Risk Factors Comparison 2024-03-22 to 2023-03-28 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text Moved Text Section

Risks Related to Our Financial Position and Need for Additional Capital We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future. We have incurred significant net losses since our inception. We continue to incur significant research and development and other expenses related to our ongoing operations. For the years ended December 31, **2023,** 2022 ~~,~~ **and** 2021 ~~and 2020~~ , we reported net losses before noncontrolling interest of $ **135. 4 million, $** 148. 1 million ~~,~~ **and** $ 55. 1 million ~~and $ 26. 7 million~~ , respectively. As of December 31, **2023 and** 2022 ~~and 2021~~ , we had an accumulated deficit of $ 1, **139. 7 million and $ 1,** 104. 1 ~~million and $ 161. 5~~ million, respectively. We have devoted substantially all of our resources and efforts to research and development, and we expect that it will be several years, if ever, before we generate revenue from product sales. Even if we receive marketing approval for, and commercialize our lead product candidate, REACT, we expect that we will continue to incur substantial research and development and other expenses to develop and market additional potential product candidates. Our product candidate, REACT, is still in clinical testing. We expect to continue to incur significant losses for the foreseeable future, and we anticipate that our expenses will increase substantially if, and as, we: • advance the development of REACT and any other future product candidates through clinical development, and, if successful, later- stage clinical trials; • experience delays or interruptions to any future preclinical studies, our current clinical trials, our receipt of services from our third- party service providers on whom we rely, or our supply chain, including delays due to ~~the COVID- 19 pandemic, other~~ health crises or events or circumstances beyond our control; • seek regulatory approvals for any future product candidates that may successfully complete clinical trials; • commercialize REACT and any future product candidates, if approved; • increase the amount of research and development activities to discover and develop product candidates and line extensions; • manufacture the materials needed for clinical trials or, following receipt of necessary regulatory approvals, commercial sales, at our manufacturing facilities; • establish and validate commercial- scale cGMP manufacturing facilities and partner with Contract **Development and** Manufacturing Organizations (" ~~CMOs~~ **CDMOs** "); • establish a commercialization infrastructure and scale up internal and external manufacturing and distribution capabilities to commercialize any product candidates for which we may obtain regulatory approval; • hire additional executives in clinical development, regulatory, manufacturing, quality control, quality assurance, scientific, public / investor relations general and administrative and management personnel; • expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development and manufacturing efforts, general and administrative functions and our operations as a public company; • establish domestic and global sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval and intend to commercialize on our own or jointly with third parties; • maintain, expand and protect our intellectual property portfolio; and • invest in or in- license other technologies or product candidates. To become and remain profitable, we must develop and eventually commercialize products with significant market potential. This will require us to be successful in a range of challenging activities, including completing non- clinical studies and clinical trials, obtaining marketing approval for REACT and any future product candidates, manufacturing, marketing and selling products for which we may obtain marketing approval and satisfying any post- marketing requirements. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. We may never succeed in any or all of these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. We will continue to require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and / or eliminate one or more of our research and product development programs, future commercialization efforts or other operations. Developing biopharmaceutical products, including conducting clinical trials, is a very time- consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception. We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing and planned clinical trials of REACT and any future product candidates that we may develop, seek regulatory approvals for REACT and our future product candidates, and manufacture, launch and commercialize any products for which we receive regulatory approval. We also expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in order to maintain our continuing operations. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and product development programs or future commercialization efforts. As of December 31, ~~2022~~ **2023** , we had approximately $ ~~490~~ **363** . ~~3~~ **0** million in cash, cash equivalents and short- term investments. Based on our current operating plan ~~and having completed the Business Combination and accounting for $ 574. 8 million received in the concurrent private placement of our Class A ordinary shares~~ , we believe that our cash, cash equivalents and short- term investments will be sufficient to fund our operating expenses and capital expenditure requirements ~~through~~ **into the fourth quarter of** ~~2024~~ **2025** . However, this does not reflect the possibility that we may not be able to access a portion of our existing cash, cash equivalents and investments due to market conditions. For example, on March 10, 2023, the Federal Deposit Insurance Corporation, or the FDIC, took control and was appointed receiver of Silicon Valley Bank. 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. Furthermore, our future capital requirements and the period for which our existing resources will support our operations may vary significantly from what we expect, and we will in any event require additional capital to complete clinical development of any of our current programs. Our monthly spending levels will vary based on new and ongoing development and corporate activities. Because the length of time and activities associated with development of REACT and any future product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development, marketing and commercialization activities. Our future funding requirements, both near and long- term, will depend on many factors, including, but not limited to: • the initiation, progress, timing, costs and results of clinical trials for REACT and any future product candidates; • the clinical development plans we establish for these product candidates ~~; • the timelines of our clinical trials and the overall costs to finish the clinical trials due to the COVID- 19 pandemic~~ ; • the number and characteristics of product candidates that we develop; • the outcome, timing and cost of meeting regulatory requirements established by the FDA, the EMA and other comparable foreign regulatory authorities; • whether we are able to enter into and maintain collaboration agreements, including the terms of and timing of payments under any such agreements; • the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights; • the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against us, REACT or any of our future product candidates; • the effect of competing clinical, technological and market developments; • the costs of maintaining our own commercial- scale cGMP manufacturing facility; • the cost of establishing 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; • the revenue, if any, received from commercial sales of REACT and any of our future product candidates for which we receive marketing approval; and • the costs of operating as a public company. We currently do not have any committed external source of funds or other support for our development efforts, and we cannot be certain that additional funding will be available on acceptable terms, or at all. Until we can generate sufficient revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. If we raise additional funds through public or private equity offerings, the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Further, to the extent that we raise additional capital through the sale of ordinary shares or securities convertible or exchangeable into ordinary shares, your ownership interest will be diluted. In addition, any debt financing may subject us to fixed payment obligations and covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish certain valuable intellectual property or other rights to REACT and any future product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us. We also may be required to seek collaborators for REACT or any of our future product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to REACT and any future product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Market volatility ~~resulting from the COVID- 19 pandemic or other factors~~ could also adversely impact our ability to access capital as and when needed. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of REACT or any of our future product candidates or one or more of our other research and development initiatives. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our ordinary shares to decline. Risks Related to Research and Development of REACT and Our Future Product Candidates We have a limited operating history and have not generated any revenue to date, and may never become profitable. We are a clinical- stage biopharmaceutical company with a limited operating history. We were founded in 2018, have no products approved for commercial sale and have not generated any revenue. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, undertaking non- clinical studies, conducting clinical trials, developing a network of key opinion leaders, and performing research and development of REACT. Our approach to the discovery and development of product candidates is unproven, and we do not know whether we will be able to develop any products of commercial value. REACT and any other product candidates we develop will require substantial additional development and clinical research time and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We have not yet demonstrated the ability to progress any product candidate through later- stage clinical trials leading to successful marketing authorization. We may be unable to obtain regulatory approval, manufacture a commercial scale product, or arrange for a third party to do so on our behalf, achieve market access, and acceptance with insurers and health care providers, or conduct sales and marketing activities necessary for successful product commercialization. Investment in biopharmaceutical product development is highly speculative because it 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 and become commercially viable. If and when one of our product candidates were to receive regulatory approval, we would need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by early- stage biopharmaceutical companies in rapidly evolving and complex fields. Consequently, we have no meaningful history of operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing medical products. Due to the uncertainties and risks associated with these

activities, we are unable to accurately and precisely predict the timing and amount of revenues, the extent of any further losses or if or when we might achieve profitability. We may never succeed in these activities and, even if we succeed in commercializing one or more of our product candidates, we may never generate revenue that is significant enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable could decrease the value of our shares and impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. The market for biologics and for the treatment of kidney disease is highly competitive. If we fail to effectively compete, our business, financial condition and operating results will suffer. We face significant competition in the biologics market and in the area of treatment of kidney disease. We face competition from companies that develop and manufacture cell therapies, including major and specialty pharmaceutical and biotechnology companies, developers of tubular and glomerular cell drug modulators, antifibrosis medications, induced pluripotent cells, other autologous mesenchymal stem cells and mechanical renal assist devices such as implantable and wearable renal dialysis machines, and advances in peritoneal dialysis and home dialysis. Cell- based clinical trials by other companies are underway globally with umbilical, adipose and bone marrow derived mesenchymal stem cells for CKD. Early- phase human induced pluripotent stem cell therapies for kidney diseases are ongoing in Japan. We believe that our principal competitors include developers of SGLT2 inhibitors and MRAs, which are small- molecule therapies recently approved to lower risks of CKD progression. Many of our current competitors may have competitive advantages over us, including significantly greater financial resources and expertise in research and development, pre- clinical testing, clinical trials, manufacturing, and marketing than we have. We believe that the principal competitive factors in our target markets include: • accuracy, including sensitivity and specificity, and reproducibility of results; • reputation among customers; • innovation in offerings or products, if approved; • efficacy and safety profile; • cost; • effectiveness of promotional support; • intellectual property protection; • the intended patient population; and • relative convenience of dosing and administration. Even if approved, our products may not compete favorably or may not be successful in the face of increasing competition from new products and technologies introduced by existing competitors or new companies entering our target markets **. Notably, we may face additional competition from GLP- 1 agonists, approved for type 2 diabetes and obesity, which have shown to reduce mortality in patients with advanced- stage CKD and ESRD, slow the progression of CKD and may lead to long term weight loss. Ongoing and increased adoption of GLP- 1 agonists or other new or innovative technologies, drugs or other treatments have the potential to impact the rate of growth of our intended patient population or decrease the size of our addressable market. Any sustained or significant decline in the rate of growth of our intended patient population or demand for our products, whether as a result of developments related to new or innovative technologies, drugs, treatments or otherwise, may adversely impact our business** . In addition, our competitors may have or develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours. Any failure to compete effectively could materially and adversely affect our business, financial condition and operating results. Our business is highly dependent on the success of our lead product candidate, REACT, as well as any other future product candidates that we may advance into clinical development. REACT and our future product candidates will require significant additional clinical development and funding before we may be able to seek regulatory approval for and launch a product commercially. We currently have no products that are approved for commercial sale and may never be able to develop marketable products. REACT, our lead product candidate, is in Phase 3 clinical development. We cannot offer any assurances or predict with any certainty that such Phase 3 clinical development will be successfully completed, that positive clinical data will be obtained from such Phase 3 clinical development efforts or that regulatory authorities will grant marketing approval for REACT, in any such case on the expected timelines. Furthermore, regulatory approvals for REACT, even if obtained, may limit the type of patients in which REACT may be used for CKD or otherwise require specific warning or labeling language, each of which may reduce the commercial potential of REACT. Even if approved, we might not be successful in commercializing REACT. Should we fail to obtain regulatory approvals for REACT or fail to successfully commercialize REACT upon such regulatory approvals, our business and financial condition could be materially harmed and we may be more heavily dependent on the success of our other therapeutic programs. As an organization, we have not previously conducted any later stage or pivotal clinical trials, have limited experience in preparing, submitting and pursuing regulatory filings and have not previously submitted a BLA for any product candidate. Before we can generate any revenue from sales of our lead product candidate, REACT, or any of our future product candidates, we must complete clinical development, regulatory review and approval in one or more jurisdictions. We also need to obtain substantial additional funding to support our continuing operations and pursue our growth strategy. In addition, if REACT or any of our future product candidates is approved, we must ensure access to sufficient commercial manufacturing capacity and conduct significant marketing efforts in connection with any commercial launch. These efforts will require substantial investment, and we may not have the financial resources to continue development of REACT or any of our future product candidates. We may experience setbacks that could delay or prevent regulatory approval of, or our ability to commercialize, REACT and any of our future product candidates, including: • negative or inconclusive results from our clinical trials or positive results from the clinical trials of others for product candidates similar to ours leading to their approval, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or to abandon a program; • product- related side effects or adverse events experienced by patients or subjects in our clinical trials or by individuals using medicines or therapeutics that we, the FDA, other regulators or others view as relevant to the development of REACT or any of our future product candidates; • delays in submitting INDs 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 of a clinical trial once commenced; • conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials, including our clinical endpoints, and any requirement for additional confirmatory trials; • delays in enrolling subjects in

clinical trials and completion of clinical trials, including under the FDA' s GCPs, the guidelines from International Conference on Harmonization (" ICH Guidelines "), GLP, and cGTPs; • inability to maintain compliance with regulatory requirements, including cGMPs, and complying effectively with other procedures; • high drop- out rates of subjects from clinical trials; • inadequate supply or quality of REACT or our future product candidates or other materials necessary for the conduct of our clinical trials; • greater than anticipated clinical trial costs; • inability to compete with other therapies; • poor efficacy of REACT or our future product candidates during clinical trials; • trial results taking longer than anticipated; • trials being subjected to fraud or data capture failure or other technical mishaps leading to the invalidation of our trial results; • the results of our trials not supporting application for conditional approval in the European Union, the Asia- Pacific region, and Latin America; • unfavorable FDA or other regulatory agency inspection and review of a clinical trial site; • failure of our third- party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all; • delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical development generally or with respect to our technology in particular; • varying interpretations of data by the FDA and similar foreign regulatory agencies; • the completion of Health Technology Assessment (" HTA ") procedures with governmental authorities; • any policy level review of REACT by CMS; • the financing on our other ongoing or future programs; • evolving scientific discovery and technology of cell- based therapies and bioprocessing; or • obsolescence of manufacturing automation which could require a re- design of parts or equipment to ensure quality replacement component, the delays of which could cause significant delays in manufacturing and loss of sales. We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and our manufacturing, marketing, distribution and sales efforts or that of any future collaborator. ~~Our business and operations may be adversely affected by the evolving and ongoing COVID- 19 global pandemic. Our business and operations may be adversely affected by the ongoing effects of the evolving COVID- 19 virus, which was declared a global pandemic by the World Health Organization (" WHO "). The continuing effects of the pandemic may impact the availability or cost of materials, which would disrupt our supply chain and manufacturing efforts and could affect our ability to conduct ongoing and planned clinical trials and preparatory activities. Although we have been able to effectively manage our supply chain and manufacturing capabilities despite the COVID- 19 pandemic to date, we may experience related disruptions in the future that could severely impact our clinical trials, including: • delays or difficulties with patient enrollment in clinical trials; • delays, difficulties or a suspension in clinical trial site initiation, including difficulties in recruiting investigators, proceduralists and clinical staff; • interruptions in our ability to manufacture and deliver the required supply of REACT or future product candidates for clinical trials; • diversion of health care resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials; • potential cancellation or postponement of elective procedures scheduled at our clinical trial sites and reduction in operating hours at a significant number of our clinical trial sites; • changes in local regulations as part of a response to the COVID- 19 outbreak that among other things (i) may interrupt our ability to manufacture REACT and (ii) may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether; • interruption of key clinical trial activities, such as clinical trial site monitoring, and the ability or willingness of subjects to travel to trial sites for scheduled visits and laboratory testing due to limitations on travel imposed or recommended by federal or state governments, employers and others; • limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; • delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; • refusal of the FDA and other regulatory agencies to accept data from clinical trials in these affected geographies; and • decreases or shifts of government funding from regulatory agencies, university research and education. The spread of COVID- 19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID- 19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID- 19 could materially affect our business and the value of our securities. The global COVID- 19 pandemic continues to rapidly evolve. The extent to which the COVID- 19 pandemic impacts our business and operations, including our clinical development and regulatory efforts, will depend on future developments that are highly uncertain and cannot be predicted with confidence at the time of the filing of this Annual Report, such as the duration and effect of business disruptions and the short- term effects and ultimate effectiveness of the travel restrictions, quarantines, social distancing requirements and business closures in the United States and other countries to contain and treat the disease. Accordingly, we do not yet know the full extent of potential delays or impacts on our business, our clinical and regulatory activities, health care systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects. In addition, to the extent the ongoing COVID- 19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this " Risk Factors " section.~~ REACT is based on a novel technology, which makes it difficult to predict the time and cost of product development and of subsequently obtaining regulatory approval. The clinical trial requirements of the FDA, the EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty, and intended use and market of the potential products. The regulatory approval process for product candidates such as ours can be more expensive and take longer than for other, better known, or more extensively studied pharmaceutical or other product candidates. Regulatory requirements in the United States and in other countries governing cell therapy products are evolving and the FDA or other regulatory bodies may change the requirements, or identify different regulatory pathways, for approval for REACT or any of our

future product candidates. For example, the FDA has established the Office of Tissues and Advanced Therapies within the Center for Biologics Evaluation and Research (“ CBER ”) to consolidate the review of cell therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review when called upon. It is possible that over time new or different divisions may be established or be granted the responsibility for regulating cell therapy products, including regenerative cell- based products, such as ours. Further, additional regulatory involvement from FDA advisory bodies, including the Cardio- Renal Advisory Committee, may delay review or make additional recommendations requiring further investigation. As a result, we may be required to change our regulatory strategy or to modify our applications for regulatory approval, which could delay and impair our ability to complete the non- clinical and clinical development and manufacture of, and obtain regulatory approval for, REACT or any future product candidates. Changes in regulatory authorities and advisory groups, or any new requirements or guidelines they promulgate, may lengthen the regulatory review process, require us to perform additional studies, increase our development and manufacturing costs, lead to changes in regulatory pathways, positions and interpretations, delay or prevent approval and commercialization of REACT or any future product candidates or lead to significant post- approval limitations or restrictions. We have concentrated our research and development efforts on utilizing regenerative renal cell- based therapies. To date, the FDA has approved a relatively small number of cell-based therapies for commercialization, and no regenerative renal- based cell therapy has been approved for commercial use by any regulatory authority. The processes and requirements imposed by the FDA or other applicable regulatory authorities may cause delays and additional costs in obtaining approvals for marketing authorization for REACT or any future product candidates. Because our platform is novel, and cell- based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like REACT. This novelty may lengthen the regulatory review process, including the time it takes for the FDA to review our IND applications if and when submitted, increase our development costs and delay or prevent commercialization of REACT. Additionally, advancing novel CKD therapies creates significant challenges for us, including: • educating medical personnel regarding the potential side- effect profile of REACT and, as the clinical development program progresses, on observed side effects with REACT; • training medical personnel on the proper use and delivery of REACT; • enrolling sufficient numbers of subjects in clinical trials; and • continuing to develop a manufacturing process to support the clinical development of REACT. We must be able to overcome these challenges in order for us to develop, commercialize and manufacture REACT. As we advance REACT, we will be required to consult with the FDA and other regulatory authorities, and REACT will likely be reviewed by an FDA advisory committee. We also must comply with applicable requirements, and if we fail to do so, we may be required to delay or discontinue development of REACT. Delays or unexpected costs in obtaining, or the failure to obtain, the regulatory approval necessary to bring a potential product to market could impair our ability to generate sufficient product revenues to maintain our business. In addition, adverse developments in preclinical studies or clinical trials conducted by others in the field of cell therapy products may cause the FDA, the EMA, and other regulatory bodies to revise the requirements for approval of any product candidates we may develop, and may otherwise negatively affect our ability to develop and commercialize REACT or future product candidates. Similarly, the European Commission may issue new guidelines concerning the development and marketing authorization for cell therapies and require that we comply with these new guidelines, which could require additional studies or clinical trials to support the marketing approval of REACT or any product candidates we may develop in the future or which could make our product candidates unable to successfully obtain approval. The regulatory review committees and advisory groups described above and the new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies or clinical trials, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of these treatment candidates, or lead to significant post- approval limitations or restrictions. As we advance our research programs and develop future product candidates, we will be required to consult with these regulatory and advisory groups and to comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of any product candidates we identify and develop. Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of nonclinical studies, previous clinical trials, or interim results of ongoing clinical trials of REACT and any of our future product candidates may not be predictive of future results. Further, we may encounter substantial delays in completing the development of REACT and any of our future product candidates. Our product candidate, REACT, is in clinical development, and its risk of failure is high. The clinical trials, manufacturing and marketing of REACT or any of our future product candidates, if approved, are and will continue to be subject to extensive and rigorous review and regulation by numerous government authorities in the United States and in other countries where we intend to test and market REACT and any of our future product candidates. Before obtaining regulatory approvals for the commercial sale of REACT or any of our future product candidates, we must demonstrate through lengthy, complex and expensive testing and clinical trials that our product candidates are both safe and effective for use in each target indication. In particular, because REACT is subject to regulation as a biological product, we will need to demonstrate that it is safe, pure and potent for use in its target indication and lacks latent untoward cell effects. REACT and any other product candidate we may develop must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use. The process of administration of REACT involves taking a small biopsy of tissue from the kidney. The risks associated with a biopsy include bleeding, pain, hematoma, or bruising, scarring, and infarcts, or loss of blood supply resulting in loss of function. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new therapeutic modality can include dispositive data from two adequate well- controlled clinical trials of the relevant product in the relevant patient population. Our Phase 3 development program may involve one to two thousand patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier nonclinical studies or clinical trials. The outcome of nonclinical studies and early clinical trials of REACT and our future product candidates may not be predictive of the success of the Phase 3 registrational development program, and interim results of a clinical trial do not

