Risk Factors Comparison 2024-03-19 to 2023-03-29 Form: 10-K

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Investing in our securities involves a high degree of risk. You should consider carefully the risks described below, together with all of the other information included or incorporated by reference in this Annual Report on Form 10- K. The risks described below are material risks currently known, expected or reasonably foreseeable by us. However, the risks described below are not the only ones that we face. Additional risks not presently known to us or that we currently deem immaterial may also affect our business, operating results, prospects or financial condition. If any of these risks actually materialize, our business, prospects, financial condition and results of operations could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment. Summary of Risks Associated with our Business Our business and an investment in our Company is subject to numerous risks and uncertainties, including those highlighted in the section titled " Risk Factors " immediately following this summary. Some of these risks include: • We are a clinical- stage biopharmaceutical company with no product (s) approved for commercial sale. • We rely on our license agreements to provide certain intellectual property rights relating to autologous regulatory Treg technology. If the license is terminated, we could lose the use of rights material to the development of our product candidates. • If we are unable to receive non- dilutive funding in the form of a government grant, or through a partnership with an established pharmaceutical company, then we may not be able to advance COYA 101 into a Phase 2b clinical trial. • We have incurred significant losses since inception. We expect to continue to incur losses for the foreseeable future, and we may not generate sufficient revenue to achieve or maintain profitability. • ~~The audit report with respect to our financial statements contains a paragraph expressing substantial doubt about our ability to continue as a going concern. •~~ We will need to raise significant additional capital, which may not be available to us on acceptable terms, or at all. If we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long- term viability may be threatened. • If we issue additional securities in the future, including issuances of shares of common stock upon exercise of our outstanding options and warrants, our existing stockholders will be diluted and our stock price may be negatively affected. • Our business may be materially adversely affected by ~~the coronavirus~~ **public health outbreaks, epidemics, or pandemics** (~~"~~ **such as the** COVID- 19 ~~"~~ **pandemic**) ~~pandemic. While our operations have not been materially adversely affected to date, should the pandemic or its aftereffects continue for a prolonged period of time, our business operations could be delayed or interrupted~~ . • We may encounter substantial delays in our planned clinical trials, or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all. • We do not currently own, lease or operate a principal laboratory, research and development or manufacturing facility of our own. We currently collaborate with various research institutions to perform these activities, including The Methodist Hospital in Houston, Texas. Establishing our own facilities would result in significant additional expense and may result in potential delays in testing and production. • Any clinical trials that are planned or are conducted on our product candidates may fail. Clinical trials are lengthy, complex and extremely expensive processes with uncertain outcomes and results and frequent failures. • Our dependence on third parties to manufacture our product candidates may increase the risk that preclinical development, clinical development and potential commercialization of our product candidates could be delayed, prevented or impaired. • Our business is subject to, and may be affected by, extensive and costly government regulation. • We may not obtain approval for our products and any product for which we obtain required regulatory marketing authorization could be subject to post- approval regulation, and we may be subject to penalties if we fail to comply with such post- approval requirements. • Even if we obtain regulatory approval to market our product candidates, our product candidates may not be accepted by the market. • We face competition from companies that have greater resources than we do, and we may not be able to effectively compete against these companies. • **Global events, including political instability, natural disasters, events of terrorism and wars, including the war between Ukraine and Russia, and the corresponding tensions created from such conflict between Russia, the United States and countries in Europe as well as other countries such as China; and the conflict between Hamas and Israel may negatively impact our business. •** If others claim we are infringing on the intellectual property rights of third parties, we may be subject to costly and time- consuming litigation. Risks Related to Our Business, Financial Condition and Capital Requirements We are a clinical- stage biotechnology company with limited resources, have a limited operating history and have no products approved for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability. We are a clinical- stage biotechnology company that commenced operations in 2020. In addition, we have no products approved for commercial sale and therefore all sources of capital have been obtained solely through financing. Pharmaceutical development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have completed a Phase 2a clinical trial for just one of our product candidates, and have not obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Given the highly uncertain nature of drug development, we may never complete clinical trials beyond Phase 2 for any of our product candidates or initiate clinical trials for any of our product candidates, obtain marketing approval for any product candidates, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Our limited operating history as a company makes any assessment of our future success and viability subject to significant uncertainty. We will encounter risks and difficulties frequently experienced by early- stage pharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not address these risks and difficulties successfully, our business, operating results and financial condition will suffer. We have

incurred significant losses since our inception and we expect to incur significant losses for the foreseeable future, **and we will** ~~which raise substantial doubt regarding our ability to continue as a going concern. Our ability to continue as a going concern requires~~ **require** ~~that we obtain~~ sufficient additional funding to finance our operations **, which may not be available** . Since our inception in 2020, we have incurred significant operating losses. Our net ~~losses~~ **loss** ~~were~~ **was** $ ~~12~~ **8** . ~~2~~ **0** million for the year ended December 31, ~~2022~~ **2023** , and our accumulated deficit as of December 31, ~~2022~~ **2023** was $ ~~17~~ **25** . 9 million. We expect to continue to incur increasing operating losses for the foreseeable future as we continue to develop our product candidates. In addition, we anticipate that our expenses will increase substantially if, and as, we: • advance the development of COYA 301 and COYA 302; • advance additional product candidates to clinical trials, including COYA 201 and COYA 206 ~~; • continue clinical development of COYA 101~~ ; • seek to discover and develop additional product candidates; • establish and validate our own clinical- and commercial- scale current good manufacturing practices, or cGMP, facilities; • submit a BLA or marketing authorization application (" MAA ") for COYA 301 or seek marketing approvals for any of our other product candidates that successfully complete clinical trials; • maintain, expand and protect our intellectual property portfolio; • acquire or in- license other product candidates and technologies; • incur additional costs associated with operating as a public company; and • increase our employee headcount and related expenses to support these activities. We may never succeed in any or all of these activities and, even if we do, we may never generate revenues that are significant or large enough to achieve profitability. ~~Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. Our independent registered public accounting firm included an explanatory paragraph in its audit report on the financial statements for the period from April 30, 2020 (date of inception) to December 31, 2020 and for the years ended December 31, 2021 and 2022, with respect to this uncertainty. Our ability to continue as a going concern depends on our ability to raise additional capital. If we seek additional financing after our initial public offering to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. Further, if we cannot continue as a going concern, we may be forced to discontinue operations and liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, which would cause our stockholders to lose all or a part of their investment.~~ We have never generated revenue from product sales and may never achieve or maintain profitability. We continue to incur significant research and development and other expenses related to ongoing operations and the development of our product candidates, including COYA 301, COYA 302, COYA 201, **and** COYA 206 ~~and COYA 101~~ . All of our product candidates will require substantial additional development time, capital and resources before we would be able to apply for or receive regulatory approvals and begin generating revenue from product sales. We do not anticipate generating revenues from product sales unless and until such time as our product candidates may be approved by ~~the U. S. Food and Drug Administration (the "~~ FDA ~~")~~ or other applicable regulatory authorities, and we are able to successfully market and sell a product candidate. Our ability to generate revenues from product sales depends on our, or potential future collaborators, success in: • completing clinical development of our product candidates; • seeking and obtaining regulatory approvals for product candidates for which we successfully complete clinical trials, if any; • launching and commercializing product candidates, by establishing a sales force, marketing and distribution infrastructure or, alternatively, collaborating with a commercialization partner; • qualifying for adequate coverage and reimbursement by government and third- party payors for our product candidates; • establishing, maintaining and enhancing a sustainable, scalable, reproducible and transferable manufacturing process for our cell therapy product candidates; • establishing and maintaining supply and manufacturing relationships with third parties that can provide adequate products and services, in both amount and quality, to support clinical development and the market demand for our product candidates, if approved; • obtaining market acceptance of our product candidates as a viable treatment option; • addressing any competing technological and market developments; • implementing additional internal systems and infrastructure, as needed; • negotiating favorable terms in any collaboration, licensing or other arrangements into which we may enter and performing our obligations in such collaborations; • maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets, know- how, and trademarks; • avoiding and defending against third- party interference or infringement claims; and • attracting, hiring and retaining qualified personnel. We anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond our current expectations if we are required by the FDA or other global regulatory authorities to perform clinical trials and other preclinical studies in addition to those that we currently anticipate. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable or be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable could decrease the value of our Company and impair our ability to raise capital, thereby limiting our research and development programs and efforts to expand our business or continue our operations. We will need to raise additional capital and if we are unable to successfully raise additional capital, our future clinical trials and product development could be limited and our long- term viability may be threatened. We believe that ~~the net proceeds from our initial public offering and~~ our existing cash, together with interest thereon, will be sufficient to fund our operations into ~~second quarter of 2024~~ **2026** . We intend to use ~~the net proceeds from our initial public offering and~~ our existing cash to, among other uses, advance our pipeline product candidates through preclinical and clinical development. Developing pharmaceutical products and conducting preclinical studies and clinical trials is expensive. We will need to raise significant additional capital to do so. Market volatility resulting from of the ongoing conflict between Russia and Ukraine **, and Hamas' attack against Israel and the ensuing conflict** , generally rising prices, increasing interest rates, effects of the COVID- 19 pandemic or other factors could adversely impact our ability to access capital as and when needed. We have no commitments for any additional financing, and will likely be required to raise such financing through the sale of additional equity securities or debt, which, in the case of equity securities, may occur at prices lower than the price of our common stock and warrants. These financings could result in substantial dilution to the holders of our common stock and warrants or require contractual or other restrictions on our

