issuance. The issuance of shares of common stock upon exercise of the PIPE Warrants or PIPE Placement Agent Warrants may result in material dilution to existing stockholders~~ . Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected. On January 15, 2022, outstanding warrants to purchase an aggregate of 5, 958, 600 shares of our common stock **(595, 860 shares following the Reverse Stock Split)** became exercisable, in accordance with the terms of the warrant agreement governing those securities. The exercise price of these warrants is $ ~~11~~ **115** . ~~50~~ **00** per share **following the Reverse** ~~. On June 7, 2023, outstanding PIPE Warrants and PIPE Placement Agent Warrants to purchase up to 7, 363, 377 and 210, 913 shares, respectively, of our common stock~~ **Stock Split** ~~will become exercisable, in accordance with the terms of the warrant agreement governing those securities. The respective exercise price of these warrants is $ 1. 08 and $ 1. 35~~ . To the extent such warrants are exercised, additional shares of our common stock will be issued, which will result in dilution to the holders of shares of our common stock and increase the number of shares eligible for resale in the public market. Sales of substantial numbers of such shares in the public market or the fact that such warrants may be exercised could adversely affect the market price of our common stock. **On November 28, 2023, we registered up to 344, 626, 967 shares of our common stock (34, 462, 696 shares following the Reverse Stock Split), in connection with a private placement of securities consummated in October 2023. The shares of common stock offered for resale by these selling stockholders represented approximately 658. 7 % of our total common stock outstanding as of October 30, 2023, and represents approximately 373. 6 % of our total common stock outstanding as of March 15, 2024 (reflecting subsequent conversions of preferred stock and the**

Reverse Stock Split). Although each stockholder for whom the shares of common stock registered for resale is not permitted to convert their Preferred Stock into shares of common stock to the extent that after giving effect to such conversion, such holder would (together with such holder' s affiliates and related parties) beneficially own in excess of 4. 99 % (or 9. 99 % at the election of the holder) of the shares of common stock outstanding immediately after giving effect to such conversion, the market price of our common stock could decline if the holders of such shares sell them over time or are perceived by the market as intending to sell them. Risks Related to Capital Markets ~~The global credit and financial markets have experienced extreme volatility and disruptions in the past, most recently as a result of the COVID- 19 pandemic. These disruptions can result in severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. Additionally, in March 2023 the Federal Deposit Insurance Corporation, or the FDIC, took control and was appointed receiver of Silicon Valley Bank, or SVB. We have no exposure to SVB. If other banks and financial institutions enter receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened and could have a material adverse effect on our business and financial condition. In addition, U. S. and global markets are experiencing volatility and disruption following the escalation of geopolitical tensions and the start of the military conflict between Russia and Ukraine. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, 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 operations, growth strategy, financial performance and stock price and could require it to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers may not survive an economic downturn, which could directly affect our ability to attain our operating goals on schedule and on budget.~~ If securities or industry analysts do not publish research or reports about our business or publish negative reports, the market price of our common stock could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If regular publication of research reports ceases, we could lose visibility in the financial markets, which in turn could cause the market price or trading volume of our common stock to decline. Moreover, if one or more of the analysts who cover us downgrade our common stock or if reporting results do not meet their expectations, the market price of our securities could decline. Reports published by analysts, including projections in those reports that differ from our actual results, could adversely affect the price and trading volume of our common stock. Securities research analysts may establish and publish their own periodic projections for us. These projections may vary widely and may not accurately predict the results we actually achieve. The price of our common stock may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on us downgrades our stock or publishes inaccurate or unfavorable research about our business, the price of our common stock could decline. If one or more of these analysts ceases coverage of us or fails to publish reports on us regularly, the price or the trading volume of our common stock could decline. The market price of our securities may be volatile and, in the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert management' s attention from other business concerns, which could seriously harm our business. Risks Related to ~~Financing and~~ Tax ~~We may require additional capital to support business growth, and this capital might not be available on acceptable terms, if at all. We intend to continue to make investments to support our business growth and may require additional funds to respond to business challenges, advance or begin clinical trial and research initiatives, enhance our operating infrastructure, and acquire complementary businesses and technologies. In order to achieve these objectives, we may need to engage in equity or debt financings to secure additional funds. If we raise additional funds through further issuances of equity or convertible debt securities, our existing stockholders could suffer dilution, and any new equity securities we issue could have rights, preferences, and privileges superior to those of holders of our common stock. Any debt financing secured by us in the future could involve restrictive covenants relating to our capital raising activities and other financial and operational matters. In addition, we may not be able to obtain additional financing on terms favorable to us, if at all. If we are unable to obtain adequate financing or financing on terms satisfactory to us, when we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly limited. The ability of the Company to continue as a going concern is dependent, among other things, on the Company' s ability to raise additional capital resources. The Company plans to seek additional funding through a combination of equity or debt financings, or other third- party financing, collaborative or other funding arrangements. Should the Company seek additional financing from outside sources, the Company may not be able to raise such financing on terms acceptable to the Company or at all. If the Company is unable to raise additional capital when required or on acceptable terms, the Company may be required to scale back or discontinue the advancement of product candidates, reduce headcount, liquidate our assets, file for bankruptcy, reorganize, merge with another entity, or cease operations. Management believes there is substantial doubt about the Company' s ability to continue as a going concern for the one- year period following the date that the consolidated financial statements for December 31, 2022 were issued. The consolidated financial statements for December 31, 2022 have been prepared on the basis that the Company will continue as a going concern, and does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability for the Company to continue as a going concern. Changes in legislation in U. S. and foreign taxation of international business activities or the adoption of other tax reform policies, as well as the application of such laws, could adversely impact our financial position and operating results.~~ As we expand the scale of our business activities, any changes in the U. S. or foreign taxation of such activities may

increase our worldwide effective tax rate and harm our business, results of operations, and financial condition. For example, the Biden administration has proposed changes to federal income tax laws that would, among other things, impose a 15 % minimum tax on corporate book income for certain taxpayers and strengthen the global intangible low- taxed income regime imposed by the **Tax Cuts and** Jobs Act of 2017 while eliminating related tax exemptions. The impact of future changes to U. S. and foreign tax law on our business is uncertain and could be adverse, and we will continue to monitor and assess the impact of any such changes. ~~Beginning in 2022, the Jobs Act eliminated the option to deduct research and development expenditures and requires taxpayers to amortize them over five years pursuant to IRC Section 174. Although Congress is considering legislation that would defer the amortization requirement to later years, we have no assurance that the provision will be repealed or otherwise modified. If the requirement is not modified or deferred, it may materially reduce our cash flows beginning in 2023. Please refer to Note 15, Income Taxes, for additional information.~~