necessarily predict final results. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through nonclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as therapeutic products and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of REACT or any of our future product candidates. Product candidates and delivery methods for cellular therapeutics and tissue engineered products that appear promising in the early phases of development may fail to reach the market for several reasons, including: • nonclinical or preclinical studies or clinical trials may show the product candidates to be less effective than expected (e. g., a clinical trial could fail to meet its primary endpoint (s)) or to have unacceptable side effects or toxicities associated with the product or delivery method; • failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful and relevant; • failure to receive the necessary regulatory approvals; • manufacturing costs, formulation issues, pricing or reimbursement issues, mechanism of action, logistical constraints or other factors that make a product candidate uneconomical; and • the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized. In addition, differences in trial design between early- stage clinical trials and later- stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. Additionally, our earlier stage trials are open- label studies, where both the subject and investigator know whether the subject is receiving REACT or standard of care therapy. Most typically, open- label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open- label clinical trials are subject to various limitations and biases that may exaggerate any therapeutic effect as subjects in open- label clinical trials are aware when they are receiving treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which subjects have received treatment and may interpret the information of the treated group more favorably given this knowledge. Given that our earlier stage trials include an open- label dosing design, while we believe our trials utilize objective assessment measures for measuring our endpoints and therefore are unlikely to be influenced in any manner by subject or investigator bias, it is unknown whether the open- label design may not be predictive of future clinical trial results with this or other product candidates for which we conduct an open- label clinical trial when studied in a controlled environment or with only objective endpoints. Furthermore, the standards that the FDA and comparable foreign regulatory authorities use when regulating REACT require judgment and may change over time, which makes it difficult to predict with certainty how they will be applied. Any analysis we perform of data from nonclinical and clinical activities is subject to validation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. Specifically, some countries, such as China, have enacted or are considering enacting restrictions on the import and export of human genetic materials, cells and tissues. Such laws and regulations could impair our ability to import and export human cells and cell- based therapies, which could have a material adverse impact on our business. We cannot predict whether legislative changes will be enacted, whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop. To date, we have not completed any pivotal trials required for the approval of REACT. We may experience delays in conducting any clinical trials, need to be redesigned, recruit and enroll subjects on time or be completed on schedule, or at all. Clinical trials can be delayed suspended or terminated for a variety of reasons, including in connection with: • delays in sufficiently developing, characterizing, standardizing or controlling a manufacturing process and quality criteria suitable for advanced clinical trials; • delays in developing suitable assays for screening patients for eligibility for trials with respect to certain product candidates; • delays in reaching agreement with the FDA, EMA or other regulatory authorities as to the design or implementation of our clinical trials; • obtaining additional regulatory authorizations to conduct future clinical trials; • reaching agreements on acceptable terms with additional / future clinical trial sites or prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical trial sites; • obtaining IRB or Ethics Committee approval at each additional / future trial site; • recruiting suitable patients to participate in a clinical trial; • having subjects complete a clinical trial or return for post- treatment follow- up; • inspections of clinical trial sites or operations by applicable regulatory authorities, or the imposition of a clinical hold; • clinical sites, CROs or other third parties deviating from trial protocol or dropping out of a trial; • failure to perform in accordance with the applicable regulatory requirements, including FDA' s GCP requirements, or applicable regulatory requirements in other countries; • addressing patient safety concerns that arise during the course of a trial, including occurrence of adverse events associated with the product candidate or the delivery procedure that are viewed to outweigh its potential benefits; • adding a sufficient number of clinical trial sites; • manufacturing sufficient quantities of a product candidate for use in clinical trials; • disruptions in our supply chain, which could result in improper storage, transport or development conditions for our product components, whose treatment is time- sensitive and temperature- sensitive and which are patient- specific; or • interruption of our manufacturing processes, which could lead to our inability to properly administer treatment. We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive

marketing approval or commercialize REACT or any of our future product candidates or significantly increase the cost of such trials, including: • changes in regulatory requirements or guidance, or receive feedback from regulatory authorities that requires us to modify the design of our clinical trials; • clinical trials of REACT or our future product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon development programs; • the number of subjects required for clinical trials of REACT or our future product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or subjects may drop out of these clinical trials at a higher rate than we anticipate; • our third- party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all; • we or our investigators might have to suspend or terminate clinical trials of REACT or our future product candidates for various reasons, including non- compliance with regulatory requirements, a finding that REACT or our future product candidates have undesirable side effects or other unexpected characteristics, or a finding that the subjects are being exposed to unacceptable health risks; • the cost of clinical trials of REACT or our future product candidates may be greater than we anticipate and we may not have funds to cover the costs; • the supply or quality of REACT or our future product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate; • regulators may revise the requirements for approving REACT or our future product candidates, or such requirements may not be as we anticipate; and • any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us. If we are required to conduct additional clinical trials or other testing of REACT or any of our future product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of REACT or our future product candidates or other testing, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may: • incur unplanned costs; • be delayed in obtaining marketing approval for REACT or any of our future product candidates or not obtain marketing approval at all; • obtain marketing approval in some countries and not in others; • obtain marketing approval for indications or patient populations that are not as broad as intended or desired; • obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings or REMS; • be subject to additional post- marketing testing requirements; • be subject to changes in the way the product is administered; or • have regulatory authorities withdraw or suspend their approval of the product or to impose restrictions on its distribution after obtaining marketing approval. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the DSMB for such trial or by the FDA or other regulatory authorities. Such authorities may impose such a suspension or termination 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, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using REACT or one of our future product candidates, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. REACT, our lead product candidate, will require extensive clinical testing before we are prepared to submit a BLA or MAA for regulatory approval. We cannot predict with any certainty if or when we might complete the clinical development for REACT and submit a BLA or MAA for regulatory approval of REACT or whether any such BLA or MAA will be approved. We may also seek feedback from the FDA, EMA or other regulatory authorities on our clinical development program, and the FDA, EMA or such regulatory authorities may not provide such feedback on a timely basis, or such feedback may not be favorable, which could further delay our development programs. We are currently conducting clinical trials in foreign countries, as well as in the United States. If we continue to seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third- party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval from foreign regulatory agencies may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa. Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business. Any topline data or interim analyses from our nonclinical studies and clinical trials that may be announced or published from time to time may change as more data becomes available and will remain subject to audit and verification procedures that could result in material changes in the final data. We have disclosed interim analyses of certain ongoing clinical trials and may continue to disclose publicly interim or topline data from its nonclinical studies and clinical trials in the future. These interim updates will be based on a preliminary analysis of then- available data, and the results and related findings and conclusions will be subject to change following a more comprehensive review of the data related to the particular study or trial. We will be required to make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim or topline results that we may report might differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Interim and topline data will remain subject to audit and verification procedures that may result in the final data being materially different from the data we previously published. As a result, any interim or topline data should be viewed with caution until the final data are available. Interim data from clinical trials that we may complete will be subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data

becomes available. Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and us in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, investors or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim or topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidate may be harmed, which could harm our business, operating results, prospects or financial condition. The regulatory approval processes of the FDA, EMA and comparable foreign authorities are lengthy, time- consuming and inherently unpredictable. If we are not able to obtain required regulatory approval for REACT, our lead product candidate, or any of our future product candidates, our business may be materially and adversely affected. The time required to obtain approval or other marketing authorizations by the FDA, EMA and comparable foreign authorities is unpredictable, and it typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, and 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. We have not obtained regulatory approval for any product candidate, and it is possible that we may never obtain regulatory approval for any product candidates we may seek to develop in the future. Neither we nor any current or future collaborator is permitted to market any biologic product candidates in the United States until we receive regulatory approval of a BLA from the FDA, and we cannot market it in the European Union until we receive approval from the FDA or approval for a MAA from the EMA, or other required regulatory approval in other countries. To date, we have had only limited discussions with the regulatory agencies of the United States, the European Union, Argentina, Israel, Canada and Brazil regarding clinical development programs or regulatory approval for any product candidate within such jurisdictions. Prior to obtaining approval to commercialize any biologic product candidate in the United States or abroad, we must demonstrate with substantial evidence from well- controlled clinical trials, and to the satisfaction of the FDA, EMA or other foreign regulatory agencies, that such product candidates are safe and effective for their intended uses. Results from nonclinical or preclinical studies and clinical trials may be interpreted differently by different regulatory agencies. Even if we believe the nonclinical or clinical data for REACT are promising, such data may be insufficient to support approval by the FDA and other regulatory authorities. The FDA may also require us to conduct additional nonclinical studies or clinical trials for REACT either prior to or after approval, or it may object to elements of our clinical development programs. REACT could fail to receive regulatory approval for many reasons, including the following: • the FDA or comparable foreign regulatory authorities may disagree with the 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 a product candidate is safe and effective for its proposed indication; • 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 a product candidate' s clinical and other benefits outweigh its safety risks; • the FDA or comparable foreign regulatory authorities may fail to approve our manufacturing processes or facilities of third- party suppliers with which we contract for clinical and commercial supplies; and • the approval policies or regulations of the FDA or comparable foreign authorities may significantly change in a manner rendering our clinical data insufficient for approval. Of the large number of product candidates developed by biologics manufacturers, only a small percentage successfully complete the FDA or foreign regulatory approval processes and are commercialized. The lengthy approval and marketing authorization process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval and marketing authorization to market REACT or any of our future product candidates, which would significantly harm our business, financial condition, results of operations and prospects. We have invested a significant portion of our time and financial resources in the development of REACT. Our business is dependent on our ability to successfully complete nonclinical and clinical development of, obtain regulatory approval for, and, if approved, successfully commercialize REACT and any future product candidates in a timely manner. Even if we eventually complete clinical testing and receive approval of a BLA or foreign marketing application for REACT or any future product candidates, the FDA, EMA or the applicable foreign regulatory agency may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post- marketing clinical trials. The FDA, EMA or the applicable foreign regulatory agency also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA, EMA or applicable foreign regulatory agency may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate. Any delay in obtaining, or inability to obtain, applicable regulatory approval or other marketing authorization would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects. In addition, the FDA, EMA and other regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future product candidates on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained. Our nonclinical studies and clinical trials may fail to demonstrate substantial evidence of the safety and efficacy of REACT or our future product candidates, or serious adverse or unacceptable side effects may be identified during the development of REACT or any of our future product candidates, which could prevent, delay or limit the scope of regulatory approval of REACT or any of our future product candidates, limit their commercialization, increase our costs or necessitate the abandonment or limitation of the development of REACT or our future product candidates.

To obtain the requisite regulatory approvals for the commercial sale of REACT and any of our future product candidates, we must demonstrate through lengthy, complex and expensive nonclinical testing and clinical trials that our product candidates are safe, pure and potent for use in each target indication. Nonclinical testing and clinical trials are expensive and time consuming, and their outcomes are inherently uncertain. Failures can occur at any time during the development process. The outcome of nonclinical studies and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, nonclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their product candidates. 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 REACT is safe and potent for its intended uses. Possible adverse side effects that could occur with treatment with autologous cell therapy products include thrombocytopenia, chills, anemia, febrile neutropenia, diarrhea, neutropenia, vomiting, hypotension, dyspnea, cytokine release syndrome and neurotoxicity. Side effects may be unrecognized and mismanaged by medical personnel and considered unrelated due to unfamiliarity with the REACT cell- based treatments. REACT treatment necessitates a renal biopsy to obtain tissue to manufacture the bioactive component and subsequent injections to deposit the REACT product into the kidney. Each intervention poses well- known risks of adverse events such as renal bleeding, cortical scarring, decline in kidney function or other adverse events that may require hospitalization, blood transfusion or angiographic intervention. In the RMCL- 002 trial, which used a different formulation of the REACT product and a different procedure than that presently used in our Phase 3 trials, one participant experienced serious adverse events that included scarring or fibrosis and a decrease in kidney function. A second participant experienced decreased kidney blood flow observed on computed tomography (“ CT ”) imaging and a decrease in kidney function. If other adverse events, or other unexpected serious adverse events, occur, our clinical trials could be suspended or terminated. If we cannot demonstrate that adverse events experienced by subjects enrolled in our current and planned clinical trials were not caused by the REACT product candidate or procedure, the FDA, EMA or other foreign regulatory authorities could order us to cease further development of, or deny approval of, our product candidate for any or all targeted indications. Even if we are able to demonstrate that serious adverse events experienced by subjects enrolled in our current and planned clinical trials are not product- related, such occurrences could affect patient recruitment or the ability of enrolled subjects to complete the trial. Moreover, if we elect, or are required, to not initiate, delay, suspend or terminate any future clinical trial of any of our product candidates, the commercial prospects of such product candidates may be harmed and our ability to generate product revenues from any of these product candidates may be delayed or eliminated. Any of these occurrences may harm our ability to develop other product candidates, and may harm our business, financial condition and prospects significantly. Furthermore, if REACT or any of our future product candidates is associated with undesirable effects in nonclinical studies or clinical trials or have characteristics that are unexpected, we may decide or be required to perform additional nonclinical studies or to halt or delay further clinical development of our product candidates or to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe, or more acceptable from a risk- benefit perspective, which may limit the commercial expectations for the product candidate, if approved. The FDA, EMA, and other health authorities, an IRB, or an IEC may also require that we suspend, discontinue, or limit our clinical trials based on safety information, or that we conduct additional animal or human studies regarding the safety and efficacy of our product candidates which we have not planned or anticipated. Such findings could further result in regulatory authorities failing to provide marketing authorization for our product candidates or limiting the scope of the approved indication, if approved. Many product candidates that initially showed promise in early stage testing have later been found to cause side effects that prevented further development of the product candidate. Additionally, if REACT or any of our future product candidates receives marketing approval, and we or others identify unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including: • regulatory authorities may suspend, withdraw or limit approvals of such product, or seek an injunction against its manufacture or distribution; • regulatory authorities may require additional warnings on the label; • we may be required to create a medication guide outlining the risks of such side effects for distribution to patients or other requirements subject to a REMS; • we may be required to change the way the product is administered or conduct additional nonclinical studies or clinical trials; • we could be sued and held liable for harm caused to patients; • we may decide to remove the product from the market; • we may not be able to achieve or maintain third- party payor coverage and adequate reimbursement; • we may be subject to fines, injunctions or the imposition of civil or criminal penalties; and • our reputation and physician or patient acceptance of our products may suffer. There can be no assurance that we will resolve any issues related to any product- related adverse events to the satisfaction of the FDA or foreign regulatory agencies in a timely manner or at all. Moreover, any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects. Negative public opinion and increased regulatory scrutiny of autologous cell therapy using REACT may adversely impact the development or commercial success of our current and future product candidates. The clinical and commercial success of REACT will depend in part on public acceptance of the use of autologous cell therapy for treatment of kidney disease. Any adverse public attitudes about the use of REACT may adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians prescribing, and their patients being willing to receive, treatments that involve the use of product candidates we may develop in lieu of, or in addition to, existing treatments with which they are already familiar and for which greater clinical data may be available. More restrictive government regulations or negative public opinion would have a negative effect on our business or financial condition and may delay or impair the development and commercialization of REACT or any of our future product candidates or demand for any products once approved. Adverse events in our or others’ clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in increased governmental regulation,

unfavorable public perception, potential regulatory delays in the testing or approval of REACT or our future product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates, all of which would have a negative impact on our business and operations. We are conducting our first Phase 3 clinical trials and may be unable to successfully complete them or any future clinical trials. The conduct of a Phase 3 clinical trial is a complicated process. Although members of our management team have conducted Phase 3 clinical trials in the past while employed at other companies, we as a company are currently conducting our first Phase 3 development program, and as a result may require more time and incur greater costs than we anticipate. Failure to include the correct treatment regimen, complete, or delays in, our Phase 3 clinical trials could prevent us from or delay us in commencing future clinical trials for REACT, obtaining regulatory approval of and commercializing REACT, which would adversely impact our financial performance. In addition, some of our competitors are currently conducting clinical trials for product candidates that treat the same indications as REACT, and patients who are otherwise eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. ~~If we~~ **We have and may continue to** encounter difficulties enrolling patients in our clinical trials, **and** our clinical development activities ~~could~~ **have been and may continue to** be delayed or otherwise adversely affected. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates, or approved products for the conditions for which we are developing our product candidates. Clinical trials may be subject to delays as a result of patient enrollment taking longer than anticipated or greater than anticipated subject withdrawal. We may not be able to initiate or continue clinical trials for REACT or our future product candidates 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 foreign regulatory authorities. We cannot predict how successful we will be at enrolling subjects in future clinical trials. The enrollment of patients depends on many factors, including: • the patient eligibility and exclusion criteria defined in the protocol; • the size and demographics of the patient population required for analysis of the clinical trial' s primary endpoints and the process for identifying patients; • the proximity of subjects to clinical trial sites; • the design of the trial; • our ability to recruit clinical trial investigators with the appropriate competencies and experience; • clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating; • the availability of competing commercially available therapies and other competing product candidates' clinical trials; • our ability to obtain and maintain clinical trial subject informed consents; and • the risk that subjects enrolled in clinical trials will drop out of the trials before completion. For example, we are initially developing REACT for the treatment of CKD due to diabetes or congenital anomalies of the kidney and urinary tract. In the United States, CKD is estimated to affect over 38 million adults. We **have and** may **continue to** encounter difficulties enrolling subjects in our clinical trials of REACT due, in part, to the stringent inclusion criteria for subjects, the novelty of the treatment modality and the fact that it involves a physically invasive procedure. In addition, our clinical trials ~~may~~ compete with other clinical trials for product candidates that are in the same therapeutic areas as REACT, and this competition **has and** may **continue to** reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may reduce the number of patients who are available for our clinical trials in such clinical trial site. Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. Delays in patient enrollment **have and** may **continue to** result in increased costs ~~or~~ **and have and** may **continue to** affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of REACT or any of our future product candidates. Furthermore, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance. Furthermore, due to the follow- up period and maximum study duration of five years (60 months) and the requirement for on-site visits, subjects may drop out of our clinical trials at a higher rate than we anticipate or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as REACT and any future product candidates. Even if we are able to enroll a sufficient number of subjects for our clinical trials, we may have difficulty maintaining enrollment of such subjects in our clinical trials **. In addition, Congress recently amended the FDCA to require sponsors of a Phase 3 clinical trial, or other " pivotal study " of a new drug or biologic to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Our Phase 3 REGEN- 006 and REGEN- 016 were initiated before this requirement became effective, but for any future Phase 3 trials we plan to conduct, we must submit a diversity action plan to the FDA by the time we submit plans for such Phase 3, or pivotal study, protocol to the agency for review as part of an IND, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. It is unknown at this time how the diversity action plan may affect the planning and timing of any future Phase 3 trial for our product candidates or what specific information FDA will expect in such plans. However, initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 trial for our product candidates, and we may experience difficulties recruiting a diverse population of subjects in attempting to fulfill the requirements of any approved diversity action plan** . The design or execution of our ongoing and future clinical trials may not support marketing approval. The design or execution of a clinical trial can determine whether its results will support marketing approval, and flaws in the design or execution of a clinical trial may not become apparent until the clinical trial is well advanced. Additionally, in some instances,