operations or on alternatives that may be available to us. If we issue debt, we may need to dedicate a substantial portion of our operating cash flow to paying principal and interest on such debt and we may need to comply with operating restrictions, such as limitations on incurring additional debt, which could impair our ability to acquire, sell or license intellectual property rights which could impede our ability to conduct our business. Furthermore, the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common stock to decline. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. Any such required financing may not be available in amounts or on terms acceptable to us, and the failure to procure such required financing could have a material and adverse effect on our business, financial condition and results of operations, or threaten our ability to continue as a going concern. Our present and future capital requirements will be significant and will depend on many factors, including: • the progress and results of our development efforts for our product candidates; • the costs, timing and outcome of regulatory review of our product candidates; • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims; • the effect of competing technological and market developments; • the degree and rate of market acceptance of our product candidates; • costs associated with prosecuting or defending any litigation that we are or may become involved in and any damages payable by us that result from such litigation; • the extent to which we acquire or in- license other products and technologies; • the cost associated with being a public company, including obligations to regulatory agencies, and increased investor relations and corporate communications expenses; and • legal, accounting, insurance and other professional and business- related costs. We may not be able to acquire additional funds on acceptable terms, or at all. If we are unable to raise adequate funds, we may have to liquidate some or all of our assets or delay, reduce the scope of or eliminate some or all of our development programs. If we do not have, or are not able to obtain, sufficient funds, we may be required to delay development or commercialization of our product candidates. We also may have to reduce the resources devoted to our product candidates or cease operations. Any of these factors could harm our operating results. As a public company, we are obligated to develop and maintain proper and effective controls over financial reporting. If we fail to maintain proper and effective internal controls over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our securities. ~~Pursuant to~~ Section 404 of **the** Sarbanes- Oxley Act **of 2002** ~~, our management will be required~~ **requires us** to **evaluate** ~~report upon~~ the effectiveness of our internal control over financial reporting ~~beginning with~~ **as of** the **end of each fiscal year, and to include a management report assessing the effectiveness of our internal control over financial reporting in our** annual report **on Form 10- K** for ~~our~~ **that** fiscal year ~~ending December 31, 2023~~ . ~~When we lose~~ **Our management, including** our ~~status as~~ **principal executive officer** ~~an~~ **and** ~~" emerging growth~~ **principal financial officer, does not expect that our internal control over financial reporting will prevent all error and all fraud. We continue to operate with a small staff for financial reporting. Though the process and design of our internal controls over financial reporting have not been altered, the small number of staff involved in financial reporting may limit our ability to properly segregate internal control procedures which could result in deficiencies or material weaknesses in our internal controls in the future. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system' s objectives will be met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud involving a** company **have been** , **or will be** ~~" as defined in the JOBS Act~~ , ~~and reach~~ **detected. The design of** ~~an~~ **any** ~~accelerated filer threshold~~ **system of controls is based in part on certain assumptions about the likelihood of future events** , **and we cannot assure you that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become ineffective because of changes in conditions or deterioration in the degree of compliance with policies or procedures. Because of the inherent limitations in a cost- effective control system, misstatements due to error or fraud may occur and not be detected. We cannot assure you that we or** our independent registered public accounting firm will **not identify a material weakness in** ~~be required to attest to the effectiveness of~~ our internal control over financial reporting **in** ~~. However, for so long as we remain an emerging growth company, we intend to take advantage of an exemption available to emerging growth companies from these~~ -- **the future** ~~auditor attestation requirements~~ . **A material weakness in** ~~The rules governing the standards that must be met for management to assess~~ our internal control over financial reporting **would** ~~are complex and~~ require **management to consider our internal control over financial** ~~significant documentation, testing, and possible remediation. To comply with the requirements of being a~~ reporting **as ineffective** ~~company under the Exchange Act, we will need to upgrade our systems including information technology; implement additional financial and management controls, reporting systems, and procedures; and hire additional accounting and finance staff~~ . If ~~we or, if required, our auditors are unable to conclude that~~ our internal control over financial reporting is **not considered** effective, ~~investors~~ **we** may **experience a** ~~lose~~ **loss of public** confidence ~~in our financial reporting~~ , **which could have** ~~and~~ - **an adverse effect on our business and on** the ~~trading~~ **market** price of our common stock ~~or warrants may decline. Prior to our initial public offering, we operated as a private company that was not required to comply with the obligations of a public company with respect to internal control over financial reporting. We have historically operated with limited accounting personnel and other resources with which to address our internal control over financial reporting. In connection with the audits of our financial statements in preparation for our initial public offering, we and our independent registered public accounting firm identified material weaknesses in our internal control over financial reporting. While we have remediated these material weaknesses, we cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we~~

~~are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock or warrants could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities. Failure to remedy any material weakness or significant deficiencies in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets~~ . Any acquisitions or strategic collaborations may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities or subject us to other risks. From time to time, we may evaluate various acquisitions and strategic collaborations, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including, but not limited to: • increased operating expenses and cash requirements; • the assumption of indebtedness or contingent or unknown liabilities; • assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel; • the diversion of our management' s attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition; • retention of key employees, the loss of key personnel, and uncertainties about our ability to maintain key business relationships; • risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or product candidates and regulatory approvals; and • our inability to generate revenue from acquired drugs, intellectual property rights, technologies, and / or businesses sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs. In addition, if we engage in acquisitions or strategic partnerships, we may issue dilutive securities, assume or incur debt obligations, incur large one- time expenses or acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, and this inability could impair our growth or limit access to technology or drugs that may be important to the development of our business. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have never generated any revenue from product sales, we may never generate any revenue from product sales, and we may fail to generate further revenue from grants or contracts or to be profitable. We have no products approved for commercial sale and have not generated any revenue from product sales. Our ability to successfully commercialize our existing product candidates depends on our ability to successfully obtain regulatory approvals, among other factors. Thus, we may not generate meaningful revenue until after we have successfully begun and completed clinical development and received regulatory approval for the commercial sale of a product candidate. We may never complete clinical development or receive regulatory approval for the commercial sale of a product candidate and thus may never generate revenue from product sales. Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when, if ever, we will be able to generate any meaningful revenue or achieve or maintain profitability. In addition, our expenses could increase beyond our current expectations if we are required by the FDA or foreign regulatory agencies to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our or our future collaborators' clinical trials or the development of any of our product candidates. Even if one or more of our product candidates is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate and ongoing compliance efforts. Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Revenue from the sale of any product candidate for which regulatory approval is obtained will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to get reimbursement at any price and whether we own the commercial rights for that territory. If the number of addressable patients is not as significant as we anticipate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably accepted population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. Even 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, expand our business, maintain our research and development efforts, diversify our pipeline of product candidates or continue our operations, and cause a decline in the value of our securities, all or any of which may adversely affect our viability. Due to the significant resources required for the development of our programs, and depending on our ability to access capital, we may prioritize development of certain product candidates over others. We may expend our limited resources on programs that do not yield a successful product candidate and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Due to the significant resources required for the development of our programs, we may focus our programs on specific diseases and disease pathways and decide which product candidates to prioritize and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or **potential** therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, our potential decisions to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. We may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights. If we make incorrect determinations regarding the viability or market potential of any or all of our programs or product candidates or misread trends in the