there can be significant variability in safety or efficacy results between different trials with the same product candidate due to numerous factors, including differences in trial protocols, size and type of the patient populations, variable adherence by investigators and subject to protocol requirements and the rate of dropout among clinical trial subjects. We do not know whether any clinical trials we conduct will demonstrate consistent or adequate efficacy and safety to obtain marketing approval to market REACT or any of our future product candidates. Further, the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether marketing approval will be obtained for REACT or any of our future product candidates. REACT may not be approved even if it achieves its primary endpoints in our Phase 3 clinical trials or registrational trials. The FDA or comparable foreign regulatory authorities may disagree with our trial designs and our interpretation of data from nonclinical studies or clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal Phase 3 or registrational clinical trial. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post- marketing clinical trials. The FDA or comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of REACT or any of our future product candidates, if approved. We have obtained RMAT Designation from the FDA for REACT, but this may not lead to a faster development or regulatory review process, and such designation does not increase the likelihood that any of our product candidates will receive marketing approval in the United States and the FDA may withdraw such designation. We intend to evaluate regulatory strategies that could enable us to take advantage of expedited development pathways for REACT, including the RMAT designation that we have already received, although we cannot be certain that REACT will qualify for any additional expedited development pathways or that regulatory authorities will grant, or allow us to maintain, the relevant designations. RMAT designation is intended to expedite the development and review of product candidates that are designed to treat serious or life- threatening diseases and unmet need when " preliminary clinical evidence indicates that a product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. " The designation of REACT with expedited designation provides potential benefits that include: more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient cell therapy program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review if supported by clinical data at the time of the submission of the BLA. Cell and gene therapies, therapeutic tissue engineered products, human cell and tissue products, and combination products using any such therapies or products that are intended to treat, modify, reverse, or cure a serious or life- threatening disease or condition are eligible for designation by the FDA as RMATs. The RMAT designation is intended to facilitate efficient development and expedite review of regenerative medicine therapies by offering eligibility for priority review or accelerated approval, as well as early interactions with FDA to discuss any potential surrogate or intermediate endpoint to be used to support accelerated approval. We applied for RMAT designation for REACT, which was granted by the FDA on October 28, 2021. As contemplated by the RMAT designation and as directed by the FDA, we requested a comprehensive, multidisciplinary Type B meeting with the FDA to review the status of preclinical and clinical development and manufacturing of REACT, and to discuss the planned clinical program intended to support approval of the product candidate. The FDA provided detailed written responses to our questions included in the meeting request, and the Type B meeting was held in March 2022. As a result of that meeting, we will continue to advance the clinical development program for REACT in the United States with the benefit of enhanced clarity as to the FDA' s expectations and requirements for a registrational program, including the design of the trials needed for approval, manufacturing assays, and comparability studies. The FDA' s input is more fully set forth under the heading " Phase 3 Clinical Development (REGEN-006 and REGEN- 016) " in the section titled " Part I — Item 1, Business. " Even though we obtained RMAT designation in October 2021, such a designation does not change the standards for product approval, and there is no assurance that this designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by RMAT designation. Thus, even though RMAT designation was granted for REACT, we may not experience a faster development process, review or marketing approval compared to conventional FDA procedures. The FDA may withdraw RMAT designation if it believes that the product no longer meets the qualifying criteria. It is also possible that the FDA could provide further input on our trial design, in which case our timelines to completion of the clinical development of REACT could be delayed. Our business may be harmed if we are unable to avail ourselves of these or any other expedited development and regulatory pathways. We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and management resources, we must focus on development programs and product candidates that we identify for specific indications. As such, we are only focused on the development of REACT for the treatment of CKD and CAKUT. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications for these product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. We have conducted and may in the future continue to conduct additional clinical trials for REACT outside the United States, and the FDA and similar foreign regulatory authorities may not accept data from such trials conducted in locations outside of their

jurisdiction. We have conducted additional clinical trials for REACT in the Asia- Pacific region, European Union, and Latin America, and may in the future continue to conduct clinical trials outside the United States, including in South America, Australia, New Zealand, or other foreign jurisdictions. The acceptance of data from clinical trials conducted outside the United States by the FDA may be subject to certain conditions or may be rejected. In cases where data from clinical trials conducted outside the United States are intended to serve as the sole basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless: (i) the data are applicable to the United States population and United States medical practice; (ii) the trials were performed **in compliance with GCP** by clinical investigators of recognized competence; and (iii) the data may be considered valid without the need for an on- site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. Additionally, the FDA' s clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign clinical trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any similar foreign regulatory authority will accept data from clinical trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any similar foreign regulatory authority does not accept such data, it would result in the need for additional clinical trials, which would be costly and time- consuming and delay aspects of our business plan, and which may result in REACT not receiving approval or clearance for commercialization in the applicable jurisdiction. We may not be successful in our efforts to identify or discover additional product candidates in the future. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including: • our inability to design such product candidates with the pharmacological properties that we desire or attractive pharmacokinetics; • our inability to design and develop a suitable manufacturing process; or • potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be medicines that will receive marketing approval and achieve market acceptance. Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for clinical development, we will not be able to obtain product revenue in future periods, which likely would result in significant harm to our financial position. Due to our limited resources and access to capital, we must make decisions on the allocation of resources to certain programs and product candidates; these decisions may prove to be wrong and may adversely affect our business. We have limited financial and human resources and intend to initially focus on research programs and product candidates for a limited set of indications. As a result, we may forgo or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. In addition, we may seek to accelerate our development timelines, including by initiating certain clinical trials of REACT or our future product candidates before earlier- stage studies have been completed. This approach may cause us to commit significant resources to prepare for and conduct later- stage trials for one or more product candidates that subsequently fail earlier- stage clinical testing. Therefore, our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities or expend resources on product candidates that are not viable. There can be no assurance that we will ever be able to identify additional therapeutic opportunities for REACT or our future product candidates or to develop suitable potential product candidates through internal research programs, which could materially adversely affect our future growth and prospects. We may focus our efforts and resources on potential product candidates or other potential programs that ultimately prove to be unsuccessful. If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed or never achieved. From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of clinical trials and the submission of regulatory filings, including IND submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize REACT or any of our future product candidates. Risks Related to the Manufacturing of REACT and Our Future Product Candidates Cell therapies are complex and difficult to manufacture, and we ~~could~~ **have experienced and may continue to** experience manufacturing problems that result in delays in the development or commercialization of REACT, our lead product candidate, or otherwise harm our business. The manufacture of cell therapy products is technically complex and necessitates substantial expertise and capital investment. Production difficulties caused by unforeseen events may delay the availability of material for our clinical trials. Further, we are not aware of any other cell therapy that has been manufactured for a market of the anticipated size for REACT. If REACT is approved for commercial sale, as to which no assurance can be given, we may be unable to meet market demand for the product in a timely manner due to the complex processes that are involved in its manufacturing. Additionally, all entities involved in the preparation of therapeutics for clinical trials or commercial sale are subject to extensive cGMP, state and federal regulations, as well as foreign requirements when applicable **. In October 2023, an audit by the Company' s contracted Qualified Person (QP) to evaluate our readiness for release and distribution of REACT in the EU identified certain deficiencies in the documentation of the quality management systems to be addressed prior to release and distribution of product for EU clinical sites. In response, we paused manufacturing in order to optimize our capabilities to meet EU and global standards for our Phase 3 program and to prepare for a transition to commercial manufacturing. Manufacturing activities are planned to resume by the end of June 2024** . Components of a finished therapeutic product approved for commercial sale or used in late- stage clinical trials must be manufactured in accordance with cGMP regulations. These regulations govern manufacturing processes and procedures (including record keeping) and the

implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants, or to inadvertent changes in the properties or stability of REACT that may not be detectable in final product testing. We must supply all necessary documentation in support of a BLA or MAA on a timely basis. Our facilities and quality systems, including those of any third parties we contract with to manufacture any critical component of the final product, must pass a pre- approval inspection for compliance with the applicable regulations as a condition of regulatory approval of REACT or any of our other potential products. In addition, the FDA and other regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of REACT or our other potential products or the associated quality systems for compliance with the regulations applicable to the activities being conducted at such facilities, and they could put a hold on one or more of our clinical trials if our facilities, or those of our contracted third parties, do not pass such audits or inspections. If such facilities do not pass a pre- approval plant inspection, FDA approval of the products will not be granted. Any failure to adhere to or document compliance with such regulatory requirements could lead to a delay or interruption in the availability of REACT for clinical trials or enforcement action from the FDA, EMA or foreign regulatory authorities. If we or our suppliers were to fail to comply with the requirements of the FDA, EMA or other regulatory authority, it could result in regulatory actions or sanctions being imposed on us, including the issuance of FDA Form 483 notices of inspectional observations, warning letters or untitled letters, clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of REACT. Our potential future dependence upon others for the manufacture of REACT may also adversely affect our future profit margins and our ability to commercialize REACT or any future product candidates that receive regulatory approval on a timely and competitive basis. Biological products are inherently difficult to manufacture. REACT is manufactured using technically complex processes requiring specialized equipment and facilities, highly specific raw materials, autologous cells collected from patients, and reagents, and the process involves various production constraints. Even though we aim to have backup supplies of raw materials and reagents whenever possible, we cannot be certain they will be sufficient if our primary sources are unavailable. A shortage of a critical raw material or reagent, or a technical issue during manufacturing may lead to delays in clinical development or commercialization plans. Any changes in the manufacturing of components of the raw materials we use could result in unanticipated or unfavorable effects in our manufacturing processes, resulting in delays. Delays or failures in the manufacture of cell therapies can result in a patient being unable to receive their cell therapy or a requirement to re- manufacture which itself then causes delays in manufacture for other patients. Any delay or failure or inability to manufacture on a timely basis can adversely affect a patient' s outcomes and delay the timelines for our clinical trials. Such delays or failure or inability to manufacture can result from: • a failure in the manufacturing process itself, for example by an error in manufacturing equipment or reagent failure, failure in any step of the manufacturing process, failure to maintain a cGMP environment or failure in quality systems applicable to manufacture, sterility failures, or contamination during process; • product loss or failure due to logistical issues associated with the collection of a patient' s autologous cells or other samples, shipping that material to analytical laboratories, and shipping the final cell therapy back to the location using cold chain distribution where it will be administered to the patient, manufacturing issues associated with the differences in patient starting materials, inconsistency in cell growth and variability in product characteristics; • a lack of reliability or reproducibility in the manufacturing process itself, leading to variability in end manufacture of the cell therapy, which may lead to regulatory authorities placing a hold on a clinical trial or requesting further information on the process, which could in turn result in delays to the clinical trials; • product loss or failure due to logistical issues including issues associated with the differences between patients' autologous cells or characteristics, interruptions to process, contamination, failure to supply patient apheresis material within required timescales (for example, as a result of an import or export hold- up) or supplier error; • inability to have enough manufacturing slots to manufacture cell therapies for patients as and when those patients require manufacture; • inability to procure starting materials or to manufacture starting materials; • interruptions in our supply chain, which may require us to find an alternative manufacturer or supplier for one or more components that we need in the manufacture of REACT, which would in turn require such manufacturer or supplier to be qualified through a BLA and / or MAA supplement, could lead the regulatory agencies to require additional studies if a new manufacturer is relied upon for commercial production, and may involve substantial costs and delays related to switching manufacturers; • loss of or close- down of any manufacturing facility used in the manufacture of our cell therapies, or the inability to find alternative manufacturing capability in a timely fashion; • loss or contamination of patient starting material, requiring the starting material to be obtained again from the patient or the manufacturing process to be re- started; and • a requirement to modify or make changes to any manufacturing process, which may also require comparability testing that delays our ability to make the required modifications or perform any required comparability testing in a timely fashion, require further regulatory approval or require successful tech transfer to ~~CMOs~~ **CDMOs** to continue manufacturing. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of REACT, cause us to incur higher costs and prevent us from commercializing REACT successfully, if approved. We ~~expect to utilize automation in all aspects of manufacturing ranging from tissue processing, cell expansion and renal cell selection to formulation and filling of the final product. We will also extend automation to other manufacturing activities, including warehouse operations and supply chain. In addition, we~~ intend to improve bioprocess development to ~~further~~ reduce manufacturing costs of the commercial REACT product, assuming receipt of necessary regulatory approvals. Culture media represents the highest cost in REACT processing, and we are exploring reduced culture media usage via bioprocess and automation improvements. Further, our final commercial REACT product is planned to be a cryopreserved formulation, which is projected to reduce manufacturing costs compared to our fresh REACT formulation. We expect to leverage bulk purchasing to actively negotiate pricing of materials to further drive cost reductions. However, there can be no assurance that the manufacturing costs for our Phase 3 trials when we manufacture REACT at commercial scale will

actually be lower than for our ~~ongoing~~ Phase 2 RMCL- 002 study. A number of factors may contribute to an inability to achieve these cost reductions, including any failures to achieve the automation efficiencies that we anticipate, cost overruns or inefficiencies in the supply chain, and any failure to improve the formulation or bioprocessing of REACT in a manner that results in lower costs. We have our own manufacturing capabilities, which may result in increased costs being incurred by us. Our manufacturing facility for REACT is within our Winston- Salem facility in North Carolina, and this facility currently manufactures ~~SRCs~~ **SRC** for use in our clinical trials. Regulatory authorities, in particular the FDA, might not continue to approve our ability to manufacture ~~SRCs~~ **SRC** or other cell therapies at the Winston- Salem facility. Our ability to successfully manufacture our own cell therapies at the Winston- Salem facility within a reasonable period of time and within currently projected costs is dependent on a number of factors, including: • our ability to recruit the required employees at a suitable level and experience and within required timescales and to maintain employment of such required employees; • our ability to obtain regulatory approval for the facility and for the manufacture of cell therapies at the facility and to satisfy regulatory authorities on an ongoing basis; • our ability to manufacture cell therapies reliably and reproducibly and to timescales sufficient to support required patient administration; • our ability to manufacture cell therapies in compliance with the applicable regulatory requirements, including requirements applicable in both the United States and the European Union, including cGMP, enforced by the FDA and state regulatory authorities; • our ability to develop internal quality controls and processes sufficient to enable manufacture and supply of cell therapies at our Winston- Salem facility; • our ability to establish comparability with currently used manufacturing processes and for such comparability data to be accepted by the appropriate regulatory authorities; and • our ability to fund ongoing development, including equipment requirements necessary for successful manufacture of cell therapies at our facility. Any **further** delay or failure in manufacture at our facility could result in delays to the supply of cell therapies for our clinical trials. Should we become unable to produce cell therapies for use in our clinical trials or be unable to produce cell therapies at the required level, then we will be unable to support such clinical trials until alternative manufacturing capability is secured. Contract development and manufacturing organizations have a finite cell manufacturing capacity, which could inhibit the long- term growth prospects of our business. We currently produce materials for our clinical trials at our facility in Winston- Salem, North Carolina. It is possible that the demand for our products could exceed existing manufacturing capacity. We expect that, as our own cell therapy development programs progress and demand for cell therapy services in the industry expand, it may become necessary or desirable for us to expand our manufacturing vendors for cell therapy services and products in the future, which may require us to invest significant amounts of capital and to obtain regulatory approvals. If manufacturers are unable to meet our rising demand for products and services on a timely basis or unable to maintain cGMP / cGTP compliance standards, then it is likely that the progress of our own programs will be impaired which could materially and adversely affect the overall success of our development programs. Components of therapeutic products approved for commercial sale or used in late- stage clinical trials must be manufactured in accordance with cGMPs and manufacturers of cell- based product candidates must comply with cGTPs. In addition, manufacturers of therapeutic products may be required to modify their manufacturing processes from time to time in response to regulatory requests. The manufacture of live cellular- based products is complex and imposes significant regulatory burdens that may change over time. We may encounter difficulties in the production of our product candidates due to our limited manufacturing experience. Our autologous cell therapy products are patient-specific, and we need to ensure that the correct product is administered to the correct patient. Administration of autologous cell therapies is patient- specific and personalized medicine. The process requires careful handling of patient- specific products and fail- safe tracking to ensure that the tracking process is without error and that patient samples are tracked from patient collection, through manufacturing and re- administration to the same patient. While such mechanisms are in place, should the tracking process fail, whether at our own facility, a third- party facility or at any point in the manufacturing **process** and supply ~~process~~ **chain** , a patient could receive another patient' s ~~SRCs~~ **SRC** , resulting in significant toxicity and potentially patient fatality. We will need to invest in enhanced systems, such as bar coding ~~,~~ **and electronic chain of identity and chain of custody systems** to further ensure fail- safe tracking. There is always a risk of a failure in any such system. Inability to develop or adopt an acceptable fail- safe tracking methodology and handling regime may delay or prevent us from receiving regulatory approval and / or result in significant toxicity and potentially patient fatality if a patient receives another patient' s ~~SRCs~~ **SRC** . This risk may be increased where autologous cell therapies are used in clinical trials that we do not control or sponsor and, should an error be made in the administration of our autologous cell therapies in such clinical trials, this could affect the steps required in our own clinical trials and manufacturing process requiring the addition of further tracking mechanisms to ensure fail- safe tracking. The tracking systems required to further ensure safe patient administration may also require enhanced procedures and administration to satisfy other regulatory requirements, for example, data protection requirements in Europe. The need to ensure tracking systems are adequate and to comply with these additional regulatory requirements may result in delay to the start of clinical trials or the need to obtain additional regulatory licenses or consents prior to starting such trials. Delays in obtaining regulatory approval of the manufacturing process and facility to produce REACT or disruptions in the manufacturing process may delay or disrupt our commercialization efforts. Very few cGMP cell therapy manufacturing facilities in the United States have received approval from the FDA for the manufacture of an approved cell therapy product. Before we can begin to commercially manufacture REACT or any of our future product candidates, we must obtain regulatory approval from the FDA for our manufacturing processes and for the facility in which manufacturing is performed. A manufacturing authorization must also be obtained from the appropriate EU regulatory authorities prior to commercialization in the European Union. Very few cGMP cell therapy manufacturing facilities in the United States have received approval from the FDA for the manufacture of an approved cell therapy product and, therefore, the timeframe required for us to obtain regulatory approval for our product candidates is uncertain. In addition, we must pass a pre- approval inspection of the manufacturing facility, including any facilities that produce any component of REACT, by the FDA and other relevant regulatory authorities before REACT or any of our future cell therapy product candidates can obtain marketing approval. 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 to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. In order to obtain approval, we will need to ensure that all of our processes, quality systems, methods, equipment, policies and procedures are compliant with cGMP and other applicable regulations, and perform extensive audits of vendors, contract laboratories, and suppliers. If any of our vendors, contract laboratories, or suppliers is found to be out of compliance with cGMP or other applicable regulations relating to REACT, we may experience delays or disruptions in manufacturing while we work with such third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern, among other things, quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP regulations, we will be obligated to spend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we may be subject to regulatory enforcement actions or other legal sanctions and may not be permitted to sell any products that we may develop. Any problems in our manufacturing process or facilities could make us a less attractive collaborator for potential partners, including larger pharmaceutical companies and academic research institutions, which could limit our access to additional attractive development programs. We do not have experience as a company managing a complex supply chain or satisfying manufacturing- related regulatory requirements. The FDA, the EMA and other foreign regulatory authorities may require us to submit samples of any lot of any approved product together with the protocols showing the results of applicable lot release tests at any time. Under some circumstances, the FDA, the EMA or other foreign regulatory authorities may require that we not distribute a product lot until the relevant agency authorizes its release. Slight deviations in the manufacturing process, including those affecting quality attributes and stability, may result in unacceptable changes in a cell therapy product that could lead to lot failures or product recalls. Lot failures or product recalls could cause us to delay product launches or clinical trials, which could be costly to us and otherwise harm our business, financial condition, results of operations and prospects. Problems in our manufacturing processes could restrict our ability to meet market demand for our products. Managing an autologous ex vivo cell therapy supply chain is highly complex. We must identify, engage, and coordinate with treatment centers where patients' cellular source material must be collected, prepared and transported to the manufacturing facility and the cryopreserved therapeutic product must be returned to the treatment center for administration to the patient using ~~controlled temperature~~ **vapor phase liquid nitrogen** shipping containers **. Additionally, we are dependent on highly specialized vendors to provide raw materials and components for our manufacturing process** . Once collected from the patient, the cellular source material must be prepared and stored according to specified procedures. While we intend to standardize the processes at treatment centers, if there is a deviation of the processes, the cellular source material from a patient could be adversely impacted and potentially result in manufacturing failures. The patient' s cellular materials must be transported to the manufacturing facility using a shipping container that maintains the material at a sufficiently cold temperature and must typically be delivered and processed within four days of collection. While we intend to use reputable couriers and agents for the transport of such materials, if the shipping container is opened or damaged such that the appropriate storage / shipping temperature is not maintained, the cellular source material may be adversely impacted and it may not be feasible to manufacture a cell therapy product for the patient. Similarly, if a shipment is delayed due to adverse weather, misrouting, being held up at a customs point ~~, COVID- 19 impacts~~ or other events, the cellular source material may not be delivered within a time window that will allow for its use for the successful manufacture of a cell therapy product. Similarly, the patient' s autologous cell therapy product must be returned to the clinical site for administration to the patient using a specialized shipping container that maintains the material at a very low temperature. While we intend to use reputable couriers and agents for the transport of our products, if the shipping container is opened or damaged such that the very low temperature is not maintained, the cell therapy product may be adversely impacted and it may not be feasible to administer it to the patient or, if administered, it could cause harm to the patient. Similarly, if a shipment is delayed due to adverse weather, misrouting, being held up at a customs point ~~, COVID- 19 impacts~~ or other events, and is not delivered to the clinical site within the time period that the very low temperature is maintained, the cell therapy product may be adversely affected and be unable to be administered or, if administered, could cause harm to the patient. We may be delayed or unable to identify, engage, successfully coordinate with or qualify treatment centers in the regions we are targeting as part of our commercial launch strategy, which could delay or prevent patients from receiving cell therapy treatments, if approved ~~. For example, due to COVID- 19- related travel restrictions, some in- person visits to qualify certain potential treatment centers were postponed or required to take place remotely~~ . If our treatment centers fail to perform satisfactorily, we may suffer reputational, operational, and business harm. Any of the above events, should they happen, could adversely affect our development timelines and our business, financial condition, results of operations and prospects. We depend on third- party suppliers for materials that are necessary for the conduct of clinical trials of REACT, our lead product candidate, and the loss of these third- party suppliers or their inability to supply us with sufficient quantities of adequate materials, or to do so at acceptable quality levels and on a timely basis, could harm our business. Manufacturing REACT, our lead product candidate, requires many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. We currently depend on a limited number of vendors for certain materials and equipment used in the manufacture of REACT. Some of these suppliers may not have the capacity to support clinical trials and commercial products manufactured under cGMP by biopharmaceutical firms or may otherwise be ill- equipped to support our needs. We also do not have supply contracts with many of these suppliers and may not be able to obtain supply contracts with them on acceptable terms or at all. Accordingly, we may experience delays or

interruption in receiving key materials and equipment to support clinical or commercial manufacturing. Any significant delay or interruption in the supply of components or sub- assemblies, or our inability to obtain substitute components, sub- assemblies or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand of our customers and harm our business. For some of these reagents, equipment, and materials, we rely and may in the future rely on sole source vendors or a limited number of vendors. The supply of the reagents and other specialty materials and equipment that are necessary to produce REACT could be reduced or interrupted at any time. In such case, identifying and engaging an alternative supplier could result in delay, and we may not be able to find other acceptable suppliers on acceptable terms, or at all. Switching suppliers may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines. If we change suppliers for commercial production, applicable regulatory agencies may require us to conduct additional studies or trials. If key suppliers are lost, or if the supply of the materials is diminished or discontinued, we may not be able to develop, manufacture and market REACT in a timely and competitive manner, or at all. An inability to continue to source products from any of these suppliers, which could be due to a number of issues, including regulatory actions or requirements affecting the supplier, adverse financial or other strategic developments experienced by a supplier, labor disputes or shortages, unexpected demands or quality issues, could adversely affect our ability to satisfy demand for REACT, which could adversely and materially affect our product sales and operating results or our ability to conduct clinical trials, either of which could significantly harm our business. As we continue to develop and scale our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials or equipment on commercially reasonable terms, or at all, and if we are unable to alter our process in a commercially viable manner to avoid the use of such materials or equipment or find a suitable substitute, it would have a material adverse effect on our business. Even if we are able to alter our process so as to use other materials or equipment, such a change may lead to a delay in our clinical development and / or commercialization plans. If such a change occurs for product candidate that is already in clinical development, the change may require us to perform both ex vivo comparability studies and to collect additional data from subjects prior to undertaking more advanced clinical trials. These factors could cause the delay of nonclinical studies or clinical trials, regulatory submissions, required approvals or commercialization of REACT or future product candidates that we develop, cause us to incur higher costs and prevent us from commercializing our product candidates successfully. Any microbial contamination in the manufacturing process for our cell- based product, shortages of raw materials or failure of any of our key suppliers to deliver necessary components could result in delays in our clinical development or marketing schedules. Given the nature of cell product manufacturing, there is a risk of microbial contamination. Any microbial contamination could adversely affect our ability to produce, release or administer our cell therapies on schedule and could, therefore, harm our results of operations and cause reputational damage. Some of the raw materials required in our manufacturing processes are derived from biologic sources. Such raw materials are difficult to procure and may be subject to contamination or recall. A material shortage, contamination, recall or restriction on the use of biologically derived substances in the manufacture of REACT could adversely impact or disrupt the commercial manufacturing or the production of clinical material, which could adversely affect our development timelines and our business, financial condition, results of operations and prospects. REACT requires cryopreservation with specific storage, handling and administration at the clinical sites. REACT requires cryopreservation and must be stored at very low temperatures in specialized ~~freezers~~ **liquid nitrogen tanks** or specialized shipping containers until immediately prior to use. For administration, the cryopreserved product ~~container~~ must be carefully removed from storage, rapidly thawed under controlled temperature conditions in an area proximal to the patient' s bedside and immediately administered to the patient. The handling, thawing and administration of the cryopreserved cell therapy product must be performed according to specific instructions, typically using specific disposables, and some steps must be completed within specific time periods. Failure to correctly handle the product, follow the instructions for thawing and administration and or failure to administer the product within the specified period post- thaw could negatively impact the efficacy and or safety of the product. Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay. As product candidates progress through clinical trials to marketing approval and commercialization, various aspects of the development program, such as manufacturing methods and the product' s formulation, may be altered along the way in an effort to optimize yield, manufacturing batch size, minimize costs and achieve consistent quality and results. These changes carry the risk that they will not achieve their intended objectives. Any of these changes could cause REACT or any of our future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of our ongoing or planned clinical trials, require us to perform bridging clinical trials or repeat one or more clinical trials, increase clinical trial costs, delay any potential approval of REACT or any of our future product candidates and jeopardize our ability to commercialize REACT or any of our future product candidates and generate revenue. In addition, there are risks associated with process development and large- scale manufacturing for clinical trials or commercial distribution including, among others, cost overruns, potential problems with process scale- up, process reproducibility, stability issues, compliance with cGMP, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our product candidates, there is no assurance that we will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. Additionally, the manufacturing processes for biological products is more complex and expensive than with small-molecule products, and additional manufacturing suppliers may be needed to manufacture clinical trial supplies for these development programs. If we are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects. Our current operations are concentrated in a number of locations, including a single manufacturing facility in North Carolina. We or the third parties upon whom we depend may be adversely

affected by earthquakes, wildfires or other natural disasters, as well as epidemics, pandemics and other incidents, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics or pandemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of REACT or any of our future product candidates or interruption of our business operations. Earthquakes, wildfires or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event prevented us from using all or a significant portion of our manufacturing facilities, or otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place, including use of contract manufacturers and inherent risks associated therewith with respect to technology transfer and quality issues, may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects. Risks Related to the Commercialization of REACT and Our Future Product Candidates Even if REACT or a future product candidate we develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. Even if REACT or any other product candidates we develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third- party payors, such as Medicare and Medicaid programs and managed care organizations, and others in the medical community. In addition, the availability of coverage by third- party payors may be affected by existing and future health care reform measures designed to reduce the cost of health care. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of any product candidate, if approved for commercial sale, will depend on a number of factors, including: • the efficacy and potential advantages of our current or future product candidates compared to alternative treatments; • product labeling or product insert requirements of the FDA, EMA or other foreign regulatory authorities, including any limitations or warnings contained in a product' s approved labeling, including any black box warning or REMS; • the clinical indications for which our current or future product candidates are approved; • availability of alternative treatments already approved or commercially launched in the future; • the ability to offer our products, if approved, for sale at competitive prices; • convenience and ease of administration compared to alternative treatments; • the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies, including where there may be a perception that our therapies, if approved, involve an increased risk of adverse events; • the recommendations with respect to our product candidates in guidelines published by various scientific organizations applicable to us and our product candidates; • the strength of marketing and distribution support; • any restrictions on the use of our products together with other medications; • our ability to hire and retain a sales force in the United States; • the ability to obtain sufficient third- party coverage and adequate reimbursement for our products, including necessary reimbursement codes; • the prevalence and severity of any side effects; • the ability to obtain Current Procedural Terminology (" CPT ") Codes and Resource- Based Relative Value Scale for appropriate provider reimbursement; • the ability to obtain designated International Classification of Diseases (" ICD- 10 ") codes from the WHO for disease designation; • willingness of provider proceduralists to perform invasive kidney procedures that may cause increased medical liability from procedural- related or cell based adverse events; and • the ability to provide advanced procedural training for delivery of product candidates. Sales of cell- based products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other health care providers, government agencies or private insurers will determine that our products are safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable. If government and other third- party payors do not provide coverage and adequate reimbursement levels for any products we commercialize, market acceptance and commercial success would be reduced. REACT is percutaneously injected into the kidney and requires additional proceduralist technical training with possible ongoing maintenance of certification. Facilities where REACT is delivered may require additional cell- based licensing by state, federal or laboratory certification agencies and require equipment with appropriate technology and inventories. We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell any products for which we obtain regulatory approval, we may not be able to generate product revenue. We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If REACT or any of our future product candidates ultimately receives regulatory approval, we expect to establish a marketing and sales organization with technical expertise and supporting **manufacturing and**

distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming. We have no prior experience as a company in the marketing, sale and distribution of biopharmaceutical products and there are significant risks involved in building and managing a sales organization. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to market our products on our own include: • our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel; • the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, including product administration and product delivery, once approved; • 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. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may also choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop and for which we receive regulatory approval ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. The affected populations for REACT or any of our future product candidates may be smaller than we or third parties currently project, which may affect the addressable markets for REACT or our future product candidates. Our projections of the number of people who have the diseases we are seeking to treat, as well as the subset of people with these diseases who have the potential to benefit from treatment with REACT or any of our future product candidates, are estimates based on our knowledge and understanding of these diseases. These estimates may prove to be incorrect, and new studies, medications, or medical practices may further reduce the estimated incidence or prevalence of this disease. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with REACT or any of our future product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain approval for REACT or any of our future product candidates, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of REACT or any of our future product candidates. The total addressable market opportunity for REACT or any of our future product candidates will ultimately depend upon a number of factors including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward- looking and speculative. The process we have used in developing an estimated incidence and prevalence range for the indications we are targeting has involved collating limited data from multiple sources. Accordingly, the incidence and prevalence estimates included in this Annual Report should be viewed with caution. Further, the data and statistical information used in this Annual Report, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources. Obtaining and maintaining regulatory approval of REACT or any of our future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of REACT or future product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of REACT or any of our future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, similar foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval. We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining similar foreign regulatory approvals and compliance with similar foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. We do not have any product candidates approved for sale in any jurisdiction, including international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with the regulatory requirements in international markets and / or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of REACT or any of our future product candidates will be harmed. Off- label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and / or subject us to penalties if we fail to comply with regulatory

requirements or experience unanticipated problems with any product. If we have any product candidate approved, our product labeling, advertising, and promotion will be subject to regulatory requirements and continuing regulatory review. In the United States, the FDA and the Federal Trade Commission (the " FTC ") strictly regulate the promotional claims that may be made about pharmaceutical products to ensure that any claims about such products are consistent with regulatory approvals, not misleading or false, and adequately substantiated by clinical data. The promotion of a medicine or biologic product in a manner that is false, misleading, unsubstantiated, or for unapproved (or off- label) uses may result in enforcement letters, inquiries and investigations and civil and criminal sanctions by the FDA, FTC, and other regulatory authorities. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product' s approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses, and a company that is found to have improperly promoted off- label uses may be subject to significant sanctions and may result in false claims litigation under federal and state statutes, which can lead to consent decrees, civil monetary penalties, restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state health care programs. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off- label promotion. The government has also required that companies enter into consent decrees and / or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. Any off- label use of REACT or any of our future product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities and stakeholders. REACT and our future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated, and our operating results will suffer if we fail to compete effectively. Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, REACT or any of our future product candidates may face competition from biosimilar products. In the United States, REACT is expected to be regulated by the FDA as a biological product, and we intend to seek approval for REACT pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009 (the " BPCIA ") created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for REACT. We believe that any of our current or future product candidates approved as a biological product under a BLA should qualify for the 12- year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow- on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing, including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient- provider relationship and a patient' s specific medical needs, health care providers are not restricted from prescribing biosimilar products in an off- label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own nonclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved **. Furthermore, the CREATES Act was enacted in late 2019 to address concerns articulated by both the FDA and others in the industry that some brand manufacturers have improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny follow- on product developers access to samples of brand drug or biologic products. Because follow- on product developers need samples to conduct certain comparative testing required by the FDA, some have attributed the inability to timely obtain samples as a cause of delay in the entry of follow- on products. To remedy this concern, the CREATES Act established a private cause of action that permits a follow- on product developer to sue the brand manufacturer to compel it to furnish the necessary samples on " commercially reasonable, market- based terms. " Therefore, a follow- on developer may request samples of our REACT product candidate, if it receives marketing approval, in order to conduct comparative testing to support a follow- on biosimilar version, and if we refuse any such request, we may be subject to litigation under the CREATES Act. Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have settled privately; therefore, to date no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law** . In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class- specific

guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved. If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval. Competitor companies or hospitals may be able to take advantage of EU rules permitting sales of unlicensed medicines for individual patients to sell competing products without a marketing authorization. The EU medicines rules allow individual member states to permit the supply of a medicinal product without a marketing authorization to fulfill special needs, where the product is supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of a health care professional and for use by an individual patient under his direct personal responsibility. This may in certain countries also apply to products manufactured in a country outside the European Union and imported to treat specific patients or small groups of patients. In addition, designated ATMPs do not need a marketing authorization if they are prepared on a non- routine basis and are used within the same EU member state in a hospital in accordance with a medical prescription for an individual patient. These exemptions could allow our competitors to make sales in the EU without having obtained a marketing authorization and without undergoing the expense of clinical trials, especially if those competitors have cell processing facilities in the relevant EU member state. Similarly, certain hospitals may be able to compete with us on the basis of these rules. Because any such sales would be made without a marketing authorization, there would be no need for the competitor company or hospital to refer to the clinical data in our marketing authorization dossiers, and so any data exclusivity protection that we may obtain for our products would not prevent such competing sales. Coverage and reimbursement may be limited or unavailable in certain market segments for REACT or our future product candidates, if approved, which could make it difficult for us to sell any product candidates profitably. In the United States and in other countries, patients who are prescribed treatment for their conditions generally rely on third- party payors to reimburse all or part of the costs associated with their treatment. Significant uncertainty exists as to the coverage and reimbursement status of any products for which we may obtain regulatory approval. In the United States, sales of any products for which we may receive regulatory marketing approval will depend, in part, on the availability of coverage and reimbursement from third- party payors. Third- party payors include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Coverage and adequate reimbursement from governmental health care programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Even if any of our products obtains regulatory approval, patients are unlikely to use such products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, any of our products, if approved, or assure that coverage and reimbursement will be available for any product that we may develop. REACT, due to the novel cell therapy and new indication for CKD, may require formulation of CPT codes with resource- based relative value unit appropriation and ICD- 10 designation. Each are obtained through different processes and may lead to reimbursement delays of unknown lengths of times. Government authorities and other third- party payors decide which treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third- party payor may depend upon a number of factors, including the third- party payor' s determination that use of a product is: • a covered benefit under its health plan; • safe, effective and medically necessary; • appropriate for the specific patient; • supported by peer- reviewed medical journals; • included in clinical practice guidelines; • cost- effective; and • neither experimental nor investigational. Our ability to commercialize successfully any of our products for which we obtain regulatory approval will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third- party payors, including government health care programs and private health insurers. Moreover, a payor' s decision to provide coverage for a biopharmaceutical product does not imply that an adequate reimbursement rate will be approved. If coverage and adequate reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize REACT or any of our future product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment. In the United States, no uniform policy of coverage and reimbursement for products exists among third- party payors. Therefore, coverage and reimbursement for our products can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost- effectiveness data for the use of our products on a payor- by- payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Additionally, third- party payors may not cover, or provide adequate reimbursement for, long- term follow- up evaluations required following the use of product candidates, once approved. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for REACT or any of our future product candidates, if approved. Changes to current laws and state and federal health care reform measures that may be adopted in the future may result in additional reductions in Medicare and other health care funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. If product liability lawsuits are brought against us, we may incur substantial financial or other liabilities and may be required to limit commercialization of REACT or our future product candidates. We face an inherent risk of product liability as a result of testing REACT or any of our future product candidates in clinical trials and will face an even greater risk if we commercialize any products. For example, we may be sued if REACT or any of our future product candidates causes or is perceived to cause injury or are found to be otherwise

unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of REACT or any of our future product candidates. Even a successful defense of these claims would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • inability to bring a product candidate to the market; • decreased demand for our products; • injury to our reputation; • withdrawal of clinical trial subjects and inability to continue clinical trials; • initiation of investigations by regulators; • significant costs to defend the related litigation; • reduced resources of our management to pursue our business strategy; • substantial monetary awards to trial subjects; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • loss of revenue; • exhaustion of any available insurance and our capital resources; • the inability to commercialize any products that we may develop; and • decline in our share price. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of products we develop. We will need to obtain additional insurance for clinical trials as REACT continues clinical development and as additional product candidates enter the clinic. However, we may be unable to obtain, or may obtain on unfavorable terms, clinical trial insurance in amounts adequate to cover any liabilities from any of our clinical trials. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise. If we or any contract manufacturers and suppliers we engage, now or in the future, fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could substantially harm our business. We and any ~~CMOs~~ **CDMOs** and suppliers we engage, now or in the future, are subject to numerous federal, state and local environmental, health, and safety laws, regulations, and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous materials, including chemicals and biological materials. Our operations also produce hazardous waste. 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. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third- party facilities. We also could incur significant costs associated with civil or criminal fines and penalties. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty, and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could substantially harm our business. Risks Related to Our Reliance on Third Parties We rely on third parties to conduct, supervise and monitor a certain portion of our research and nonclinical testing and clinical trials for REACT, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize REACT, or such approval or commercialization may be delayed, and our business may be substantially harmed. We depend, or may depend in the future, upon third parties to conduct certain aspects of our nonclinical studies and clinical trials, and to monitor and manage data, under agreements with universities, medical institutions, CROs, strategic collaborators and others. We expect to have to negotiate budgets and contracts with such third parties, which may result in delays to our development timelines and increased costs. We expect to continue to rely on third parties, including clinical CROs, medical institutions and clinical investigators, to conduct those clinical trials. If any of our relationships with these third- party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms, if at all. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects. Any third parties conducting aspects of our nonclinical studies or clinical trials will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our nonclinical studies and clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if they need to be replaced or if the quality or accuracy of the nonclinical or clinical data they obtain is compromised due to the failure to adhere to our protocols or regulatory

requirements or for other reasons, our product development timelines, including clinical development timelines, may be extended, delayed or terminated, and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize REACT. As a result, our financial results and the commercial prospects for REACT would be harmed, our costs could increase and our ability to generate revenue could be delayed. We will rely especially heavily on third parties over the course of our clinical trials and will have limited control over the clinical investigators and limited visibility into their day- to- day activities, including with respect to their compliance with the approved clinical trial protocol. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical investigators and clinical trial sites. If we or any of these third parties fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these trials or perform additional nonclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP requirements. In addition, our clinical trials must be conducted with biologic product produced under cGMP, and likely cGTP regulations and will require a large number of test subjects. Our failure or any failure by our contracted third parties, including CROs, to comply with these regulations or to recruit a sufficient number of subjects may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or health care privacy and security laws. We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials. gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. In addition, 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. The FDA 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. The FDA 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 and may ultimately lead to the denial of marketing approval for REACT or any of our future product candidates. We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of REACT or any of our future product candidates or commercialization of REACT or any of our future product candidates, producing additional losses and depriving us of potential revenue. We rely on third parties for materials, including tissue samples, required for our research and development activities, and if we are unable to reach agreements with these third parties our research and development activities would be delayed. We rely on third parties, primarily hospitals, health clinics and academic institutions, for the provision of tissue samples and other materials required in our research and development activities. Obtaining these materials requires various approvals as well as reaching a commercial agreement on acceptable terms with the hospital or other provider of the materials. While we currently have agreements in place with the institutions from which we receive our tissue samples, we do not have any exclusive arrangements with such sources and there is no guarantee that we will be able to maintain or renew such agreements on commercially reasonable terms, if at all. If we were unable to maintain or renew such agreements we would be forced to seek new arrangements with new hospitals, clinics or health institutions. If so, we may not be able to reach agreements with alternative partners or do so on terms acceptable to us. If we are unable to enter into such agreements, our research and development activities will be delayed and our ability to implement a key part of our development strategy will be compromised. We may in the future seek to enter into collaborations with third parties for the development and commercialization of REACT and / or our future product candidates, and our future collaborations will be important to our business. If we are unable to enter into collaborations, or if these collaborations are not successful, our business could be adversely affected. A part of our strategy is to consider partnerships in indications and geographies where we believe partners can add significant commercial and / or development capabilities. Further, we have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we have entered into and may in the future enter into collaborations with other companies to provide us with important technologies and funding for our programs and technology. Any future collaborations we enter into may pose a number of risks, including the following: • collaborators have significant discretion in determining the efforts and resources that they will apply; • 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 or license arrangements based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as a strategic transaction that may divert resources or create competing priorities; • collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products and product candidates if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours; • product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of REACT or our future product candidates; • collaborators may fail to comply with

applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product; • collaborators with marketing and distribution rights to REACT or one or more of our future product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product or products; • collaborators may not provide us with timely and accurate information regarding development progress and activity under any future license agreement, which could adversely impact our ability to report progress to our investors and otherwise plan development of REACT or our future product candidates; • disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time- consuming and expensive; • collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; • collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; • if a collaborator of ours 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; and • collaborations may be terminated by the collaborator, and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates. If any future collaborations we enter into do not result in the successful discovery, development and commercialization of product candidates or if one of our collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such collaboration. All of the risks relating to product development, regulatory approval and commercialization described in this Annual Report also apply to the activities of our collaborators. Additionally, 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 face significant competition in seeking appropriate collaborators for REACT and future product candidates, and the negotiation process is time- consuming and complex. In order for us to successfully establish a collaboration for REACT or any of our future product candidates, potential collaborators must view these product candidates as economically valuable in markets they determine to be attractive in light of the terms that we are seeking and other available products for licensing by other companies. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into future collaborations or do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop REACT or future product candidates, bring them to market and generate revenue from sales of such products or continue to develop our technology, and our business may be materially and adversely affected. Even if we are successful in our efforts to establish new strategic collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such strategic collaborations if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. Any delay in entering into new strategic collaboration agreements related to REACT or our future product candidates could delay their development and commercialization and reduce their competitiveness even if it reaches the market. **Finally, the pursuit of any collaboration with third parties will require investment of time and resources of the Company which may prove to be a distraction to management and, consequently, the business in the event that the Company is unable to consummate or enter into new strategic collaboration agreements.** Risks Related to Legal and Regulatory Compliance Matters Our relationships with customers, health care providers, physicians, prescribers, purchasers, third- party payors, charitable organizations and patients will be subject to applicable anti- kickback, fraud and abuse and other health care laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings. Although we do not currently have any products on the market, upon commercialization of REACT or any of our future product candidates, if approved, we will be subject to additional health care statutory and regulatory requirements and oversight by federal and state governments in the United States as well as foreign governments in the jurisdictions in which we conduct our business. Health care providers, including physicians, in the United States and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third- party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other health care laws and regulations, including, without limitation, the AKS and the FCA, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of REACT or any of our future product candidates, as well as the promotion, sales and marketing of health care items and services, as well as certain business arrangements in the health care 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 commission (s), 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. The health care laws that may affect us include: the federal fraud and abuse laws, including the AKS; false claims and civil monetary penalties laws, including the FCA and Civil Monetary Penalties Law; federal data privacy and security laws, including HIPAA, as amended by HITECH; and the federal Physician Payments Sunshine Act requiring reports of payments and / or other transfers of value made to or held by physicians (including doctors, dentists, optometrists, podiatrists, and chiropractors), certain non- physician health practitioners, and teaching hospitals, as well as certain ownership and investment interests held by physicians, during the previous year. In addition, many states have similar laws and regulations that may differ from each other and federal law in significant ways, thus complicating compliance efforts. Moreover, several states require biopharmaceutical companies to comply with the biopharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures. Additionally, some state and local laws require the registration of biopharmaceutical sales representatives in the jurisdiction. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of health care reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable health care laws, as well as responding to possible investigations by government authorities, can be time- and resource- consuming and can divert a company' s attention from other aspects of its business. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other health care laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded health care programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non- compliance with these laws. Further, if any of the physicians or other health care providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded health care programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management' s attention from the operation of the business. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. Even if we receive regulatory approval of any product candidates, we will be subject to ongoing regulatory oversight and continued regulatory review, which may result in significant additional expense and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with REACT or any of our future product candidates. If REACT or any of our future product candidates is approved, activities such as the manufacturing, labeling, packaging, storage, advertising, promotion, sampling, and record keeping for the products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMP and cGTP regulations. Biopharmaceutical manufacturers and any ~~CMOs~~ **CDMOs** responsible for any product manufacturing processes are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP and cGTP regulations and any applicable foreign equivalents. As such, we and any ~~CMOs~~ **CDMOs** we may employ in the future will be subject to continual review and inspections to assess compliance with cGMP and cGTP and adherence to commitments made in any BLA, other marketing application, and previous responses to inspection observations. Accordingly, we and others with whom we work must continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production and quality control. The FDA or a comparable foreign regulatory authority may also impose requirements for costly post- marketing nonclinical studies or clinical trials (often called Phase 4 trials) and post- marketing surveillance to monitor the safety or efficacy of the product. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant noncompliance with applicable cGMP regulations, a regulator may impose restrictions on that product, the manufacturing facility or us. If we or our third- party providers fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products. Later discovery of previously unknown problems with REACT or any of our future product candidates, including adverse events of unanticipated severity or frequency, or with our manufacturing processes, or failure to comply with regulatory requirements, may result in the following, among other things: • restrictions on the manufacturing of the product, the approved manufacturers or the manufacturing process; • restrictions on the labeling or marketing of a product; • restrictions on product distribution or use; • requirements to conduct post- marketing studies or clinical trials; • withdrawal of the product from the market; • product recalls; • warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities; • refusal of the FDA or other applicable regulatory authority to approve pending applications or supplements to approved applications; • fines, restitution or disgorgement of profits or revenues; • suspension or withdrawal of marketing approvals; • suspension of any of our ongoing clinical trials; • product seizure or detention or refusal to permit the import or export of products; and • consent decrees, injunctions or the imposition of civil or criminal penalties. In addition, regulatory authorities' policies (such as those of the FDA or EMA) may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of REACT or any of our future product candidates. 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 otherwise not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would

adversely affect our business, prospects and ability to achieve or sustain profitability. Non- compliance with EU requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union' s requirements regarding the protection of personal information can also lead to significant penalties and sanctions. The FDA' s policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of REACT or any of our future product candidates. 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, which would adversely affect our business, prospects and ability to achieve or sustain profitability. Changes in health care policies, laws and regulations, including legislative measures aimed at reducing health care costs, may impact our ability to obtain approval for, or commercialize REACT or any of our future product candidates, if approved. All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U. S. federal and state laws and agency regulation, as well as foreign laws and regulations, could have a materially negative impact on our business. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the health care system that could prevent or delay marketing approval of our product candidates or any potential future product candidates of ours, restrict or regulate post- approval activities, or affect our ability to profitably sell any product candidates for which we obtain marketing approval. Increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing testing and other requirements. Congress also must reauthorize the FDA' s user fee programs every five years and often makes changes to those programs in addition to policy or procedural changes that may be negotiated between the FDA and industry stakeholders as part of this periodic reauthorization process. Congress most recently reauthorized the user fee programs in September 2022 without any substantive policy changes. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in health care systems with the stated goals of containing health care costs, improving quality and / or expanding access. In the United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. In March 2010, Congress passed the ACA, which substantially changed the way health care is financed by both the government and private insurers, and significantly impacts the U. S. pharmaceutical industry. ~~There remain judicial and Congressional challenges to certain aspects of the ACA, and as a result, certain sections of the ACA have not been fully implemented or effectively repealed. 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 law' s constitutionality. Further legislative and regulatory changes under the ACA remain possible, although the new federal administration under President Biden has signaled that it plans to build on the ACA and expand the number of people who are eligible for health insurance subsidies under it. It is unknown what form any such changes or any law would take, and how or whether it may affect the pharmaceutical industry as a whole or our business in the future.~~ We expect that changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other health care reform measures, especially with regard to health care access, financing or other legislation in individual states, could have a material adverse effect on the health care industry in the United States. The **DSCSA** ~~uncertainty around the future of the ACA, and in particular the impact to reimbursement levels, may lead to uncertainty or delay in the purchasing decisions of our customers~~ , which ~~may in turn negatively impact our product sales. If there are not adequate reimbursement levels, our business and results of operations could be adversely affected. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of up to 2 % per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and was extended by the Consolidated Appropriations Act for 2023, and~~ will ~~remain in~~ **become fully** ~~effect~~ **effective** ~~through~~ **and applicable in November** ~~2032~~ ~~.~~ **2024** ~~unless additional Congressional action is taken. In addition~~ , ~~the Drug Supply Chain Security Act enacted in 2013 imposed~~ **imposes** obligations on manufacturers of pharmaceutical products related to product tracking and tracing **. Furthermore** , ~~and~~ in February 2022, FDA released proposed regulations to amend the national standards for licensing of wholesale drug distributors by the states; establish new minimum standards for state licensing third- party logistics providers; and create a federal system for licensure for use in the absence of a ~~State~~ **state** program, each of which is mandated by the DSCSA. Other legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We are unsure whether additional legislative changes will be enacted, or whether the current regulations, guidance or interpretations will be changed, or whether such changes will have any impact on our business. Additionally, there has been heightened governmental scrutiny in the United States of biopharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent 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 for products. For example, **President Biden' s Executive Order 14087, issued October 2022, called for CMS to prepare and submit a report to the White House on potential payment and delivery modes that would complement to IRA, lower drug costs, and promote access to innovative drugs. In February 2023, CMS published its report which described three potential models focusing on affordability, accessibility and feasibility of implementation for further testing by the CMS Innovation Center. As of February 2024, the CMS Innovation Center continues to test the proposed models and has started to roll out plans for access model testing of certain product types (e. g., cell and gene therapies) by states and manufacturers. At the** state **level,** legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical 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

December 2020, the U. S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers **(" PBMs ")** and other members of the health care and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area **. Then, in mid- 2022, the FTC launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements. In addition, in the last few years, several states have formed PDABs, with the authority to implement UPLs, on drugs sold in their respective jurisdictions. There are several pending federal lawsuits challenging the authority of states to impose UPLs, however** . Most recently, in August 2022, President Biden signed into the law the Inflation Reduction Act of 2022, or the IRA. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. Starting in 2023, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the product' s price increases faster than the rate of inflation. This calculation is made on a drug product by drug product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, starting in payment year 2026, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. Any additional federal or state health care reform measures could limit the amounts that third- party payers will pay for future health care products and services, and, in turn, could significantly reduce the projected value of certain development projects and reduce our profitability. Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, or if global health concerns 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 to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. EU medicine marketing and reimbursement regulations may materially affect our ability to market and receive coverage for our products in the European member states. We intend to seek approval to market REACT in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for REACT, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of medicines and cell based therapeutics is subject to governmental control and other market regulations which could put pressure on the pricing and usage of REACT. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of REACT will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for REACT and may be affected by existing and future health care reform measures. Additionally, the international regulatory landscape related to reimbursement is uncertain, and likely will continue to evolve before we are able to commercialize REACT. Much like the federal AKS prohibition in the United States, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the European Union. The provision of benefits or advantages to physicians is governed by the national anti- bribery laws of EU Member States, and in respect of the United Kingdom (which is no longer a member of the European Union), the UK Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain EU Member States must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician' s employer, his or her competent professional organization and / or the regulatory authorities of the individual EU Member States. These requirements are provided in the national laws, industry codes or professional codes of conduct, applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. In addition, in most foreign countries, including the EEA, the proposed pricing for a medicine must be approved before it may be lawfully marketed. The requirements governing medicine pricing and reimbursement vary widely from country to country. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low- priced and high- priced member states, can further reduce prices. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. In some countries, we may be required to conduct a clinical study or other studies that compare the cost- effectiveness of any of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. In

addition, these regulations are evolving and subject to change, possibly before we are able to commercialize REACT. There can be no assurance that any country that has price controls or reimbursement limitations for biopharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the European Union do not follow price structures of the United States and generally prices tend to be significantly lower. Publication of discounts by third- party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If pricing is set at unsatisfactory levels or if reimbursement of our products is unavailable or limited in scope or amount, our revenues from sales and the potential profitability of any of our product candidates in those countries would be negatively affected. We may incur substantial costs in our efforts to comply with evolving global data protection laws and regulations, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations. The global data protection landscape is rapidly evolving, and we may be or become subject to or affected by numerous federal, state and foreign laws and regulations, as well as regulatory guidance, governing the collection, use, disclosure, transfer, security and processing of personal data, such as information that we collect about subjects and health care providers in connection with clinical trials. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, which may create uncertainty in our business, affect our or our service providers' ability to operate in certain jurisdictions or to collect, store, transfer use and share personal data, result in liability or impose additional compliance or other costs on us. Any failure or perceived failure by us to comply with federal, state, or foreign laws or self- regulatory standards could result in negative publicity, diversion of management time and effort and proceedings against us by governmental entities or others. In the United States, numerous federal and state laws and regulations, including federal health information privacy laws (e. g., HIPAA, as amended by HITECH, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, or other privacy and data security laws. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose protected health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. However, determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If we are unable to properly protect the privacy and security of protected health information or other personal, sensitive, or confidential information in our possession, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face significant administrative, civil and criminal penalties. Enforcement activity can also result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal and outside resources. Furthermore, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems. Many state laws govern the privacy and security of personal information and data in specified circumstances, many of which differ from each other in significant ways, are often not pre- empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts. For example the CCPA, which went into effect in January 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. In addition, the California Consumer Rights Act (the " CPRA ") was recently enacted to strengthen elements of the CCPA and became effective on January 1, 2023. A number of other states have **enacted similar comprehensive privacy laws or** considered similar privacy proposals **. The** ~~, and states like Virginia and~~ Colorado ~~have recently enacted their own privacy~~ **Privacy** ~~laws. The~~ **Act, the Connecticut Personal Data Privacy and Online Monitoring Act, the Utah Consumer Privacy Act, and the** Virginia Consumer Data Protection Act **all** became effective **during** ~~on January 1,~~ 2023 **. ,** ~~and the Colorado~~ Privacy ~~Act is scheduled to come into~~ **laws in Montana, Oregon, and Texas will take** effect **in** ~~on July 1, 2023~~ **2024 . In addition, laws in other U. S. states are set to take effect beyond 2024, and additional U. S. states have proposals under consideration** . These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data. In addition to our operations in the United States, which may be subject to health care and other laws relating to the privacy and security of health information and other personal information, we are conducting, and we may conduct in the future, clinical trials in EEA and may become subject to additional European data privacy laws, regulations and guidelines. The General Data Protection Regulation, (EU) 2016 / 679 (" GDPR ") became effective on May 25, 2018, and deals with the collection, use, storage, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals in the EEA. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, keeping personal information secure, having data processing agreements with