pharmaceutical industry, in particular, for neurodegenerative diseases, our business, prospects, financial condition and results of operations could be materially adversely affected. We face risks related to **public** health epidemics and ~~outbreaks~~ **pandemics**, including COVID- 19, which could significantly disrupt our preclinical studies and clinical trials. **We are subject to risks associated with public health crises, such as** ~~The duration and the geographic impact of the business disruption and related financial impact resulting from the COVID- 19 pandemic~~ **pandemics** ~~cannot be reasonably estimated at this time and our business could be adversely impacted by its effects. In an~~ **and epidemics** ~~effort to halt the outbreak of COVID- 19~~, ~~the United States has, at times, placed significant restrictions on travel and many businesses have announced extended closures~~ which ~~could adversely impact our operations. Enrollment of patients in our clinical trials and our planned and ongoing preclinical and clinical trials may be delayed due to COVID- 19. The impact of the COVID- 19 pandemic on the operations of the FDA and other health authorities may delay potential approvals of our clinical trial protocols. In addition, we rely on independent clinical investigators, contract research organizations and other third- party service providers to assist us in managing, monitoring and otherwise carrying out our preclinical studies and clinical trials, and the pandemic may affect their ability to devote sufficient time and resources to our programs. We also rely on third party suppliers and contract manufacturers to produce the drug product we utilize in our clinical trials, and the pandemic may cause delays in the delivery of raw materials and drug product. Temporary closure of facilities at which our clinical or preclinical trials are conducted, or restrictions on the ability of our employees, clinicians or patients enrolled in our trials to travel could adversely affect our operations and our ability to conduct and complete our preclinical and clinical trials. In addition, the COVID- 19 pandemic, including insufficient vaccination of the general population and the emergence of new variants, including the delta variant and the omicron variant, could affect the health and availability of our workforce as well as those of the third parties on whom we rely. If new, more infectious or severe variants emerge, it is possible that the impact of the pandemic on our business may increase or lengthen in duration. As a result of the foregoing factors, the expected timeline for data readouts of our preclinical studies and clinical trials and certain regulatory filings may be negatively impacted, which would adversely affect our business. Disruptions in the global economy and supply chains~~ may have a material adverse effect on our business **. Global health outbreaks, such as COVID- 19, have and may continue to adversely affect our employees, disrupt our business operations and practices, as well those of our customers, partners, vendors and suppliers. Public health measures by government authorities such as travel bans, social- distancing, lockdown measures, vaccination requirements may cause us to incur additional costs, limit our operations, modify our business practices, diminish employee productivity or disrupt our supply chain, which may have a material adverse effect on our business. To the extent a public health crisis will impact our business**, financial condition and results of operations **depends on factors outside of our control, including severity, duration and the measures to contain the health outbreak**. ~~The~~ **. Disruptions in the global economy and supply chains may have a material adverse effect on our business, financial condition and results of operations. Recent** disruptions to the global economy since 2020 ~~and into 2023~~ have impeded global supply chains, resulting in longer lead times and also increased critical component costs and freight expenses. We have taken and may have to take steps to minimize the impact of these disruptions in lead times and increased costs by working closely with our suppliers and other third parties on whom we rely for the conduct of our business. Despite the actions we have undertaken or may have to undertake to minimize the impacts from disruptions to the global economy, there can be no assurances that unforeseen future events in the global supply chain will not have a material adverse effect on our business, financial condition and results of operations. Furthermore, inflation can adversely affect us by increasing the costs of clinical trials, the research and development of our product candidates, as well as administration and other costs of doing business. We may experience increases in the prices of labor and other costs of doing business. In an inflationary environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this happens, we may need to raise additional capital to fund our operations, which may not be available in sufficient amounts or on reasonable terms, if at all, sooner than expected. Unfavorable global economic conditions and adverse developments with respect to financial institutions and associated liquidity risk could adversely affect our business, financial condition and stock price. The global credit and financial markets are currently, and have from time to time experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the ongoing conflict between Russia and Ukraine **and Hamas' attack against Israel and the ensuing conflict**, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts ~~, including the one in Ukraine~~, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability ~~. More recently, the closures of Silicon Valley Bank, or SVB, and Signature Bank and their placement into receivership with the Federal Deposit Insurance Corporation, or FDIC created bank- specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve, and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair the ability of companies to access near- term working capital needs, and create additional market and economic uncertainty~~. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short- term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants

and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget. Adverse global conditions, including economic uncertainty, may negatively impact our financial results. Global conditions, dislocations in the financial markets, any negative financial impacts affecting United States corporations operating on a global basis as a result of tax reform or changes to existing trade agreements or tax conventions, or inflation, could adversely impact our business in a number of ways, including longer sales cycles, lower prices for our products, reduced licensing renewals, customer disruption or foreign currency fluctuations. In addition, the global macroeconomic environment could be negatively affected by **public health emergencies** ~~, among other things, the COVID- 19~~ pandemic or other epidemics, instability in global economic markets, increased U. S. trade tariffs and trade disputes with other countries, instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine and the resulting prolonged conflict and other political tensions **, Hamas' attack against Israel and the ensuing conflict** , and foreign governmental debt concerns. Such challenges have caused, and may continue to cause, uncertainty and instability in local economies and in global financial markets. Changes in U. S. tax law may materially adversely affect our financial condition, results of operations and cash flows. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, was signed into law to address the COVID- 19 crisis. The CARES Act is an approximately $ 2 trillion emergency economic stimulus package that includes numerous U. S. federal income tax provisions, including the modification of: (i) net operating loss rules, (ii) the alternative minimum tax refund and (iii) business interest deduction limitations under Section 163 (j) of the Internal Revenue Code of 1986, as amended, or the Code. On December 22, 2017, President Trump signed into law federal tax legislation commonly referred to as the " Tax Cuts and Jobs Act " (the " TCJA "), which also significantly changed the U. S. federal income taxation of U. S. corporations. TCJA remains unclear in many respects and has been, and may continue to be, subject to amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, or the IRS, any of which could lessen or increase certain adverse impacts of TCJA. In addition, it is unclear how these U. S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. While some of these U. S. federal income tax changes may adversely affect us in one or more reporting periods and prospectively, other changes may be beneficial on a going- forward basis. We continue to work with our tax advisors and auditors to determine the full impact TCJA and the CARES Act will have on us. We urge our investors to consult with their legal and tax advisors with respect to both TCJA and the CARES Act and the potential tax consequences of investing in our securities. Our ability to use our net operating loss carryovers and certain other tax attributes may be limited. We have incurred significant losses since our inception and we expect to continue to incur significant losses for the foreseeable future ~~, which raise substantial doubt regarding our ability to continue as a going concern. Our ability to continue as a going concern requires that we obtain sufficient additional funding to finance our operations~~ . Under the Internal Revenue Code of 1986, or the Code, a corporation is generally allowed a deduction for net operating losses (" NOLs "), carried over from a prior taxable year. **Any NOLs generated after 2017** ~~As of December 31, 2022, our tax losses and tax credits~~ have no expiration ~~date~~ . Net operating loss and tax credit carry- forwards are subject to review and possible adjustment by the Internal Revenue Service (" IRS ") and **are** ~~may become~~ subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three- year period in excess of 50 % as defined under Sections 382 and 383 in the Internal Revenue Code **. Based upon our analysis** , ~~which could~~ **we have determined that such an ownership change has occurred and a Section 382 limitation has been applied in the current year to** limit the amount of tax attributes ~~that can be~~ utilized ~~annually to offset future taxable income or tax liabilities. The amount of the annual limitation is determined based on the Company' s value immediately prior to the ownership change. Subsequent ownership changes may further affect the limitation in future years. We have not yet conducted a study to determine if any such limitation exists~~ . Risks Related to Development, Regulatory Approval and Commercialization Our business depends upon the success of our **potential** therapeutic modalities and product candidates. Our success depends on our ability to utilize our three Treg- modifying **potential** therapeutic modalities (the " Treg Modalities ") and to obtain regulatory approval for our product candidates, to generate other product candidates derived from our Treg Modalities, and to then commercialize our other product candidates for one or more indications. Our Treg Modalities and our product candidates have not been approved and may never become commercialized. All of our product candidates developed from our Treg Platforms will require significant additional clinical and non- clinical development, review and approval by the FDA or other applicable regulatory authorities in one or more jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before they can be successfully commercialized. If any of our product candidates encounter safety or efficacy problems, developmental delays or regulatory issues or other problems, such problems could impact or halt the development plans for our other product candidates because all of our product candidates are based on the same core Treg engineering technology. Utilizing Treg cells represents a novel approach to the treatment of neurodegenerative and auto immune diseases, and we must overcome significant challenges in order to develop, commercialize and manufacture our product candidates. We have concentrated our research and development efforts on utilizing Treg cells as an immunotherapy. To date, the FDA has approved only a small number of cell- based therapies for commercialization. We are not aware of any Treg therapy approved by any regulatory authority for commercial use. 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 our product candidates. Because our Treg Modalities are novel, and cell- based therapies are relatively new, regulatory agencies may lack experience in evaluating product candidates like our Treg product candidates. 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 our products. Additionally, advancing novel therapies for neurodegenerative and auto immune diseases creates significant challenges for us, including: • educating medical personnel regarding the potential side- effect profile of our cells and, as the clinical program progresses, on observed side effects with the therapy; • training a sufficient number of medical personnel on how to properly administer the clinical trials; • enrolling sufficient numbers of patients in clinical trials; • developing a reliable, safe and effective means of genetically modifying our cells; • manufacturing our cells on a large scale and in a cost- effective manner; • sourcing starting material suitable for clinical and commercial manufacturing; and • establishing sales and marketing capabilities, as well as developing a manufacturing process and distribution network to support the commercialization of any approved products. We must be able to overcome these challenges in order for us to develop, commercialize and manufacture COYA 301, COYA 302, COYA 201, COYA 206 and COYA 101 and any of our other product candidates. Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control. Clinical trials are expensive, time consuming and subject to substantial uncertainty. Failure can occur at any time during the clinical trial process, due to scientific feasibility, safety, efficacy, changing standards of medical care and other variables. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA, or other applicable regulatory authorities may suspend or terminate clinical trials of a product candidate at any time for various reasons, including, but not limited to, a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects, or other adverse initial experiences or findings. The FDA, or other applicable regulatory authorities may also require us to conduct additional testing, preclinical studies or clinical trials due to negative or inconclusive results or other reasons, fail to approve the raw materials, manufacturing processes or facilities of third- party manufacturers upon which we rely, find deficiencies in the manufacturing processes or facilities upon which we rely, and change their approval policies or regulations or their prior guidance to us during clinical development in a manner rendering our clinical data insufficient for approval. In addition, data collected from clinical trials may not be sufficient to support the submission of a Biologics License Application (“ BLA ”) or other applicable regulatory filing. We cannot guarantee that any clinical trials that we may plan or initiate will be conducted as planned or completed on schedule, if at all. A failure of one or more of our clinical trials could occur at any stage. Events that may prevent successful initiation, timely completion, or positive outcomes of our clinical development include, but are not limited to: • delays in obtaining regulatory approval to commence a clinical trial; • delays in reaching agreement on acceptable terms with prospective clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different trial sites; • our ability to recruit sufficient patients for our clinical trials in a timely manner or at all; • delays in achieving a sufficient number of clinical trial sites or obtaining the required institutional review board, or IRB, approval at each clinical trial site; • imposition of a temporary or permanent clinical hold by us or by the FDA or other regulatory agencies based on emerging data; • clinical sites deviating from trial protocol or dropping out of a trial; • suspension or termination of a clinical trial by the IRBs of the institutions in which such trials are being conducted or by the Data Safety Monitoring Board, or DSMB (where applicable); • delays in sufficiently developing, characterizing or controlling a manufacturing process suitable for advanced clinical trials; • delays in reaching a consensus with regulatory agencies on the design or implementation of our clinical trials; • changes in regulatory requirements or guidance that may require us to amend or submit new clinical protocols, or such requirements may not be as we anticipate; • changes in the standard of care on which a clinical development plan was based, which may require new or additional trials; • insufficient or inadequate quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates; • clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; • failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, or additional administrative burdens associated with foreign regulatory schemes; or • failure of ourselves or any third- party manufacturers, contractors or suppliers to comply with regulatory requirements, maintain adequate quality controls, or be able to provide sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates. ~~In addition, disruptions caused by the COVID- 19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing preclinical studies and clinical trials, as applicable.~~ 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. If we experience delays in the initiation, enrollment or completion of any preclinical study or clinical trial of our product candidates, or if any preclinical studies or clinical trials of our product candidates are canceled, the commercial prospects of our product candidates may be materially adversely affected, and our ability to generate product revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs and slow down our product candidate development and approval process ~~. Our goal is to advance COYA 101 into a Phase 2b clinical trial utilizing non- dilutive funding in the form of a grant from a government organization, or by partnering with an established pharmaceutical company. If we are unable to receive such a grant or any other grant we may apply and qualify for in the future, or we are unable to find a suitable strategic partner with whom we can collaborate on terms that are favorable to us, or at all, we may delay or terminate the clinical development of COYA 101, which could materially adversely affect our business, financial condition, results of operations and growth prospects~~ . There is no assurance that we will develop our product candidates successfully or be able to obtain regulatory approval for them. We cannot guarantee that any of our product candidates will be safe and effective, or will be approved for commercialization, on a timely basis or at all. Although certain of our employees have prior experience with clinical trials, regulatory approvals and cGMP manufacturing, we have not previously completed any clinical trials or submitted a BLA to the

FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. The FDA, and other comparable global regulatory authorities can delay, limit or deny approval of a product candidate for many reasons. For further details about such reasons, see "- Clinical development involves a lengthy and expensive process with an uncertain outcome, and we may encounter substantial delays due to a variety of reasons outside our control. " Any delay in obtaining, or inability to obtain, applicable regulatory approval will delay or harm our ability to successfully commercialize any of our products and materially adversely affect our business, financial condition, results of operations and growth prospects. Furthermore, because our product candidates are based on similar technology as COYA 301, if our clinical trials of COYA 301 encounter safety, efficacy or manufacturing problems, development delays, regulatory issues or other problems, our development plans for our other product candidates in our pipeline could be significantly impaired, which could materially adversely affect our business, financial condition, results of operations and growth prospects. We currently collaborate with various research institutions to perform the research and development activities needed to develop our product candidates, and if we ever choose to or need to find alternative research institutions, we may not be able to do so at all or, if we are able to do so, it may be costly and may cause significant delays in the development and commercialization of our product candidates. We do not currently own, lease or operate a principal laboratory, research and development or manufacturing facility of our own. Currently, we collaborate with various research institutions to perform research and development for our products, including The Methodist Hospital located in Houston, Texas. Establishing our own facilities would result in significant additional expense and may result in potential delays in testing and production. Building and operating our own production facilities would require substantial additional funds and other resources, of which there can be no assurance that we will be able to obtain. In addition, there can be no assurances that we would be able to enter into any arrangement with third parties to manufacture our product, if any, on acceptable terms or at all. The commercial success of products outside the United States will also be dependent on the successful completion of arrangements with future partners, licensees or distributors in each territory. There can be no assurance that we will be successful in continuing to contract with research institutions to perform research and development for our products, that we would be able to establish our own facilities should we choose to or find it necessary to do so, that we would be successful in establishing additional collaborative arrangements or that, if established, such future partners will be successful in commercializing our products. Positive results from early studies of our product candidates are not necessarily predictive of the results of later studies and any future clinical trials of our product candidates. If we cannot show positive results or replicate any positive results from our earlier studies of our product candidates in our later studies and future clinical trials, we may be unable to successfully develop, obtain regulatory approval for and commercialize our product candidates. The results of preclinical studies may not be predictive of the results of clinical trials, and the results of any early- stage clinical trials we commence may not be predictive of the results of the later- stage clinical trials. For example, preclinical models do not adequately represent the clinical setting, and thus cannot predict clinical activity nor all potential risks, and may not provide adequate guidance as to appropriate dose or administration regimen of a given therapy. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. Interim data from clinical trials that we may conduct are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously announced. Negative differences between preliminary or interim data and final data could materially adversely affect the prospects of any product candidate that is impacted by such data updates. Any positive results from studies of our product candidates may not necessarily be predictive of the results from later studies and clinical trials. Similarly, even if we are able to complete our planned studies or any future clinical trials of our product candidates according to our current development timeline, the positive results from such studies and clinical trials of our product candidates may not be replicated in subsequent studies or clinical trial results. Many companies in the pharmaceutical industry have suffered significant setbacks in mid and late- stage clinical trials after achieving positive results in early- stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, findings made while clinical trials were underway, or safety or efficacy observations made in studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in studies and clinical trials nonetheless failed to obtain regulatory approval. Our planned clinical trials are expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND or, in the case of the European Medicines Agency (the " EMA "), a clinical trial application (a " CTA "), will result in the FDA or EMA allowing clinical trials to begin in a timely manner, if at all. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Events that may prevent successful or timely initiation or completion of clinical trials include: • inability to generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials; • delays in confirming target engagement, patient selection or other relevant biomarkers to be utilized in preclinical and clinical product candidate development; • delays in reaching a consensus with regulatory agencies on study design; • delays in reaching agreement on acceptable terms with prospective contract research organizations (" CROs ") and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites; • delays in identifying, recruiting and training suitable clinical investigators; • delays in obtaining required IRB approval at each clinical trial site; • imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including, but not limited to, after review of an IND or amendment, CTA or amendment, or equivalent application or amendment; as a result of a new safety finding that presents unreasonable risk to clinical trial participants; a negative finding from an inspection of our clinical trial operations or

study sites; developments in trials conducted by competitors that raise FDA or EMA concerns about risk to patients broadly; or if the FDA or EMA finds that the investigational protocol or plan is clearly deficient to meet its stated objectives; • delays or difficulties resulting from the COVID- 19 pandemic; • delays in identifying, recruiting and enrolling suitable patients to participate in our clinical trials, and delays caused by patients withdrawing from clinical trials or failing to return for post-treatment follow- up; • difficulty collaborating with patient groups and investigators; • failure by our CROs, other third parties, or us to adhere to clinical trial requirements; • failure to perform in accordance with the FDA' s or any other regulatory authority' s current good clinical practices, requirements, or applicable EMA or other regulatory guidelines in other countries; • occurrence of adverse events associated with a product candidate that are viewed to outweigh its potential benefits; • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; • the cost of clinical trials of our product candidates being greater than we anticipate; • clinical trials of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical trials or abandon product development programs; and • delays in manufacturing, testing, releasing, validating, or importing / exporting sufficient stable quantities of our product candidates for use in clinical trials or the inability to do any of the foregoing. Any inability to successfully initiate or complete future clinical trials could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to or we may elect to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical trial delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. We could also encounter delays if a clinical trial is suspended or terminated by us, by the data safety monitoring board for such trial or by the FDA, EMA or any other regulatory authority, or if the IRBs of the institutions in which such trials are being conducted suspend or terminate the participation of their clinical investigators and sites subject to their review. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA 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 a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. We may be unable to obtain regulatory approval for our product candidates under applicable regulatory requirements. If we are unable to design, conduct and complete our planned clinical trials successfully, our product candidates will not be able to receive regulatory approval. In order to obtain FDA approval for any of our product candidates, we must submit to the FDA a new drug application with substantial evidence that demonstrates that the product candidate is both safe and effective in humans for its intended use. This demonstration will require significant research, preclinical studies and clinical trials. Clinical trials are time- consuming, expensive and difficult to design and implement, in part because they are subject to rigorous requirements and the outcomes are inherently uncertain. Clinical testing may take many years to complete, and failure can occur at any time during the clinical trial process, even with active ingredients that have previously been approved by the FDA as safe and effective. If we receive authorization to conduct our planned clinical trials, we could encounter problems that could halt our planned clinical trials or require us to repeat such clinical trials. If patients participating in our planned clinical trials suffer drug- related adverse reactions during the course of such clinical trials, or if we or the FDA believe that patients are being exposed to unacceptable health risks, such clinical trials may have to be suspended or terminated. Suspension, termination or the need to repeat a clinical trial can occur at any stage. The clinical trial success of each of our product candidates depends in part on reaching statistically significant changes in patients' symptoms based on clinician- rated scales. There is a lack of consensus regarding standardized processes for assessing clinical outcomes based on clinician- rated scales. Accordingly, the scores from our clinical trials may not be reliable, useful or acceptable to the FDA or other regulatory agencies. Changes in standards related to clinical trial design could have a material adverse effect on our ability to design and conduct clinical trials as planned. For example, we expect to conduct clinical trials comparing our product candidates to both placebo and other approved drugs, but regulatory authorities may not allow us to compare our product candidates to a placebo in a particular clinical indication where approved products are available. In that case, both the cost and the amount of time required to conduct such a planned clinical trial could increase. The FDA may disagree with our trial design and our interpretation of data from our planned clinical trials, or may change the requirements for approval even after it has reviewed and commented on the design for our planned clinical trials. The FDA 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- approval clinical trials. In addition, the FDA may not approve the labeling claims or removal of certain warnings that we believe are necessary or desirable for the successful commercialization of our product candidates. Approval may be contingent on a Risk Evaluation and Mitigation Strategy, which could have a material adverse effect on the labeling, distribution or promotion of a drug product. Any of these delays or additional requirements could cause our product candidates to not be approved, or if approved, significantly impact the timing and commercialization of our product candidates and significantly increase our overall costs of drug development. Enrollment and retention of patients in clinical trials is an expensive and time- consuming process and could be delayed, made more difficult or rendered impossible by multiple factors outside our control. Identifying and qualifying patients to participate in our clinical trials is critical to our success. Clinical trials of a new product candidate require the enrollment of a sufficient number of patients, including patients who are suffering from the disease that the product candidate is intended to treat and who meet other eligibility criteria. The rates of patient enrollment, a significant component in the timing of clinical trials, are affected by many factors, including: • our ability to open clinical trial sites; • the size and nature of the patient population; • the design and eligibility criteria of the clinical trial; • the proximity of subjects to clinical sites; • the patient referral practices of physicians; • changing medical practice patterns or guidelines related to the indications we are investigating; • competing clinical trials or approved therapies which present an attractive alternative to