third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non- compliance, including fines of up to € 10, 000, 000 or up to 2 % of our total worldwide annual turnover for certain comparatively minor offenses, or up to € 20, 000, 000 or up to 4 % of our total worldwide annual turnover, whichever is greater, for more serious offenses. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross- border data transfers. Further, national laws of member states of the European Union have been adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. **The GDPR also regulates the transfer of personal data subject to the GDPR to so- called third countries that have not been found by the European Commission to provide an adequate level of data protection. Legal developments in Europe have created complexity and uncertainty regarding such transfers. For instance, on July 16, 2020, the Court of Justice of the European Union, or CJEU, invalidated, by means of the so- called Schrems II judgment, the EU- U. S. Privacy Shield Framework, or the Privacy Shield, under which personal data could be transferred from the EEA to U. S. entities who had self- certified under the Privacy Shield scheme. However, on July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the European Union to the United States – the EU- U. S. Data Privacy Framework – which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data, and allows U. S. companies to self- certify to the U. S. Department of Commerce their compliance with a set of agreed privacy principles in order to freely receive EU personal data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address the points raised in the Schrems II judgment. The European Commission will continually review developments in the United States along with its adequacy decision.** Following the United Kingdom' s withdrawal from the European Union (i. e., Brexit), and the expiry of the Brexit transition period, which ended on December 31, 2020, the EU GDPR has been implemented in the United Kingdom (as the UK GDPR). The UK GDPR sits alongside the UK Data Protection Act 2018 which implements certain derogations in the EU GDPR into UK law. Under the UK GDPR, companies not established in the UK but who process personal data in relation to the offering of goods or services to individuals in the UK, or to monitor their behavior will be subject to the UK GDPR – the requirements of which are (at this time) largely aligned with those under the EU GDPR and as such, may lead to similar compliance and operational costs with potential fines of up to £ 17. 5 million or 4 % of global turnover. In **June of** ~~2022~~ **2021** , the ~~government of~~ **European Commission issued a decision, which will sunset on June 27, 2025 without further action, that** the United Kingdom ~~proposed~~ **ensures** ~~and~~ **an** ~~debated~~ **adequate level of protection for personal data transferred under the EU GDPR from the EU to the United Kingdom. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. In addition, the Parliament of the United Kingdom is currently considering** the Data Protection and Digital Information Bill to harmonize the 2018 Data Protection Act, ~~UK~~ **U. K.** GDPR, and the Privacy and Electronic Communications Regulations under one legislative framework ~~. However, progress on the bill stalled as the government continues to assess the most optimal approach to data protection reform~~ . We are conducting clinical trials in the EEA, and the GDPR increases our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we are required to have in place additional mechanisms and safeguards to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR is a rigorous and time- intensive process that increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. We expect that we will continue to face uncertainty as to whether our efforts to comply with any obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or biopharmaceutical partners. We may also experience hesitation, reluctance, or refusal by European or multi- national vendors or biopharmaceutical partners to continue to use our products due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such vendors or biopharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the forgoing could materially harm our business, prospects, financial condition and results of operations. Legal, political and economic uncertainty relating to our international operations could negatively impact or restrict our operations. Following the result of a referendum in 2016, Brexit took effect on January 31, 2020. Pursuant to the formal withdrawal arrangements agreed to by the United Kingdom and the European Union, as of January 1, 2021, the United Kingdom is no longer subject to the transition period during which EU rules continued to apply (the " Transition Period "). Negotiations between the United Kingdom and the European Union are expected to continue in relation to the customs and trading relationship between the United Kingdom and the European Union following the expiry of the Transition Period. Since a significant proportion of the regulatory framework in the United Kingdom is applicable to our business, and REACT, our lead product candidate, is derived from EU directives and regulations, Brexit, following the Transition Period, could materially

impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of REACT in the United Kingdom or the European Union. For example, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the United Kingdom will no longer be covered by the centralized procedures for obtaining EU- wide marketing authorizations from the EMA, and unless a specific agreement is entered into, a separate process for authorization of cell- based products will be required in the United Kingdom, the potential process for which is currently unclear. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing REACT in the United Kingdom or the European Union and limit our ability to generate revenue and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of REACT into the European Union, or we may incur expenses in establishing a manufacturing facility in the European Union in order to circumvent such hurdles. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the European Union for REACT, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import / export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non- tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the European Union. Further, we must dedicate additional resources to comply with numerous laws and regulations in each jurisdiction in which we plan to operate. The FCPA prohibits any U. S. individual or business entity from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the biopharmaceutical industry, because in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals and health care providers in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non- U. S. nationals, of information products classified for national security purposes, as well as certain products, technology and technical data relating to those products. As we expand our operations throughout the world, we will be required to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U. S. exchanges for violations of the FCPA' s accounting provisions. We are subject to certain U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations. Among other matters, U. S. and foreign anti- corruption, anti- money laundering, export control, sanctions, and other trade laws and regulations (collectively, the " Trade Laws ") prohibit companies and their employees, agents, clinical research organizations, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We plan to engage third parties for clinical trials and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals and we can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Our executive officers, directors, security holders and their respective affiliates may have competitive pecuniary interests that conflict with our interests. We have not adopted a policy that expressly prohibits our directors, executive officers, security holders or affiliates from having a direct or indirect pecuniary or financial interest in any investment to be acquired or disposed of by us or in any transaction to which we are a party or have an interest. Nor do we have a policy that expressly prohibits any such persons from engaging for their own account in business activities of the types conducted by us. Accordingly, such persons or entities may have a conflict between their interests and ours. Our second amended and restated memorandum and articles of association (" Charter ") provides that we renounce, to the maximum extent permitted by law, our interest in any corporate opportunity offered to any director who is not also an employee of the Company or about which any such director acquires knowledge unless such opportunity is expressly offered to such person solely in his or her capacity as a director of the Company and such opportunity is one we are legally and contractually permitted to undertake and would otherwise be reasonable for us to pursue. In addition, our Charter contains provisions to exculpate and indemnify, to the maximum extent permitted by law, such persons in respect of any liability, obligation or duty to our company that may arise as a consequence of such persons becoming aware of any business opportunity or failing to present such business opportunity. The personal and financial interests of our directors and officers may result in a conflict of interest and may result in a breach of their fiduciary duties to us as a matter of Cayman Islands law and we or our shareholders might have a claim against such individuals for infringing on our shareholders' rights. However, we might not ultimately be successful in any claim we may make against them for such reason. Because we are incorporated under the laws of the Cayman Islands, you may face difficulties in protecting your interests, and your ability to protect your rights through the U. S. federal courts may be limited. We are an exempted company incorporated under the laws of the Cayman Islands. As a

result, it may be difficult for investors to effect service of process within the United States upon our directors or executive officers, or enforce judgments obtained in the United States courts against our directors or officers. Our corporate affairs are governed by our Charter, the Cayman Islands Companies Act and the common law of the Cayman Islands. We are also subject to the federal securities laws of the United States. The rights of shareholders to take action against the directors, actions by minority shareholders and the fiduciary responsibilities of our directors to us under Cayman Islands law are to a large extent governed by the common law of the Cayman Islands. The common law of the Cayman Islands is derived in part from comparatively limited judicial precedent in the Cayman Islands as well as from English common law, the decisions of whose courts are of persuasive authority, but are not binding on a court in the Cayman Islands. The rights of our shareholders and the fiduciary responsibilities of our directors under Cayman Islands law are different from what they would be under statutes or judicial precedent in some jurisdictions in the United States. In particular, the Cayman Islands has a different body of corporate and securities laws as compared to the United States, and certain states, such as Delaware, may have more fully developed and judicially interpreted bodies of corporate law. In addition, Cayman Islands companies may not have standing to initiate a shareholder derivative action in a Federal court of the United States. We have been advised by our Cayman Islands legal counsel that the courts of the Cayman Islands are unlikely (i) to recognize or enforce against us judgments of courts of the United States predicated upon the civil liability provisions of the federal securities laws of the United States or any state; and (ii) in original actions brought in the Cayman Islands, to impose liabilities against us predicated upon the civil liability provisions of the federal securities laws of the United States or any state, so far as the liabilities imposed by those provisions are penal in nature. In those circumstances, although there is no statutory enforcement in the Cayman Islands of judgments obtained in the United States, the courts of the Cayman Islands will recognize and enforce a foreign money judgment of a foreign court of competent jurisdiction without retrial on the merits based on the principle that a judgment of a competent foreign court imposes upon the judgment debtor an obligation to pay the sum for which judgment has been given provided certain conditions are met. For a foreign judgment to be enforced in the Cayman Islands, such judgment must be final and conclusive and for a liquidated sum, and must not be in respect of taxes or a fine or penalty, inconsistent with a Cayman Islands judgment in respect of the same matter, impeachable on the grounds of fraud or obtained in a manner, or be of a kind the enforcement of which is, contrary to natural justice or the public policy of the Cayman Islands (awards of punitive or multiple damages may well be held to be contrary to public policy). A Cayman Islands court may stay enforcement proceedings if concurrent proceedings are being brought elsewhere. As a result of all of the above, shareholders may have more difficulty in protecting their interests in the face of actions taken by management, members of the board of directors or controlling shareholders than they would as shareholders of a United States company. Risks Related to Our Intellectual Property Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection. Our business will depend in large part on obtaining and maintaining patent, trademark and trade secret protection of our proprietary technologies and REACT, our lead product candidate, its respective components, synthetic intermediates, formulations, combination therapies, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third- party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing REACT is dependent upon the extent to which we have rights under valid and enforceable patents that cover these activities and whether a court would issue an injunctive remedy. If we are unable to secure and maintain patent protection for any product or technology we develop, or if the scope of the patent protection secured is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to commercialize any product candidates we may develop may be adversely affected. The patenting process is expensive and time- consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. The patenting process is subject to numerous risks and there can be no assurance that we will be successful in obtaining patents for which we have applied. In addition, we may not pursue, obtain, or maintain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors or licensees. The strength of patents in the biotechnology and biopharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in- license may fail to result in issued patents with claims that cover REACT or uses thereof in the United States or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our technology, including REACT, or prevent others from designing around the claims in our patents. If the breadth or strength of protection provided by the patent applications we hold with respect to REACT is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, REACT. Further, if we encounter delays in our clinical trials, the period of time during which we could market REACT under patent protection would be reduced. We cannot be certain that we were the first to file any patent application related to our technology, including REACT, and, if we were not, we may be precluded from obtaining patent protection for our technology, including REACT. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. Furthermore, for United States applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. Similarly, for United States applications in which at least one claim is not entitled to a priority date before March 16, 2013, derivation proceedings can be instituted to determine whether the subject matter of a patent claim was derived from a prior inventor’ s disclosure. We may be required to disclaim part or all of the term

of certain patents. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent or patent application claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, would adequately protect REACT, or would be found by a court to be infringed by a competitor' s technology or product. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to REACT, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in REACT or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that may issue that cover our products. Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. Under the enacted Leahy- Smith America Invents Act (the " America Invents Act ") after March 2013, the United States moved from a " first- to- invent " to a " first- to- file " system. Under a " first- to- file " system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U. S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post- grant review system. In addition, the courts have yet to address many of these provisions and the applicability of the America Invents Act and new regulations on specific patents discussed herein, for which issues have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example: • others may be able to make or use compounds that are similar to the compositions of REACT but that are not covered by the claims of our patents or those of our licensors; • we or our licensors, as the case may be, may fail to meet our obligations to the U. S. government in regards to any in- licensed patents and patent applications invented or developed using U. S. government funding, leading to the loss of patent rights; • we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies; • it is possible that our pending patent applications will not result in issued patents; • it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents; • it is possible that others may circumvent our owned or in- licensed patents; • it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours; • the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States; • the claims of our owned or in- licensed issued patents or patent applications, if and when issued, may not cover REACT; • our owned or in- licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties; • the inventors of our owned or in- licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors; • it is possible that our owned or in- licensed patents or patent applications omit individual (s) that should be listed as inventor (s) or include individual (s) that should not be listed as inventor (s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable; • we have engaged in scientific collaborations in the past, and will continue to do so in the future. Such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents; • we may not develop additional proprietary technologies for which we can obtain patent protection; • it is possible that product candidates or diagnostic tests we develop may be covered by third parties' patents or other exclusive rights; • if any of our owned or in- licensed patents or applications were made with U. S. government funds, it is possible that the U. S. government may assert certain march- in rights to force us or our licensor to grant a license to third- parties to allow them to practice the claimed invention; or • the patents of others may have an adverse effect on our business. We may enter into license or other collaboration agreements in the future that may impose certain obligations on us. If we fail to comply with our obligations under such future agreements with third parties, we could lose license rights that may be important to our future business. In connection with our efforts to expand our pipeline of product candidates, we may enter into certain licenses or other collaboration agreements in the future pertaining to the in- license of rights to additional candidates. Such agreements may impose various diligence, milestone payment, royalty, insurance or other obligations on us. If we fail to comply with these obligations, our licensor or collaboration partners may have the right to terminate the relevant agreement, in which event we would not be able to develop or market the products covered by such licenses or agreements. Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including: • the scope of rights granted under the license agreement and other interpretation- related issues; • the extent to which REACT, our lead product candidate, or any other product candidate' s technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; • the sublicensing of patent and other rights under our collaborative development relationships; • our diligence obligations under the license agreement and what activities satisfy those diligence obligations; • the inventorship and ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and • the priority of invention of patented technology. In addition, the agreements under which we may license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any

contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology ~~,~~ or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects. In addition, we may have limited control over the maintenance and prosecution of these in- licensed patents and patent applications, or any other intellectual property that may be related to our in- licensed intellectual property. For example, we cannot be certain that such activities by any future licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which our licensors initiate an infringement proceeding against a third- party infringer of the intellectual property rights ~~,~~ or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement ~~proceeding~~ **proceedings** or defense activities may be less vigorous than had we conducted them ourselves. If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be negatively impacted, and our business and competitive position would be harmed. In addition to patent protection, we rely heavily upon know- how and trade secret protection, as well as non- disclosure agreements and invention assignment agreements with our employees, consultants and third- parties, to protect our confidential and proprietary information, especially where we do not believe patent protection is appropriate or obtainable. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third- party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and **the** recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition, trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If one or more third parties obtain or are otherwise able to replicate these techniques, an important feature and differentiator of our clinical development strategy will become available to potential competitors. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed. In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third- party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party' s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our current or planned business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We also plan to adopt policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. Third- party claims of intellectual property infringement may be costly and time consuming to defend and could prevent or delay our product discovery, development and commercialization efforts. Our commercial success depends in part on our ability to develop, manufacture, market and sell REACT, our lead product candidate, and use our proprietary technologies without infringing the proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and biopharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post- grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that REACT and / or proprietary technologies infringe their intellectual property rights. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing REACT. As the biotechnology and biopharmaceutical industries expand and more patents are issued, the risk increases that REACT may give rise to claims of infringement of the patent rights of others. The Purple Book Continuity Act, enacted in December 2020 under Title II § 325, directs the FDA for the first time to publicly list certain patent information in the " Purple Book, " a database of approved biological products. Specifically, a reference product sponsor (" RPS ") is required to provide to FDA the list of patents and corresponding expiry dates (referred to here as the " initial list "), not later than 30 days after the RPS has provided the initial list to a 351 (k) applicant under section 351 (l) (3) (A) or (l) (7) of the Public Health Service Act. Accordingly, the RPS must only provide information on its patents to the FDA for listing in the Purple Book after it engages in the patent dance with a follow- on developer or biosimilar. As such, it is not always clear to industry participants, including us, which patents cover various types of medicines, products or their methods of use or manufacture, especially in the earlier stages of product discovery and development. Thus, because of the large number of patents issued and patent applications filed in our

fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidate, technologies or methods. If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to: • infringement and other intellectual property claims which, regardless of merit, may be expensive and time- consuming to litigate and may divert our management' s attention from our core business; • substantial damages for infringement, which we may have to pay if a court decides that the product or technology at issue infringes on or violates the third- party' s rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner' s attorneys' fees; • a court prohibiting us from developing, manufacturing, marketing or selling REACT, or from using our proprietary technologies, unless the third- party licenses its product rights to us, which it is not required to do; • if a license is available from a third- party, we may have to pay substantial royalties, upfront fees and other amounts, and / or grant cross- licenses to intellectual property rights for our products and any license that is available may be non- exclusive, which could result in our competitors gaining access to the same intellectual property; and • redesigning REACT or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents of which we are currently unaware with claims to compositions of matter, materials, formulations, methods of manufacture or methods for treatment that encompass the composition, use or manufacture of REACT. There may be currently pending patent applications of which we are currently unaware which may later result in issued patents that REACT or their use or manufacture may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third- party patent were held by a court of competent jurisdiction to cover REACT, intermediates used in the manufacture of REACT or our materials generally, aspects of our formulations or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, our ability to commercialize REACT may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize REACT. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of REACT. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize REACT, which could harm our business significantly. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. As is common in the biotechnology and biopharmaceutical industries, we employ individuals who were previously employed at universities or other biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, and although we try to ensure that our employees and consultants do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of

patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent which might adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third- party patent and pending application in the United States and abroad that may be relevant to or necessary for the commercialization of REACT in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third- party patent or may incorrectly predict whether a third party' s pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market REACT. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products. We may not be successful in obtaining or maintaining necessary intellectual property rights to develop any future product candidates on acceptable terms. REACT, our current product candidate, may require specific formulations to work effectively and efficiently and these rights may be held by others. We may develop products containing our compounds and pre- existing biopharmaceutical compounds. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third- party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize REACT. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire. We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, or challenging the patent rights of others, which could be expensive, time- consuming and unsuccessful. Competitors may infringe our patents or the patents of our current or future licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents 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 the technology in question or for other reasons. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may choose to challenge the patentability of claims in a third- party' s U. S. patent by requesting that the USPTO review the patent claims in an ex- parte re-examination, inter partes review or post- grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third- party' s patent in patent opposition proceedings in the European Patent Office (the " EPO ") or other foreign patent office. The costs of these opposition proceedings could be substantial ,and may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third- party alleging that the patent may be infringed by REACT or our proprietary technologies. In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in- licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our owned and in- licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U. S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in- licensed technology, the licensor may have to participate in an interference or derivation proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference or derivation proceeding involving a U. S. patent application on inventions owned by or in- licensed to us, we may incur substantial costs, divert management' s time and expend other resources, even if we are successful. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if anon- exclusive license is offered and our competitors gain access to the same technology. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are

successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. 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, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on our owned and in-licensed issued patents and patent applications are or will be due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process and following the issuance of a patent. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. In certain circumstances, even inadvertent noncompliance events may permanently and irrevocably jeopardize patent rights. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Certain patents covering REACT could be found invalid or unenforceable if challenged in court or the USPTO. If we or one of our licensors initiate legal proceedings against a third- party to enforce a patent covering REACT, the defendant could counterclaim that the patent covering REACT, as applicable, is invalid and / or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and / or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post- grant review, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover REACT. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on REACT. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Our earliest patents may expire before, or soon after, our first product achieves marketing approval in the United States or foreign jurisdictions. Upon the expiration of our current patents, we may lose the right to exclude others from practicing these inventions. The expiration of these patents could have a similar material adverse effect on our business, results of operations, financial condition and prospects. Changes in patent law in the United States, changes in the administration' s interpretation of the law, or changes in the law in other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. On March 16, 2013, under the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO on or after March 16, 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors were the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our or our licensor' s patents or patent applications. The America Invents Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U. S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our owned or in- licensed patent applications and the enforcement or defense of our owned or in- licensed issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. In addition,