patients and their physicians; • perceived risks and benefits of the product candidate under study, including as a result of adverse effects observed in similar or competing therapies; • our ability to obtain and maintain patient consents due to various reasons, including but not limited to, patients unwillingness to participate due to the ongoing COVID- 19 pandemic; • the risk that enrolled subjects will drop out or die before completion of the trial; • patients failing to complete a clinical trial or returning for post- treatment follow- up; and • our ability to manufacture the requisite materials for a patient and clinical trial. In addition, we need to compete with many ongoing clinical trials to recruit patients into our expected clinical trials. Our clinical trials may also compete with other clinical trials for product candidates that are in a similar cellular immunotherapy area as our product candidates, and this competition could 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 may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial site. If we are unable to enroll a sufficient number of patients in our clinical trials in a timely manner, our completion clinical trials may be delayed or may not be achieved, which would prevent us from commercializing our product candidates. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these programs on a timely basis or at all. In order to obtain FDA or other regulatory authority approval to market a new biological product we must demonstrate proof of safety, purity and potency, and efficacy in humans. To meet these requirements we will have to conduct adequate and well- controlled clinical trials. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned INDs in the United States. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Conducting preclinical testing is a lengthy, time- consuming and expensive process. The length of time may vary substantially according to the type, complexity and novelty of the program, and often can be several years or more per program. Any delays in preclinical testing and studies conducted by us or potential future partners may cause us to incur additional operating expenses. The commencement and rate of completion of preclinical studies and clinical trials for a product candidate may be delayed by many factors, including, for example: • inability to generate sufficient preclinical or other in vivo or in vitro data to support the initiation of clinical trials; • delays in reaching a consensus with regulatory agencies on study design; and • the FDA not allowing us to rely on previous findings of safety and efficacy for other similar but approved products and published scientific literature. Moreover, because standards for pre- clinical assessment are evolving and may change rapidly, even if we reach an agreement with the FDA on a pre- IND proposal, the FDA may not accept the IND submission as presented, in which case patient enrollment would be placed on partial or complete hold and treatment of enrolled patients could be discontinued while the product candidate is re- evaluated. Even if clinical trials do begin for our preclinical programs, our clinical trials or development efforts may not be successful. If any of our product candidates, or any competing product candidates, demonstrate serious adverse events, including the development of severe or fatal cytokine release syndrome, neurotoxicity or graft- versus- host disease, we may be required to halt or delay further clinical development. Undesirable side effects that may be caused by any of our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label than anticipated or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. In a pilot initial study of COYA 201, our Treg exosome product candidate, in a preclinical lupus nephritis model in mice, COYA 201 was administered at different dose levels and appeared to be well tolerated at the administered dose of ~~1x1010exosomes~~ **1x1010 exosomes** (the low dosage level). However, we observed fatalities as a result of toxicity when COYA 201 was administered in extremely high doses (1x1011exosomes, or ten times the low dosage level), administered twice weekly. We do not know if these findings will translate into humans, for whom we expect to require significantly lower dosage levels. Though there were fatalities at the highest dosage administered (6 deaths out of a total of 12 animals), COYA 201 appeared to be well tolerated at the administered dose of ~~1x1010exosomes~~ **1x1010 exosomes** . Dose escalation studies are standard in the early development of new treatments and the identification of the " maximum tolerated dose " and the " LD50 ", the dose that produces lethality in 50 % of animals, are common studies in early preclinical development. As such, there can be no guarantee that any toxicity, or other adverse events observed in this model, will not occur in human subjects during clinical trials. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects and / or unexpected characteristics. We continue to evaluate different potential indications to advance the development of COYA 201 into clinical studies. Following the completion of the preclinical studies in different animal models of disease, we will evaluate the data to potentially conduct further preclinical studies and to select a potential clinical indication for human studies. There can be no assurance that patients will not experience cytokine release syndrome, or CRS, neurotoxicity, graft- versus- host disease, or GVHD or other serious adverse events. Severe adverse events associated with COYA 301 may also develop. Such adverse events may cause delays in completion of our clinical programs. If unacceptable side effects arise in the development of our product candidates such that there is no longer a positive benefit risk, we, the FDA, the IRBs at the institutions in which our trials are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff, and inadequate training in recognizing or managing the

potential side effects of our product candidates could result in patient injury or death **. Approval may be delayed or denied because we cannot satisfy FDA' s Chemistry, Manufacturing and Control Requirements. Formulation and manufacturing of biologic products such as ours is complex and expensive. Our BLAs must include information about the chemistry and physical characteristics of our products, and we must demonstrate that we have a reliable process for manufacturing the products in commercial quantities in accordance with FDA' s current Good Manufacturing Practices (" cGMP ") requirements. The manufacturing process must consistently produce quality batches of the biologic, and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the final product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate the effectiveness of the packaging and that the compound does not undergo unacceptable deterioration over its shelf life. If we are unable to successfully complete any of these complex steps, approval of our biologic may be delayed or denied** . We may seek special designations by the regulatory authorities to expedite regulatory approvals, but may not be successful in receiving such designations, and even if received, they may not benefit the development and regulatory approval process. We may seek various designations by the regulatory authorities such as Regenerative Medicine Advanced Therapy Designation, or RMAT, Breakthrough Therapy Designation, Fast Track Designation, or PRIority MEdicine, or PRIME, from regulatory authorities, for any product candidate that we develop. A product candidate may receive RMAT designation from the FDA if it is a regenerative medicine therapy that is intended to treat, modify, reverse or cure a serious or life-threatening condition, and preliminary clinical evidence indicates that the product candidate has the potential to address an unmet medical need for such condition. A breakthrough therapy is defined by the FDA as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life- threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over currently approved therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. If a product is intended for the treatment of a serious or life- threatening condition and preclinical or clinical data demonstrate the potential to address an unmet medical need for this condition, the product sponsor may apply for Fast Track Designation by the FDA. PRIME is a voluntary scheme launched by the EMA to strengthen support for the development of medicines that target an unmet medical need through enhanced interaction and early dialogue with developers of promising medicines in order to optimize development plans and speed up evaluation to help such medicines reach patients earlier. Seeking and obtaining these designations is dependent upon results of our clinical program, and we cannot guarantee whether and when we may have the data from our clinical programs to support an application to obtain any such designation. The FDA and the EMA, as applicable, have broad discretion whether or not to grant any of these designations, so even if we believe a particular product candidate is eligible for one or more of these designations, we cannot assure you that the applicable regulatory authority would decide to grant it. Even if we do receive the designations we may apply for, we may not experience a faster development process, review or approval compared to conventional FDA or EMA procedures, as applicable. The FDA or EMA, as applicable, may rescind any granted designations if it believes that the designation is no longer supported by data from any source. We may seek Orphan Drug Designation for our product candidates, and we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity. We have received Orphan Drug Designation for our COYA 101 product candidate for the active moiety or the principal molecular structural features. Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200, 000 individuals annually in the United States, or a patient population greater than 200, 000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation may entitle a party to financial incentives such as grant funding towards clinical trial costs, tax advantages and user- fee waivers. Similarly, in Europe, the European Commission grants Orphan Drug Designation after receiving the opinion of the EMA Committee for Orphan Medicinal Products on an Orphan Drug Designation application. Orphan Drug Designation is intended to promote the development of drugs that are intended for the diagnosis, prevention or treatment of life- threatening or chronically debilitating conditions affecting not more than 5 in 10, 000 persons in Europe and for which no satisfactory method of diagnosis, prevention, or treatment has been authorized (or the product would be a significant benefit to those affected). Additionally, designation is granted for drugs intended for the diagnosis, prevention, or treatment of a life- threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in Europe would be sufficient to justify the necessary investment in developing the drug. In Europe, Orphan Drug Designation may entitle a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor. Generally, if a drug with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the drug is entitled to a period of marketing exclusivity, which precludes the EMA or the FDA from approving another marketing application for the same drug and indication for that time period, except in limited circumstances. The applicable period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable such that market exclusivity is no longer justified. Even if we obtain orphan drug exclusivity for our product candidates, that exclusivity may not effectively protect those product candidates from competition because different therapies can be approved for the same condition and the same therapies can be approved for different conditions but used off- label. Even after an orphan drug is approved, the FDA can subsequently approve another drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In addition, a designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received orphan

designation. Moreover, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. While we may seek Orphan Drug Designation for applicable indications for our product candidates, we may never receive such designations. Even if we do receive such designations, there is no guarantee that we will enjoy the benefits of those designations. We may not identify or discover other product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success. Our business depends upon our ability to identify, develop and commercialize product candidates. A key element of our strategy is to discover and develop additional product candidates based upon our Treg Modalities. We are seeking to do so through our internal research programs, and may also explore strategic collaborations for the discovery of new product candidates. Research programs to identify product candidates require substantial technical, financial and human resources, whether or not any product candidates are ultimately identified. In addition, targets for different neurodegenerative and auto immune diseases may require changes to our cell manufacturing platform, which may slow down development or make it impossible to manufacture our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for many reasons, including the following: • the research methodology or technology modality used may not be successful in identifying potential product candidates; • competitors may develop alternatives that render our product candidates obsolete or less attractive; • we may choose to cease development if we determine that clinical results do not show promise; • product candidates we develop may nevertheless be covered by third- party patents or other exclusive rights; • a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria; and • a product candidate may not be accepted as safe and effective by patients, the medical community or third- party payors. Because we have limited resources, we must choose to pursue and fund the development of specific types of treatment, or treatment for a specific type of neurodegenerative or auto immune disease, and we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. Our estimates regarding the potential market for our product candidates could be inaccurate, and if we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaboration, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a **potential** therapeutic area in which it would have been more advantageous to enter into a partnering arrangement. If any of these events occur, we may be forced to abandon or delay our development efforts with respect to a particular product candidate or fail to develop a potentially successful product candidate. If third parties that we rely on to conduct clinical trials do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates. We do not have the ability to independently conduct clinical trials. We rely on medical institutions, clinical investigators, contract laboratories, and other third parties, such as contract research organization, or CROs, to conduct or otherwise support clinical trials for our product candidates. We rely heavily on these parties for execution of clinical trials for our product candidates and control only certain aspects of their activities. 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 CROs and other third parties will not relieve us of our regulatory responsibilities. For any violations of laws and regulations during the conduct of our clinical trials, we could be subject to untitled letters, warning letters or enforcement action that may include civil penalties up to and including criminal prosecution. We and the third parties on which we rely for clinical trials are required to comply with regulations and requirements, including Good Clinical Practice, or GCP, for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the competent authorities of the European Union member states, and comparable foreign regulatory authorities for any drugs in clinical development. The FDA enforces GCP requirements through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or these third parties fail to comply with applicable GCP, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that, upon inspection, the FDA will determine that any of our future clinical trials will comply with GCP. In addition, our clinical trials must be conducted with product candidates produced under cGMP regulations. Our failure or the failure of these third parties to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action ~~. The COVID- 19 pandemic and government measures taken in response have also had a significant impact on our CROs, and we expect that they will face further disruption, which may affect our ability to initiate and complete our preclinical studies and clinical trials~~. We also are required to register certain ongoing clinical trials and provide certain information, including information relating to the trial' s protocol, on a government- sponsored database, ClinicalTrials. gov, within specific timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Although we intend to design the clinical trials for our product candidates, we plan to rely on third parties to conduct our clinical trials. As a result, many important aspects of our clinical development, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may: • have staffing difficulties; •

fail to comply with contractual obligations; • experience regulatory compliance issues; • undergo changes in priorities or become financially distressed; or • form relationships with other entities, some of which may be our competitors. If third parties do not perform our clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, we would be unable to rely on clinical data collected by these third parties and may be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct, which could significantly delay commercialization and require significantly greater expenditures. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, or at all. If third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain are compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such third parties are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed. If we fail to compete effectively with academic institutions and other biotechnology companies that are developing similar or alternatives to cellular immunotherapy product candidates, our business will be materially adversely affected. The development and commercialization of new cellular immunotherapy products is highly competitive. We face competition from existing and future competitors with respect to each of our product candidates currently in development, and will face competition with respect to other product candidates that we may seek to develop or commercialize in the future. In addition, numerous academic institutions are conducting preclinical and clinical research in these areas, as well as with other white blood cell types including NK- T cells and gamma- delta T cells. It is also possible that new competitors, including those developing similar or alternatives to cellular immunotherapy product candidates, may emerge and acquire significant market share. Such competitors may have an advantage over us due to their greater size, resources or institutional experience, or may develop product candidates that are safer, more effective, more widely accepted, more cost- effective or enable higher patient quality of life than ours. More established biopharmaceutical companies may also develop and commercialize their product candidates at a faster rate, which could render our product candidates obsolete or non- competitive before they are fully developed or commercialized. If we are not able to compete effectively against our existing and potential competitors, our business, financial condition, results of operations and growth prospects may be materially adversely affected. If any of our product candidates are approved for marketing and commercialization and we have not developed or secured third- party marketing, sales and distribution capabilities, we will be unable to successfully commercialize such products and may not be able to generate product revenue. We currently have no sales, marketing or distribution organizational experience or capabilities. We will need to develop internal sales, marketing and distribution capabilities to commercialize any product candidate that gains FDA or other regulatory authority approval, which would be expensive and time- consuming, or enter into partnerships with third parties to perform these services. If we decide to market any approved products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and supporting distribution, administration and compliance capabilities. If we rely on third parties to market products or decide to co- promote products with partners, we will need to establish and maintain marketing and distribution arrangements with third parties, and there can be no assurance that we will be able to enter into such arrangements on acceptable terms or at all. In entering into third- party marketing or distribution arrangements, any product revenue we receive will depend upon the efforts of the third parties and we cannot assure you that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for any approved product. If we are not successful in commercializing any product approved in the future, if any, either on our own or through third parties, our business, financial condition, results of operations and growth prospects could be materially adversely affected. If we are not able to establish pharmaceutical or biotechnology collaborations on commercially reasonable terms, or at all, we may have to alter our development and commercialization plans. The advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may seek to collaborate with pharmaceutical and biotechnology companies to develop and commercialize such product candidates. Any of these relationships may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. We face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for other collaborations will depend, among other things, upon our assessment of the collaborator' s resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator' s evaluation of a number of factors. Those factors may include the design or results of clinical trials, the progress of our clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy. Any delays in entering into new collaborations or strategic partnership agreements related to any product candidate we develop could delay the development and commercialization of our product candidates, which would harm our business prospects, financial condition, and results of operations. If we enter into collaborations with third parties to develop or commercialize our

product candidates, our prospects with respect to those product candidates will depend in significant part on the success of those collaborations. If we enter into future collaboration with third parties, we could face the following risks: • collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; • collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates; • collaborators may not properly enforce, maintain or defend our intellectual property rights or may use our proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation, or other intellectual property proceedings; • disputes may arise between a collaborator and us that cause the delay or termination of the research, development or commercialization of the product candidate, or that result in costly litigation or arbitration that diverts management attention and resources; • if a present or future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and • collaboration agreements may restrict our right to independently pursue new product candidates. If conflicts arise between our collaborators and us, our collaborators may act in a manner adverse to us and could limit our ability to implement our strategies. Future collaborators may develop, either alone or with others, products in related fields that are competitive with the products or potential products that are the subject of these collaborations. Competing products, either developed by the collaborators or to which the collaborators have rights, may result in the withdrawal of support for our product candidates. Our collaborators may preclude us from entering into collaborations with their competitors, fail to obtain timely regulatory approvals, terminate their agreements with us prematurely or fail to devote sufficient resources to the development and commercialization of products. Any of these developments could harm our product development efforts. As a result, if we enter into additional collaboration agreements and strategic partnerships or license our intellectual property, products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Our product candidates could be subject to regulatory limitations following approval, if and when such approval is granted. Following approval of a product candidate, if any, we must comply with comprehensive government regulations regarding the manufacture, labeling, marketing, distribution and promotion of biologic products. We must comply with the FDA' s regulations, which prohibit promoting off- label uses. We may not be able to obtain the labeling claims necessary or desirable to successfully commercialize our product candidates in development. The FDA and foreign regulatory authorities could impose significant restrictions on the use of an approved product including potentially restricting its use to limited clinical centers as well as through the product label, and on advertising, promotional and distribution activities associated with such approved product. The FDA or a foreign regulatory authority could also condition their approval on the performance of post-approval clinical trials, patient monitoring or testing, which could be time- consuming and expensive. If the results of such post-marketing trials are not satisfactory, the FDA or such foreign regulatory authority could withdraw marketing authorization or may condition continued marketing on commitments from us or our partners that may be expensive and / or time- consuming to fulfill. In addition, if we or others identify side- effects after any of our products are on the market, if manufacturing problems occur subsequent to regulatory approval, or if we, our manufacturers or our partners fail to comply with regulatory requirements, including those mentioned above, we or our partners could be subject to the following: • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned clinical trials; • restrictions on such products manufacturing processes; • changes to the product label; • restrictions on the marketing of a product; • restrictions on product distribution; • requirements to conduct post- marketing clinical trials; • Untitled or Warning Letters from the FDA; • withdrawal of the product from the market; • refusal to approve pending applications or supplements to approved applications that we submit; • recall of products; • fines, restitution or disgorgement of profits or revenue; • suspension or withdrawal of regulatory approvals; • refusal to permit the import or export of our products; • product seizure; • injunctions; or • imposition of civil or criminal penalties. Any one or a combination of these penalties could prevent us from achieving or maintaining market acceptance of the affected product, or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating any revenue or profit from the sale of such product and could materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, third- party payors may impose limitations on centers and personnel that may administer our products, including but not limited to requiring third-party accreditation to be obtained before the use of our products is reimbursed in such a center, which could materially adversely affect our potential commercial success and lead to slower market acceptance. The commercial success of any of our product candidates will depend upon such product candidate' s degree of market acceptance by physicians, patients, third- party payors and others in the medical community. Our product candidates may not be commercially successful. Even if requisite approvals are obtained from the FDA in the United States and other regulatory authorities internationally, the commercial success of our product candidates will depend, in part, on the acceptance by physicians, patients and healthcare payors of cell therapy products in general, and our product candidates in particular, as medically necessary, cost- effective and safe. Physicians, patients, healthcare payors and others in the medical community may not accept any product that we commercialize. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of cell therapy products and, in particular, our product candidates, if approved for commercial sale, will depend on several factors, including: • the efficacy and safety of such product candidates as demonstrated in clinical trials; • the potential and perceived advantages of product candidates over alternative treatments; • the cost of treatment relative to alternative treatments; • the clinical indications for which the product candidate is approved by the FDA; • the willingness of physicians to prescribe new therapies; • the willingness of the target patient population to try new therapies; • the prevalence and severity of any side effects; • product labeling or product insert requirements imposed by the FDA or other regulatory