the patent positions of companies in the development and commercialization of biopharmaceuticals are particularly uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. We have limited foreign intellectual property rights and may not be able to protect and enforce our intellectual property rights throughout the world. Although we have multiple patents in countries outside of the United States, we do not have intellectual property rights in all potential markets outside the United States where CKD is prevalent. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and 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, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us 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 by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, 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. Patent terms may be inadequate to protect our competitive position on REACT or our future product candidates for an adequate amount of time, and if we do not obtain protection under the Hatch- Waxman Amendments and similar non- United States legislation for extending the term of patents covering REACT or our future product candidates, our business may be materially harmed. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest claimed U. S. non- provisional filing date. Various extensions such as patent term adjustments and / or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering REACT or any of our future product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. 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, also known as the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent extension term of up to five additional years beyond the expiration date 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 may be extended. However, we may not be granted the full extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process. Also, we may not be granted any extension because of, for example, 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, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business. Any trademarks we have obtained or may obtain may be infringed or otherwise violated, or successfully challenged, resulting in harm to our business. We expect to rely on trademarks as one means to distinguish REACT, if approved for marketing, from the products of our competitors. Once we select new trademarks and apply to register them, our trademark applications may not be approved. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. Third parties may oppose or attempt to cancel our trademark applications or trademarks, or otherwise challenge our use of the trademarks. In the event that our trademarks are successfully challenged, we could be forced to rebrand our products, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe or otherwise violate our trademarks and we may not have adequate resources to enforce our trademarks. Any of the foregoing events may have a material adverse effect on our business. Moreover, any name we propose to use with REACT in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. The FDA typically conducts a review of

proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Risks Related to Managing Our Business and Operations We expect to expand our clinical development and research and regulatory capabilities, our manufacturing and administrative capacities, and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could adversely affect our operations. As of December 31, ~~2022~~ **2023** , we had approximately ~~87~~ **163** full- time employees. As our clinical development and commercialization plans and strategies develop, and as we transition into operating as a public company, we will need to expand our managerial, clinical, regulatory, manufacturing, sales, marketing, financial, development and legal capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic collaborators, suppliers and other third parties. Our future growth would impose significant added responsibilities on members of management, including: • identifying, recruiting, integrating, maintaining and motivating additional employees; • managing our development and commercialization efforts effectively, including the clinical and FDA review process for REACT and any other product candidates, while complying with our contractual obligations to contractors and other third parties; and • improving our operational, financial and management controls, reporting systems and procedures. Our ability to continue to develop and, if approved, commercialize REACT will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality, accuracy or quantity of the services provided is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain, or may be substantially delayed in obtaining, regulatory approval of REACT or any of our future product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize REACT or any other product candidates and, accordingly, may not achieve our research, development and commercialization goals. If we lose key management personnel, or if we fail to recruit additional highly skilled personnel, our ability to continue developing REACT or identify and develop new product candidates will be impaired, which could result in loss of markets or market share and could make us less competitive. Our ability to compete in the highly competitive biotechnology and biopharmaceutical industries depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel. We are highly dependent on our management, scientific and medical personnel ~~, including Tim Bertram, our Chief Executive Officer; Deepak Jain, our Chief Operating Officer; James Coulston, our Chief Financial Officer; Joseph Stavas, our SVP Global Head of Clinical Development~~ and **the** ~~Interventional Procedures; Darin J. Weber, our Senior Vice President of Regulatory Development; Ashley Johns, our Senior Vice President, Head of Global Clinical Operations; Mary Weger, our Chief People Officer and Todd C. Girolamo, our Chief Legal Officer. The~~ loss of the services of any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements could result in delays in product development and harm our business. We conduct our operations globally from several locations, including the United States and the Cayman Islands. Competition for skilled personnel in our industry is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we intend to provide equity awards that vest over time, some of which may be in the form of unregistered shares and may dilute the voting and economic rights of our shareholders. The value to employees of such equity awards that vest over time may be significantly affected by movements in our share price that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our key employees are at- will employees, which means that any of our employees could leave our employment at any time, with or without notice. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior scientific and medical personnel. Our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. We are exposed to the risk that our employees, independent contractors, consultants, collaborators, principal investigators, CROs, suppliers and vendors may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct that violates FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state health care laws and regulations, and laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended 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, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of individually identifiable information, including, without limitation, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this

activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to 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 have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, including, without limitation, damages, fines, disgorgement, imprisonment, exclusion from participation in government health care programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws, and the curtailment or restructuring of our operations. Our internal computer systems, or those of our collaborators or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs. Our ~~internal~~ **reputation and ability to operate business operations, manufacturing and clinical studies rely on the performance and security of our** computer **systems and those of third parties that we utilize in our operations. These** systems and those of any future collaborators and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary information or other similar disruptions. For example, the loss of clinical trial data from future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of REACT or any of our future product candidates could be delayed. We could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information systems and networks of our company and our vendors, including personal information of our employees and study subjects, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and / or systems. We may experience threats to our data and systems, including malicious codes and viruses, phishing and other ~~cyberattack~~ **cyber attacks** . The number and complexity of these threats continue to increase over time. If a material breach of, or accidental or intentional loss of data from, our information technology systems or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed, and our reputation and credibility could be damaged. We could be required to expend significant amounts of money and other resources to repair or replace information systems or networks. In addition, we could be subject to regulatory actions and / or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, the possibility of these events occurring cannot be eliminated entirely. As we outsource more of our information systems to vendors, engage in more electronic transactions with payors and patients, and rely more on cloud- based information systems, the related security risks will increase and we will need to expend additional resources to protect our technology and information systems. In addition, there can be no assurance that our internal information technology systems or those of our third- party contractors, or our consultants' efforts to implement adequate security and control measures, will be sufficient to protect us against breakdowns, service disruption, data deterioration or loss in the event of a system malfunction, or prevent data from being stolen or corrupted in the event of a cyberattack, security breach, industrial espionage attacks or insider threat attacks which could result in financial, legal, business or reputational harm **. We rely upon cloud services to operate certain aspects of our business and any disruption of or interference with our use of cloud services would impact our operations and our business would be adversely impacted. The cloud services we use provide distributed computing infrastructure platform and application hosting for our business operations. We have architected our software and computer systems to utilize application hosting, storage capabilities, communications and other services provided by cloud- based services. Given this, any disruption of, or interference with, our use of such services would impact our operations and our business would be adversely impacted** . Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and / or adverse publicity and could negatively affect our operating results and business. We and any potential collaborators may be subject to federal, state and foreign data protection laws and regulations (i. e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state privacy and health information privacy laws and federal and state consumer protection laws (e. g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure and protection of health- related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. International data protection laws, including GDPR, may also apply to health- related and other personal information ~~obtained~~ **collected** outside of the United States. The GDPR will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU (which also includes the

EEA) data protection rules. Further, the Brexit has created more uncertainty with regard to data protection regulation in the United Kingdom. The United Kingdom retained the GDPR in UK law, which sits alongside the amended version of the Data Protection Act 2018. The European Union adopted an adequacy decision so that data can be transferred from the European Union to the United Kingdom. Additionally, there are no new requirements for transfer from the United Kingdom to the European Union. However, going forward, the European Union' s and United Kingdom' s data protection rules could diverge, and data transfers may not be possible and / or new arrangements may need to be put in place. In particular, it is unclear to what extent the United Kingdom regime will begin diverging from the GDPR and how data transfers to and from the United Kingdom will be regulated. In addition, California recently enacted the CCPA, which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA became effective on January 1, 2020, ~~but~~ **and was significantly amended by** the CPRA **, which became** ~~was recently enacted to strengthen elements of the CCPA~~ effective ~~January 1, 2023. In addition, there are a number of other states that have considered similar privacy proposals, with states like Virginia and Colorado enacting their own privacy laws (also scheduled to come into effect~~ on January 1, 2023 ~~and July 1~~ **. Among other things** , **the CPRA established a new regulatory authority, the California Privacy Protection Agency, which is tasked with enacting new regulations under the CPRA and will have expanded enforcement authority. In** 2023, ~~respectively)~~ **comprehensive privacy laws in Virginia, Colorado, Connecticut, and Utah all took effect, and laws in Montana, Oregon, and Texas will take effect in 2024. In addition, laws in other U. S. states are set to take effect beyond 2024, and additional U. S. states have proposals under consideration** . These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U. S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. Changes in tax law or policy could increase our effective tax rate and tax liability or the taxes payable by holders of our ordinary shares, each of which could have a material adverse effect on our business, financial condition and results of operations. We could be adversely affected by changes in applicable tax laws, regulations, or administrative interpretations thereof. For example, the U. S. federal tax legislation commonly referred to as the Tax Cuts and Jobs Act (the " Tax Act "), enacted in December 2017, resulted in fundamental changes to the Internal Revenue Code of 1986, as amended (the " Code ") including, among many other things, a reduction to the federal corporate income tax rate, a partial limitation on the deductibility of business interest expense, a limitation on the deductibility of certain director and officer compensation expense, limitations on net operating loss carrybacks and carryovers and changes relating to the scope and timing of U. S. taxation on earnings from international business operations. Subsequent legislation, the Coronavirus Aid, Relief, and Economic Security Act (the " CARES Act ") enacted on March 27, 2020, relaxed certain of the limitations imposed by the Tax Act for certain taxable years, including the limitation on the use and carryback of net operating losses and the limitation on the deductibility of business interest expense. The exact impact of the Tax Act and the CARES Act for future years is difficult to quantify, but these changes could materially affect our investors, the companies in which our clients invest, or us. Legislative proposals in the U. S., if adopted, would increase the corporate income tax rate and capital gains tax rate. In addition, other changes could be enacted in the future to limit further the deductibility of interest, subject carried interests to more onerous taxation or effect other changes that could have a material adverse effect on our business, results of operations and financial condition ~~. Such changes could also include increases in state taxes and other changes to state tax laws to replenish state and local government finances depleted by costs attributable to the COVID- 19 pandemic and the reduction in tax revenues due to the accompanying economic downturn~~ . Our effective tax rate may fluctuate, and we may incur obligations in tax jurisdictions in excess of accrued amounts. We are or may become subject to taxation in more than one tax jurisdiction. As a result, our effective tax rate is derived from a combination of applicable tax rates in the various places that we operate. In preparing our financial statements, we estimate the amount of tax that will become payable in each of such places. Nevertheless, our effective tax rate may be different than experienced in the past due to numerous factors, including passage of newly enacted tax legislation, changes in the mix of our profitability from jurisdiction to jurisdiction, the results of examinations and audits of our tax filings, our inability to secure or sustain acceptable agreements with tax authorities, changes in accounting for income taxes and changes in tax laws. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations and may result in tax obligations in excess of amounts accrued in our financial statements. We may be a passive foreign investment company, or " PFIC, " which could result in adverse U. S. federal income tax consequences to U. S. investors. ProKidney believes that it is likely classified as a PFIC for U. S. federal income tax purposes. If we are a PFIC for any taxable year (or portion thereof) that is included in the holding period of a U. S. Holder of our Class A ordinary shares, such U. S. Holder may be subject to adverse U. S. federal income tax consequences and may be subject to additional reporting requirements. There can be no assurances with respect to our status as a PFIC for our current taxable year or any subsequent taxable year. Our actual PFIC status for any taxable year, moreover, will not be determinable until after the end of such taxable year. If we determine we are a PFIC for any taxable year (of which there can be no assurance), we will endeavor to provide to a U. S. Holder such information as the IRS may require, including a PFIC Annual Information Statement, upon request, in order to enable a U. S. Holder to make and maintain a " qualified electing fund " election. There can be no assurance, however, that

ProKidney will timely provide such information. We urge U. S. investors to consult their own tax advisors regarding the possible application of the PFIC rules. Unanticipated changes in effective tax rates or adverse outcomes resulting from examination of our income or other tax returns could adversely affect our financial condition and results of operations. We will be subject, directly or indirectly, to income taxes in various jurisdictions, and our tax liabilities will be subject to the allocation of expenses in differing jurisdictions. Our future effective tax rates could be subject to volatility or adversely affected by a number of factors, including: • changes in the valuation of our deferred tax assets and liabilities; • expected timing and amount of the release of any tax valuation allowances; • tax effects of share- based compensation; • costs related to intercompany restructurings; • changes in tax laws, regulations or interpretations thereof; or • lower- than- anticipated future earnings in jurisdictions where we have lower statutory tax rates and higher- than- anticipated future earnings in jurisdictions where we have higher statutory tax rates. In addition, we may be subject to audits of our income, sales and other transaction taxes by taxing authorities. Outcomes from these audits could have an adverse effect on our financial condition and results of operations. Our principal shareholders have significant influence over us, including over decisions that require the approval of shareholders, and their interests may conflict with the interests of holders of ProKidney Corp. Class A ordinary shares. The Deed of Undertaking, dated February 14, 2022, made by Control Empresarial de Capitales, S. A. de C. V. (“ CEC ”) (the “ Voting Agreement ”) provides, with respect to the election, appointment or removal of any director of the Company, that, until the third anniversary of the Closing, CEC will vote all of its voting shares in the capital of the Company in a manner proportionate to the manner in which all other ProKidney Class B ordinary shares not held by CEC are voted. As a result, Tolerantia LLC (“ Tolerantia ”) effectively controls a majority of the voting power of ProKidney Corp. with respect to the election, appointment or removal of any director. Additionally, Pablo Legorreta, as Chairperson of the Board, is affiliated with and majority owns and controls Tolerantia. As a result, Tolerantia and its affiliates have significant influence over the management and affairs of the Company, and, acting together, effectively control the election, appointment or removal of any director and have indirect control over the approval of significant corporate transactions, including any merger, consolidation or sale of all or substantially all of our assets and the issuance or redemption of equity interests in certain circumstances, to the extent such matters require approval of the Board. The interests of Tolerantia and CEC may not always coincide with, and in some cases may conflict with, our interests and the interests of our other shareholders, including the holders of ProKidney Class A ordinary shares. This concentration of ownership may also affect the prevailing market price of our ProKidney Class A ordinary shares due to investors’ perceptions that conflicts of interest may exist or arise. As a result, this concentration of ownership may not be in your best interests. Further, because these shareholders hold their economic interest in our business through PKLP, rather than through ProKidney Corp., their interests may further conflict with the interests of holders of ProKidney Class A ordinary shares. These holders’ significant ownership in ProKidney Corp. and resulting ability, acting together, to effectively control us may discourage someone from making a significant equity investment in ProKidney Corp., or could discourage transactions involving a change in control, including transactions in which a holder of ProKidney Class A ordinary shares might otherwise receive a premium for their shares over the then- current market price. Because we are a “ controlled company ” within the meaning of the Nasdaq rules, our shareholders may not have certain corporate governance protections that are available to shareholders of companies that are not controlled companies. So long as more than 50 % of the voting power for the election of directors is held by an individual, a group or another company, we will qualify as a “ controlled company ” within the meaning of the Nasdaq corporate governance standards. Pursuant to the terms of the Voting Agreement, Tolerantia effectively controls a majority of the voting power of all of our outstanding ordinary shares with respect to the election, appointment or removal of any director. As a result, we are a “ controlled company ” within the meaning of the Nasdaq corporate governance standards and are not subject to the requirements that would otherwise require us to have: (i) a majority of our board of directors consist of independent directors, (ii) subject to the exception pursuant to Nasdaq Listing Rule 5605 (b) (2), our board of directors have a compensation committee that is composed of at least two members, each of whom is an independent director, with a written charter addressing the committee’ s purpose and responsibilities and (iii) director nominees must be selected, or recommended for the board’ s selection, either by independent directors constituting a majority of the board’ s independent directors in a vote in which only independent directors participate, or by a nominating and corporate governance committee comprised solely of independent directors with a written charter addressing the committee’ s purpose and responsibilities. Pursuant to the requirements under the Business Combination Agreement, a majority of the directors of the Board are “ independent ” directors for the purposes of the Nasdaq Listing Rules, but for at least some period following the Business Combination, we may utilize the other exemptions described above. Tolerantia may have its interest in the Company diluted due to future equity issuances or its own actions in selling shares of the Company, in each case, which could result in a loss of the “ controlled company ” exemption under the Nasdaq listing rules. We would then be required to comply with those provisions of the Nasdaq listing requirements. Antitakeover provisions contained in our Charter, as well as provisions of Cayman Islands law, could impair a takeover attempt. Our Charter contains provisions that may discourage unsolicited takeover proposals that shareholders may consider to be in their best interests. These provisions may make more difficult the removal of management and may discourage transactions that otherwise could involve payment of a premium over prevailing market prices for our securities. These provisions will include, among other things: • no cumulative voting in the election of directors, which limits the ability of minority shareholders to elect director candidates; • a classified board of directors with three- year staggered terms, which could delay the ability of shareholders to change the membership of a majority of the Board; • the requirement that directors may only be removed from the Board by special resolution; • the right of the Board to elect a director to fill a vacancy of the Board created by the expansion of the Board or the resignation, death, or removal of a director in certain circumstances, which prevents shareholders from being able to fill vacancies on the Board; • a prohibition on shareholders calling an extraordinary general meeting and the requirement that a meeting of shareholders may only be called by members of the Board, which may delay the ability of our shareholders to force consideration of a proposal or to take action, including the removal of directors; and • the right of the Board to issue and

set the voting and other rights of preference shares, which could adversely affect the voting power and other rights of the holders of ordinary shares. The JOBS Act permits " emerging growth companies " like us to take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies. We currently qualify as an " emerging growth company " as defined in Section 2 (a) (19) of the Securities Act, as modified by the JOBS Act. As such, we take advantage of certain exemptions from various reporting requirements applicable to other public companies that are not emerging growth companies for as long as we continue to be an emerging growth company, including: (i) the exemption from the auditor attestation requirements with respect to internal control over financial reporting under Section 404 of SOX; (ii) the exemptions from say- on- pay, say- on- frequency and say- on- golden parachute voting requirements; and (iii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. As a result, our shareholders may not have access to certain information they deem important. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year: (a) following July 2, 2026, the fifth (5th) anniversary of our initial public offering (consummated as Social Capital Suvretta Holdings Corp. III); (b) in which we have total annual gross revenue of at least $ 1. 235 billion; or (c) in which we are deemed to be a large accelerated filer, which means the market value of our Class A ordinary shares that is held by non- affiliates equals or exceeds $ 700 million as of the last business day of our prior second fiscal quarter, and (ii) the date on which we have issued more than $ 1. 0 billion in non- convertible debt during the prior three- year period. Further, Section 102 (b) (1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that a company can elect to opt out of the extended transition period and comply with the requirements that apply to non- emerging growth companies but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company that is neither an emerging growth company nor an emerging growth company that has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used. Additionally, we are a " smaller reporting company " as defined in Item 10 (f) (1) of Regulation S- K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company until the last day of the fiscal year in which (i) the market value of our ordinary shares that is held by non- affiliates exceeds $ 250 million as of the last business day of the prior fiscal quarter, or (ii) our annual revenues equaled or exceeded $ 100 million during such completed fiscal year, and the market value of our ordinary shares that is held by non- affiliates equals or exceeds $ 700 million as of the last business day of the prior second fiscal quarter. We cannot predict if investors will find our Class A ordinary shares less attractive because we rely on these exemptions. If some investors find our Class A ordinary shares less attractive as a result, there may be a less active trading market for our Class A ordinary shares, and our share price may be more volatile. Our internal controls over financial reporting may not be effective and our independent registered public accounting firm may not be able to certify as to their effectiveness, which could have a significant and adverse effect on our business and reputation. As a public company, we are required to comply with the SEC' s rules implementing Sections 302 and 404 of the Sarbanes- Oxley Act of 2022, as amended, which require management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. To comply with the requirements of being a public company, we may need to undertake various actions, such as implementing additional internal controls and procedures and hiring additional accounting or internal audit staff. As an emerging growth company, our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 until the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm may issue a report that is adverse in the event that it is not satisfied with the level at which our controls are documented, designed or operating. Testing and maintaining these controls can divert our management' s attention from other matters that are important to the operation of our business. If we identify material weaknesses in our internal control over financial reporting or are unable to comply with the requirements of Section 404 or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal controls over financial reporting when we no longer qualify as an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our ordinary shares could be negatively affected, and we could become subject to investigations by the SEC or other regulatory authorities, which could require additional financial and management resources. Increased prices and inflation could negatively impact our margin performance and our financial results. Increased inflation, including rising prices for raw materials, parts and components, freight, packaging, labor and energy increases, the costs to manufacture and distribute our products, and we may be unable to pass these costs on to our customers. Additionally, we are exposed to fluctuations in other costs such as packaging, freight, labor and energy prices. If inflation in these costs increases beyond our ability to control for them through measures such as implementing operating efficiencies, we may not be able to increase prices to sufficiently offset the effect of various cost increases without negatively impacting customer demand, thereby negatively impacting our margin performance and results of operations. Geopolitical risks ~~associated with Russia' s invasion of Ukraine~~ could result in increased market volatility and uncertainty, which could negatively impact our business, financial condition, and results of operations. The uncertain nature, scope, magnitude, and duration of hostilities stemming from **geopolitical conflicts** ~~Russia' s recent military invasion of Ukraine~~ , including the potential effects of such hostilities as well as sanctions, embargoes, asset freezes, cyberattacks and other actions taken in response to such hostilities on the world economy and markets, have disrupted