authorities, including any limitations or warnings contained in a product approved labeling; • relative convenience and ease of administration; • the timing of market introduction of competitive products; • adverse publicity concerning our product candidates or favorable publicity about competing products and treatments; • sufficient third- party payor coverage, any limitations in terms of center or personnel training requirement imposed by third parties and adequate reimbursement; • limitations or warnings contained in the FDA- approved labeling for our product candidates; • any FDA requirement to undertake a Risk Evaluation and Mitigation Strategy, or REMS; • the effectiveness of our sales, marketing and distribution efforts; and • potential product liability claims. Even if a product candidate displays a favorable efficacy and safety profile in preclinical studies and clinical trials, market acceptance of the product will not be fully known until after such product is launched. Our product candidates may not achieve broad market acceptance. Furthermore, the FDA' s and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of a product. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. The insurance coverage and reimbursement status of newly approved products is uncertain. Failure to obtain or maintain adequate coverage and reimbursement for our product candidates, if approved, could limit our ability to market such products and to generate product revenue. We expect the cost of administration of our product candidates to be substantial, when and if they achieve regulatory approval. We expect that coverage and reimbursement by government and private payors will be essential for most patients to be able to afford these treatments. Accordingly, sales of our products, if approved, will depend substantially, both domestically and internationally, on the extent to which the costs of our product candidates will be reimbursed by government authorities, private health coverage insurers and other third- party payors. Coverage and reimbursement by a third- party payor could depend upon several factors, including the third- party payor' s determination that use of a product is (i) a covered benefit under its health plan, (ii) safe, effective and medically necessary, (iii) appropriate for the specific patient, (iv) cost- effective and (v) neither experimental nor investigational. Obtaining coverage and reimbursement for a product from third- party payors is a time- consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost- effectiveness data. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement. If coverage and reimbursement are not available, or are available only at limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be adequate to realize a sufficient return on our investment. There is significant uncertainty related to third- party coverage and reimbursement of newly approved drug products. In the United States, third- party payors, including government payors such as Medicare and Medicaid, play an important role in determining the extent to which new drugs and biologics will be covered and reimbursed. Medicare and Medicaid are increasingly used as models for the development of private payors' and government payors' coverage and reimbursement policies. Currently, few cell therapy products have been approved for coverage and reimbursement by the Centers for Medicare & Medicaid Services (the " CMS "), the agency responsible for administering Medicare. It is difficult to predict what CMS will decide with respect to coverage and reimbursement for fundamentally novel products such as ours, since there is a limited body of established protocols and precedents for these types of drug products. Moreover, reimbursement agencies in the European Union may be more conservative than CMS. For example, several immunotherapy drugs have been approved for reimbursement in the United States, whereas they have not been approved for reimbursement in certain European Union member states. It is difficult to predict what third- party payors will decide with respect to the coverage and reimbursement for our product candidates. Outside the United States, international operations vary significantly by country and are subject to extensive government price controls and other market regulations, and increasing emphasis on cost- containment initiatives in the European Union, Canada and other countries could place pricing pressure on us. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. It can also take a significant amount of time after approval of a product to secure pricing and reimbursement for such product in many counties outside the United States. In general, the prices of medicines under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for medical products, but monitor and control Company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable product revenues. Moreover, increasing efforts by government and third- party payors in the United States and abroad to cap or reduce healthcare costs could limit coverage and the level of reimbursement for our product candidates. Payors are increasingly considering new metrics as the basis for reimbursement rates, such as average sales price, or ASP, average manufacturer price, or AMP, and Actual Acquisition Cost. The existing data for reimbursement based on some of these metrics is relatively limited, although certain states have begun to survey acquisition cost data for the purpose of setting Medicaid reimbursement rates, and CMS has begun making pharmacy National Average Drug Acquisition Cost and National Average Retail Price data publicly available on at least a monthly basis. Therefore, it may be difficult to project the impact of these evolving reimbursement metrics on the willingness of payors to cover candidate products that we or our partners are able to commercialize. Furthermore, most third- party payors currently require additional accreditation for approved cell therapy drugs, which limits the centers that can administer the drugs, and similar limitations may also be imposed on the product candidates that we are developing. We expect to experience pricing pressures in connection with the sale of our product candidates, if any, due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and on prescription drugs and surgical procedures in particular, has become intense. As a result, increasingly high barriers to entry are developing

for new drug products such as ours. Healthcare reform initiatives and other administrative and legislative proposals may harm our business. In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. Specifically, there have been proposals in the United States to control the cost of drug treatments, patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. We believe that coverage and reimbursement for new therapies will be increasingly restricted. Recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability. Furthermore, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs could restrict the amount that we are able to charge for our drug products, which could render our product candidates, if approved, commercially unviable and materially adversely affect our ability to raise additional capital on acceptable terms. We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any of our product candidates. We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any BLAs that we submit for our product candidates or may conclude after review of our data that our application is insufficient to obtain marketing approval of our product candidates. If the FDA does not accept or approve our BLAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA- required studies, approval of any BLA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our BLAs. Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business. Obtaining and maintaining marketing approval or commercialization of our product candidates in one jurisdiction does not mean that we will be successful in obtaining marketing approval of our product candidates in other jurisdictions. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical 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. If we market approved products outside the United States, we expect that we will be subject to additional risks in commercialization, including: • different regulatory requirements for approval of therapies in foreign countries; • reduced protection for intellectual property rights; • unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country; • foreign reimbursement, pricing and insurance regimes; • workforce uncertainty in countries where labor unrest is more common than in the United States; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods and fires, and other public health crises, illnesses, epidemics or pandemics, such as the potential impact of the COVID- 19 outbreak We have no prior experience in these areas. In addition, there are complex regulatory, tax, labor and other legal requirements imposed by many of the individual countries in which we may operate, with which we will need to comply. Any of the foregoing difficulties, if encountered, could materially adversely affect our business, financial condition, results of operations and growth prospects. Our business operations and relationships with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers will be subject to applicable fraud and abuse and other healthcare laws and regulations, which could expose us to penalties. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, the U. S. federal Anti- Kickback Statute, the U. S. federal civil and criminal false claims and civil monetary penalties laws, including the civil False Claims Act, the Health Insurance Portability and Accountability Act, or HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, the U. S. Physician Payments Sunshine Act and its implementing regulations, U. S. state laws and regulations, including, state anti-kickback and false claims laws, laws that require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the U. S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, laws requiring the registration of pharmaceutical sales representatives, laws governing the privacy and security of health information in certain circumstances, and similar healthcare laws and regulations in other jurisdictions, including reporting requirements detailing interactions with

and payments to healthcare providers. 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will also involve substantial costs. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government- funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, integrity oversight and reporting obligations to resolve allegations of non- compliance, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business are found to not be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment, which could affect our ability to operate our business. Further, defending against any such actions can be costly, time- consuming and may require significant personnel resources. Any of the foregoing could significantly harm our business, financial condition, results of operations and growth prospects. Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates, if approved, and may affect the prices we may set. In the United States and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the " ACA ") was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following: • an annual, non- deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as orphan drugs), which is apportioned among these entities according to their market share in certain government healthcare programs; • a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point- of- sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer' s outpatient drugs to be covered under Medicare Part D; • new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting " transfers of value " made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members; • an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; • a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted, or injected; • extension of a manufacturer' s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; • expansion of eligibility criteria for Medicaid programs thereby potentially increasing a manufacturer' s Medicaid rebate liability; • a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; • establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending; and • expansion of the entities eligible for discounts under the Public Health Service program; and a licensure framework for follow on biologic products. Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. The Supreme Court upheld the ACA in the main challenge to the constitutionality of the law in 2012. Specifically, the Supreme Court held that the individual mandate and corresponding penalty was constitutional because it would be considered a tax by the federal government. The Supreme Court also upheld federal subsidies for purchasers of insurance through federally facilitated exchanges in a decision released in June 2015. This includes enactment of the TCJA (as defined below), which, among other things, removes penalties for not complying with the ACA' s individual mandate to carry health insurance. It is uncertain the extent to which any such changes may impact our business or financial condition. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations. In addition, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. On September 9, 2021, the Biden Administration published a wide- ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The United States Department of Health and Human Services (" HHS ") plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act (the " IRA ") in August 2022, which will, among other things, allow the HHS to negotiate the selling price of certain drugs and biologics that the Centers for Medicare & Medicaid Services (" CMS ") reimburses under Medicare Part B and Part D, although only high- expenditure single- source drugs that have been approved for at least 7 years (11 years for biologics) can be selected by CMS for negotiation, with the negotiated price taking effect two years after the selection year. The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to