global markets and contributed to increased market volatility and uncertainty, which could have an adverse impact on macroeconomic and other factors that affect our business and supply chain. Any disruption in our supply chain could reduce our revenue and adversely impact our financial results. Such a disruption could occur as a result of any number of events, including, but not limited to, military conflicts, geopolitical developments, war or terrorism, including the ongoing ~~conflict~~ **conflicts** in Ukraine **and Israel** ~~, regional or global pandemics like COVID- 19,~~ and disruptions in utility and other services. Any inability to obtain adequate deliveries or any other circumstance that would require us to seek alternative sources of supply or to manufacture, assemble, and test such components internally could significantly delay our ability to ship our products, which could damage relationships with current and prospective customers and could harm our reputation and brand and could adversely affect our business, financial condition, and results of operations. ~~In February 2022, in response to the military conflict between Russia and Ukraine, the United States and other North Atlantic Treaty Organization member states, as well as non- member states, announced targeted economic sanctions on Russia, including certain Russian citizens and enterprises, and the continuation of the conflict may trigger additional economic and other sanctions. The potential impacts of the conflict and related sanctions could include supply chain and logistics disruptions, macro financial impacts resulting from the exclusion of Russian financial institutions from the global banking system, volatility in foreign exchange rates and interest rates, inflationary pressures on raw materials and energy and heightened cybersecurity threats.~~ We do not and cannot know if the ~~conflict, which remains~~ ongoing **conflicts and the economic sanctions imposed as a result of the conflicts** , could escalate and result in broader economic and security concerns which could adversely affect our supply chain, suppliers, customers, and potential customers. It is not possible to predict the broader consequences of ~~this~~ **these** ~~conflict~~ **conflicts** , which could include further sanctions, embargoes, regional instability, geopolitical shifts and adverse effects on macroeconomic conditions, the availability and cost of materials, supplies, labor, currency exchange rates and financial markets, all of which could have a material adverse effect on our business, financial condition and results of operations. Risks Related to our Organizational Structure We are a limited partner of PKLP but may, in certain circumstances, lose the benefit of limited liability. We are a limited partner of PKLP, a limited partnership registered under the laws of Ireland. Under the Irish LP Act, limited partners of Irish limited partnerships will not be liable for the debts or obligations of the partnership beyond the amount of capital they have contributed. However, the Irish LP Act also provides that such limited liability may be lost if (i) a limited partner (such as ProKidney Corp.) takes part in the management of the business of **PKLP** ~~the partnership~~ , (ii) there is a failure to register PKLP as a limited partnership or any change to the registration details of PKLP, including changes to the name of PKLP, the general nature of the business of PKLP, the principal place of business of PKLP, the partners or the name of any partner of PKLP, the term of character of PKLP, the sum contributed by any limited partner or the liability of any partner by reason of his becoming a limited **partner** instead of a general partner or a general instead of a limited partner; and (iii) a limited partner withdraws some or a part of his, her or its capital, in which circumstance he, she or it will be liable for the debts and obligations of the firm up to the amount so withdrawn. We are a holding company, and our only material asset is our interest in PKLP, and we are accordingly dependent upon distributions made by our subsidiaries to pay taxes, make payments under the Tax Receivable Agreement and pay dividends. We are a holding company with no material assets other than our ownership interest in PKLP. As a result, we have no independent means of generating revenue or cash flow. Our ability to pay taxes, make payments under the Tax Receivable Agreement, dated as of July 11, 2022, by and among Social Capital Suvretta Holdings Corp. III, the TRA party representative (as defined in the Tax Receivable Agreement) and the holders of PKLP prior to the closing of the Business Combination (the " Tax Receivable Agreement ") and pay dividends, if any, will depend on the financial results and cash flows of PKLP and its subsidiaries and the distributions we receive from PKLP. Deterioration in the financial condition, earnings or cash flow of PKLP and its subsidiaries, for any reason, could limit or impair our ability to pay such distributions. Additionally, to the extent that we need funds and PKLP and / or any of its subsidiaries are restricted from making such distributions under applicable law or regulation or under the terms of any financing arrangements, or PKLP is otherwise unable to provide such funds, it could materially adversely affect our liquidity and financial condition. PKLP will continue to be treated as a partnership for U. S. federal income tax purposes and, as such, generally will not be subject to any entity- level U. S. federal income tax. Instead, the taxable income of PKLP will be allocated to holders of common units of PKLP (the " ProKidney Common Units "), including ProKidney Corp. Accordingly, we may be required to pay income taxes on our allocable share of any net taxable income of PKLP (e. g., U. S. federal income and branch profits tax to the extent such net taxable income is effectively connected to the conduct of a trade or business in the United States). Under the terms of the second amended and restated limited partnership agreement of PKLP, **as amended** ~~which went into effect upon the completion of the Business Combination~~ (the " Second Amended and Restated ProKidney Limited Partnership Agreement "), PKLP is obligated to make tax distributions to holders of ProKidney Common Units (including ProKidney Corp.) calculated at certain assumed tax rates. In addition to tax expenses, we will also incur expenses related to our operations, including payment obligations under the Tax Receivable Agreement (and the cost of administering such payment obligations), which could be significant and some of which may be reimbursed by PKLP (excluding payment obligations under the Tax Receivable Agreement). We intend to cause PKLP to make distributions to holders of ProKidney Common Units pro rata, in amounts sufficient to cover all applicable income taxes (calculated at assumed tax rates), relevant operating expenses, payments required to be made by us under the Tax Receivable Agreement and dividends, if any, declared by us. However, as discussed below, PKLP' s ability to make such distributions may be subject to various limitations and restrictions including, but not limited to, restrictions on distributions that would either violate any contract or agreement to which PKLP is then a party, including debt agreements, or any applicable law, or that would have the effect of rendering PKLP insolvent. If our cash resources are insufficient to meet our obligations under the Tax Receivable Agreement and to fund our obligations, we may be required to incur additional indebtedness to provide the liquidity needed to make such payments, which could materially adversely affect its liquidity and financial condition and subject us to various restrictions imposed by any such lenders. To the extent that we are unable to make payments under the Tax Receivable

Agreement for any reason, such payments will be deferred and will accrue interest until paid; provided, however, that nonpayment for a specified period may constitute a material breach of a material obligation under the Tax Receivable Agreement and therefore accelerate payments due under the Tax Receivable Agreement, which could be substantial. Additionally, although PKLP generally will not be subject to any entity- level U. S. federal income tax, it may be liable under federal tax legislation for adjustments to its tax return, absent an election to the contrary. In the event PKLP' s calculations of taxable income are incorrect, its members, including ProKidney Corp., in later years may be subject to material liabilities pursuant to this federal legislation and its related guidance. We anticipate that the distributions we will receive from PKLP may, in certain periods, exceed our actual tax liabilities and obligations to make payments under the Tax Receivable Agreement. The Board, in its sole discretion, may make any determination from time to time with respect to the use of any such excess cash so accumulated, which may include, among other uses, to pay dividends on ProKidney Class A ordinary shares. We will have no obligation to distribute such cash (or other available cash other than any declared dividend) to our shareholders. Dividends on ProKidney Class A ordinary shares, if any, will be paid at the discretion of the Board, which will consider, among other things, our business, operating results, financial condition, current and expected cash needs, plans for expansion and any legal or contractual limitations on our ability to pay such dividends. Financing arrangements may include restrictive covenants that restrict our ability to pay dividends or make other distributions to our shareholders. Under the Irish LP Act, a limited partner of PKLP may lose its limited liability where such limited partner withdraws some or a part of his, her or its contribution to PKLP, in which circumstance he, she or it will be liable for debts and obligations of ProKidney up to the amount so withdrawn. ProKidney' s subsidiaries are generally subject to similar legal limitations on their ability to make distributions to ProKidney. If ProKidney does not have sufficient funds to make distributions, our ability to declare and pay cash dividends may also be restricted or impaired. In certain circumstances, PKLP will be required to make distributions to us and the other holders of ProKidney Common Units, and the distributions that PKLP will be required to make may be substantial. PKLP will generally be required from time to time to make pro rata distributions in cash to us and the other holders of ProKidney Common Units at certain assumed tax rates in amounts that are intended to be sufficient to cover the taxes on our and the other holders of ProKidney Common Units respective allocable shares of the taxable income of PKLP. As a result of (i) potential differences in the amount of net taxable income allocable to us and the other holders of ProKidney Common Units, (ii) the lower tax rate applicable to corporations than individuals, (iii) our status as a non- U. S. person and (iv) the use of an assumed tax rate (the highest effective marginal combined U. S. federal, state and local income tax rate prescribed for an individual or corporate resident of New York, New York) in calculating PKLP' s distribution obligations, we may receive tax distributions significantly in excess of our tax liabilities and obligations to make payments under the Tax Receivable Agreement. We will determine in ~~its~~ **our** sole discretion the appropriate uses for any excess cash so accumulated, which may include, among other uses, dividends, the payment of obligations under the Tax Receivable Agreement and the payment of other expenses. We will have no obligation to distribute such excess cash (or other available cash other than any declared dividend) to the holders of ProKidney Class A ordinary shares. No adjustments to the redemption or exchange ratio of ProKidney Common Units for ProKidney Class A ordinary shares will be made as a result of either (i) any cash dividend by us or (ii) any cash that we retain and do not distribute to our shareholders. To the extent that we do not distribute such excess cash as dividends on ProKidney Class A ordinary shares and instead, for example, holds such cash balances or lends them to PKLP, holders of ProKidney Common Units would benefit from any value attributable to such cash balances as a result of their ownership of ProKidney Class A ordinary shares following a redemption or exchange of their ProKidney Common Units. Governmental authorities may question our intercompany transfer pricing policies or change their laws in a manner that could increase our effective tax rate or otherwise harm our business. As a company with an international structure, we are subject to U. S. and foreign tax and transfer pricing laws, including those relating to the flow of funds and allocation of profit between subsidiaries. If tax authorities challenge our intercompany transfer pricing, our operations may be negatively impacted and our effective tax rate may increase. Tax rates vary from country to country and if regulators determine that our profits in one jurisdiction should be increased, we might not be able to fully offset any associated increase in tax expense in the other jurisdiction, which would increase our effective tax rate. Additionally, within the Organization for Economic Cooperation and Development (" OECD ") / G20 Inclusive Framework on BEPS (" base erosion and profit shifting ") over ~~135~~ **140** jurisdictions have agreed to implement minimum taxation ~~. As separate taxing jurisdictions begin adopting these rules, we may need to change our international tax structure to maintain compliance with the new rules~~. Our effective tax rate may change as a result of the implementation of minimum taxation, depending on **our structure and** the footprint of **our** global operations ~~at~~ **in** the **future** ~~time of the change~~. Finally, we might not always be in compliance with all applicable customs, exchange control, value added tax and transfer pricing laws despite our efforts to be aware of and to comply with such laws. In such case, we may need to adjust our operating procedures and our business could be adversely affected. Under the Tax Receivable Agreement, we are required to pay 85 % of certain tax savings recognized by ProKidney Corp. as a result of the increases in tax basis of ProKidney assets attributable to the exchanges of ProKidney Common Units for ProKidney Class A ordinary shares and certain other tax benefits, and those payments may be substantial. Holders of PKLP prior to the Closing (" Closing ProKidney Unitholders ") **have exchanged and** may **in the future** exchange ~~their~~ **additional** ProKidney Common Units for ProKidney Class A ordinary shares or, subject to certain restrictions, cash, pursuant to the Exchange Agreement, dated as of July 11, 2022, by and among us, PKLP and the Closing ProKidney Unitholders (the " Exchange Agreement "), subject to certain conditions and transfer restrictions as set forth therein and in the Second Amended and Restated ProKidney Limited Partnership Agreement. ~~These~~ -- **The** exchanges ~~are expected~~ **that have occurred** to **date have not** ~~result~~ **resulted** in **an** ~~increases~~ **increase** in our allocable share of the tax basis of the tangible and intangible assets of PKLP **since ProKidney Corp is domiciled in a non- taxable jurisdiction. However, future exchanges may result in increases in our allocable share of the tax basis of the tangible and intangible assets of PKLP under certain circumstances** . These increases in tax basis may increase (for tax purposes) depreciation and amortization deductions and therefore reduce the amount

of income or franchise tax that we would otherwise be required to pay in the future had such exchanges never occurred. In connection with the Business Combination, we entered into the Tax Receivable Agreement, which generally provides for the payment by it of 85 % of certain tax savings, if any, that we recognize as a result of these increases in tax basis and certain other tax attributes of PKLP and tax benefits related to entering into the Tax Receivable Agreement. These payments are the obligation of ProKidney Corp. and not of PKLP. The actual increase in our allocable share of ProKidney' s tax basis in its assets, as well as the amount and timing of any payments under the Tax Receivable Agreement, will vary depending upon a number of factors, including the timing of exchanges, the market price of the Class A ordinary share at the time of the exchange, the extent to which such exchanges are taxable and the amount and timing of the recognition of our income. Many of the factors that will determine the amount of payments that we will make under the Tax Receivable Agreement are outside of our control and such payments, if any, could be substantial and could have a material adverse effect on our financial condition. Even assuming, among other things, that there are no material changes in relevant tax law, that PKLP' s enterprise value is equal to the enterprise value that was agreed to in the Business Combination at the time all ProKidney Common Units are exchanged, and that there are significant future redemptions or exchanges of ProKidney Common Units, payments under the Tax Receivable Agreement are not expected to be material because PKLP does not currently (i) plan to migrate business operations to the United States, or (ii) otherwise anticipate tax benefits outside of the United States from redemptions or exchanges of ProKidney Common Units that would trigger obligations under the Tax Receivable Agreement based upon the intended operations of PKLP outside the United States. In addition, because PKLP does not currently have business operations in the United States and does not expect to generate significant operating revenues in the near future, if at all, payments under the Tax Receivable Agreement in the near future, if any, are not expected to be material. If, contrary to current intended business operations and strategy, the business operations are migrated to the United States, the business operations outside of the United States change, or there are material changes in relevant tax law, then payments under the Tax Receivable Agreement could be material. Any payments made by us under the Tax Receivable Agreement will generally reduce the amount of overall cash flow that might have otherwise been available to us. To the extent that we are unable to make timely payments under the Tax Receivable Agreement for any reason, the unpaid amounts will be deferred and will accrue interest until paid. Furthermore, our future obligation to make payments under the Tax Receivable Agreement could make it a less attractive target for an acquisition, particularly in the case of an acquirer that cannot use some or all of the tax benefits that may be deemed realized under the Tax Receivable Agreement. In certain cases, payments under the Tax Receivable Agreement may exceed the actual tax benefits we realize or may be accelerated. Payments under the Tax Receivable Agreement will be based on the tax reporting positions that we determine, and the IRS or any other taxing authorities may challenge all or any part of the tax basis increases, as well as other tax positions that we take, and a court may sustain such a challenge. In the event any tax benefits initially claimed by us are disallowed, the ~~current~~ Closing ProKidney Unitholders will not be required to reimburse us for any excess payments that may previously have been made under the Tax Receivable Agreement, for example, due to adjustments resulting from examinations by taxing authorities. Rather, excess payments made to such holders will be netted against any future cash payments otherwise required to be made by us, if any, after the determination of such excess. However, a challenge to any tax benefits initially claimed by us may not arise for a number of years following the initial time of such payment or, even if challenged early, such excess cash payment may be greater than the amount of future cash payments that we might otherwise be required to make under the terms of the Tax Receivable Agreement and, as a result, there might not be future cash payments from which to net against. As a result, in certain circumstances we could make payments under the Tax Receivable Agreement in excess of our actual income or franchise tax savings, which could materially impair our financial condition. Moreover, the Tax Receivable Agreement provides that, in the event that (i) we exercise our early termination rights under the Tax Receivable Agreement, (ii) the Tax Receivable Agreement is rejected by operation of law in a bankruptcy case, (iii) certain changes of control of ProKidney Corp. occur (as described in the Tax Receivable Agreement) or (iv) we are more than three months late in making a payment due under the Tax Receivable Agreement (unless we in good faith determine that we have insufficient funds to make such payment) or otherwise materially breach any of our material obligations under the Tax Receivable Agreement, our obligations under the Tax Receivable Agreement will accelerate, and we will be required to make an immediate lump- sum cash payment to the Closing ProKidney Unitholders equal to the present value of all forecasted future payments that would have otherwise been made under the Tax Receivable Agreement, which lump- sum payment would be based on certain assumptions, including those relating to our future taxable income. The lump- sum payment to the Closing ProKidney Unitholders could be substantial and could exceed the actual tax benefits that we realize subsequent to such payment because such payment would be calculated assuming, among other things, that we would be able to use the assumed potential tax benefits in future years, and that tax rates applicable to us would be the same as they were in the year of the termination. There may be a material negative effect on our liquidity if the payments under the Tax Receivable Agreement exceed the actual income or franchise tax savings that we realize. Furthermore, our obligations to make payments under the Tax Receivable Agreement could also have the effect of delaying, deferring or preventing certain mergers, asset sales, other forms of business combinations or other changes of control. We may need to incur additional indebtedness to finance payments under the Tax Receivable Agreement to the extent our cash resources are insufficient to meet our obligations under the Tax Receivable Agreement as a result of timing discrepancies or otherwise. Such indebtedness may have a material adverse effect on our financial condition. Finally, because we are a holding company with no operations of our own, our ability to make payments under the Tax Receivable Agreement depends on the ability of PKLP to make distributions to us. To the extent that we are unable to make payments under the Tax Receivable Agreement for any reason, such payments will be deferred and will accrue interest until paid, which could negatively impact our results of operations and could also affect our liquidity in periods in which such payments are made. We are a Cayman Islands exempted company. The rights of our shareholders may be different from the rights of shareholders governed by the laws of U. S. jurisdictions. We are a Cayman Islands exempted company. Our corporate affairs will continue to

be governed by our Charter and by the laws of the Cayman Islands. The rights of shareholders and the responsibilities of members of the Board may be different from the rights of shareholders and responsibilities of directors in companies governed by the laws of U. S. jurisdictions. In the performance of its duties, the board of directors of a solvent Cayman Islands exempted company is required to consider that company' s best interests, which may differ from the interests of one or more of its individual shareholders.