various penalties, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions will take effect progressively starting in 2023, although they may be subject to legal challenges. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing. In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. We cannot predict the likelihood, nature, or extent of government regulation that may arise from future legislation or administrative action in the United States or any other jurisdiction. If **we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.** Risks Related to Our Employees, Managing Our Growth and Our Operations We will need to increase the size of our organization, and we may experience difficulties in managing growth. As of March 1, ~~2023~~ **2024** , we had ~~six~~ **eight** full- time employees. We will need to continue to expand our managerial, operational, quality, manufacturing, finance, sales and other resources in order to manage our operations and clinical trials, continue our development activities and eventually commercialize our product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we: • discover new product candidates, develop the process and analytical methods for IND- enabling studies and FDA submissions, complete the required IND- enabling studies for each, and receive approval from the FDA and other regulatory authorities to initiate clinical trials for such product candidates; • manage our clinical trials effectively; • identify, recruit, retain, incentivize and integrate additional employees; • complete the technology transfer to and qualification of our cGMP manufacturing CDMO partner and process; and • continue to improve our operational, financial and management controls, reports systems and procedures. If we are unable to attract skilled employees, increase the size of our organization or manage our future growth effectively, it will impair our ability to execute our business strategy and our business, financial condition, results of operations and growth prospects will be materially adversely affected. If we fail to attract and retain senior management and clinical and key scientific personnel, we may be unable to successfully develop our product candidates, conduct our clinical trials and commercialize our product candidates. Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon our senior management, particularly our chief executive officer, as well as other members of our senior management team. We are currently under contract with or have a business relationships with certain members of our senior management and clinical and key scientific personnel, and the loss of services of any of these individuals, whether due to termination of contract, illness, death, or for any other reason, would likely have an adverse consequence on our business, including, but not limited to potentially delaying or preventing the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our future product candidates. Competition for qualified personnel in the biotechnology and pharmaceuticals field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. If we are unable to hire and retain the qualified personnel we need to operate our business, our business, financial condition, results of operations and growth prospects would be materially adversely affected. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in clinical trials will face an even greater risk if we commercialize any product candidate that we may develop. If we cannot successfully defend ourselves against claims that any such product candidates caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: • decreased demand for any product candidate that we may develop; • loss of revenue; • substantial monetary awards to trial participants or patients; • significant time and costs to defend the related litigation; • withdrawal of clinical trial participants; • increased insurance costs; • the inability to commercialize any product candidate that we may develop; and • injury to our reputation and significant negative media attention. Any such outcomes could materially adversely affect our business, financial condition, results of operations and growth prospects. Our insurance policies may be inadequate, may not cover all of our potential liabilities and may potentially expose us to unrecoverable risks. We do not carry insurance for all categories of risk that our business may encounter. Although we maintain product liability insurance coverage that also covers our clinical trials, such insurance may not be adequate to cover all liabilities that we may incur, and we may be required to increase our product liability insurance coverage. We anticipate that we will need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify. However, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable

events that may occur. Any significant uninsured liability may require us to pay substantial amounts, which would materially adversely affect our business, financial condition, results of operations and growth. In addition, although we are dependent on certain key personnel, we do not have any key man life insurance policies on any such individuals. Therefore, if any of our chief executive officer or other executive officers die or become disabled, we will not receive any compensation to assist with such individual' s absence. The loss of such person could materially adversely affect our business, financial condition, results of operations and growth prospects. Our business involves the use of hazardous materials and we and our third- party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business. Our research and development activities and our third- party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at our manufacturers' facilities pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our research and development efforts and business operations, environmental damage resulting in costly clean- up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third- party manufacturers and suppliers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and / or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage. Any contamination by such hazardous materials could therefore materially adversely affect our business, financial condition, results of operations and growth prospects. Computer system interruptions, cyber- attacks or security breaches could significantly disrupt our product development programs and our ability to operate our business. Our computer systems, as well as those of various third parties on which we rely, may sustain damage from computer viruses, unauthorized access, data breaches, phishing attacks, cybercriminals, natural disasters (including hurricanes and earthquakes), terrorism, war and telecommunication and electrical failures. We rely on our third- party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. The risk of a security breach or disruption, particularly through cyber- attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any significant system failure, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our drug development programs. For example, the loss of nonclinical or clinical trial data from completed, ongoing or planned 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 personal, confidential or proprietary information, we could incur liability and the further development of any product candidate could be delayed. Furthermore, federal, state and international laws and regulations, such as the European Union' s General Data Protection Regulation, or the GDPR, which took effect in May 2018, and the California Consumer Protection Act, which took effect on January 1, 2020, can expose us to enforcement actions and investigations by regulatory authorities, and potentially result in regulatory penalties and significant legal liability, if our information technology security efforts fail or if our privacy practices do not meet the requirements of such laws. Other states are considering similar laws that could impact our use of research data with respect to individuals in those states. There are extensive documentation obligations and transparency requirements, which may impose significant costs on us. In addition, our software systems include cloud- based applications that are hosted by third- party service providers with security and information technology systems subject to similar risks. 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 our product candidates could be delayed, any of which could materially adversely affect our business, financial condition, results of operations and growth prospects. Risks Related to Manufacturing Our manufacturing process is complex and we may encounter difficulties in production, which would delay or prevent our ability to provide a sufficient supply of our product candidates for clinical trials or our products for patients, if approved. Our manufacturing process will be susceptible to product loss or failure, or product variation that may negatively impact patient outcomes, due to logistical issues associated with the collection of starting material from the donor, shipping such material to the manufacturing site, shipping the final product back to the clinical trial recipient, preparing the product for administration, infusing the patient with the product, manufacturing issues or different product characteristics resulting from the differences in donor starting materials, variations between reagent lots, interruptions in the manufacturing process, contamination, equipment or reagent failure, improper installation or operation of equipment, vendor or operator error, inconsistency in cell growth and variability in product characteristics. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If, for any reason in our clinical studies, we lose the starting material for a manufactured product for one of our clinical trial patients at any point in the process, the manufacturing process for that patient would need to be restarted, or could result in such patient no longer participating in our clinical trial. If microbial, viral or other contaminations are discovered in our product candidates or in any of the manufacturing facilities in which products or other materials are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We will be required to maintain a chain of identity with respect to materials as they move from the donor to the manufacturing

facility, through the manufacturing process and back to the clinical trial recipient. Maintaining a chain of identity is difficult and complex, and failure to do so could result in adverse patient outcomes, loss of product or regulatory action, including withdrawal of our products from the market, if licensed. Any failure in the foregoing processes could render a batch of product unusable, could affect the regulatory approval of such product candidate, could cause us to incur fines or penalties or could harm our reputation and that of our product candidates. We may make changes to our manufacturing process for various reasons, such as to control costs, achieve scale, decrease processing time, increase manufacturing success rate or for other reasons. Changes to our process made during the course of clinical development could require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial. Other changes to our manufacturing process made before or after commercialization could require us to show the comparability of the resulting product to the product candidate used in the clinical trials using earlier processes. Such showings could require us to collect additional nonclinical or clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If such data are not ultimately comparable to that seen in the earlier trials or earlier in the same trial in terms of safety or efficacy, we may be required to make further changes to our process and / or undertake additional clinical testing, either of which could significantly delay the clinical development or commercialization of the associated product candidate, which would materially adversely affect our business, financial condition, results of operations and growth prospects. We rely on third parties to manufacture our product candidates, which increases the risk that we will not have sufficient quantities of such product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts. We do not own or operate cGMP facilities for the production of clinical or commercial supplies of the product candidates that we are developing or evaluating in our development programs. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We outsource all manufacturing of our product candidates and products to third parties until we can complete a cGMP facility that will allow us to supply the product candidates needed for our early- stage clinical trials. We compete with other companies for access to cGMP facilities and cannot assure continued access. In order to conduct clinical trials of product candidates, we will need to have them manufactured in potentially large quantities. Our third- party manufacturers may be unable to increase the manufacturing capacity for any of our product candidates in a timely or cost- effective manner, or at all. In addition, quality issues may arise during scale- up activities and at any other time. If these third- party manufacturers are unable to, or do not, scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or infeasible, and regulatory approval or commercial launch of that product candidate may be delayed or not obtained, which could significantly harm our business. While we have entered into supply relationships with third- party manufacturers for supplies of certain of our product candidates for purpose of preclinical testing, we may be unable to enter into agreements with third- party manufacturers for commercial supplies of any product candidate that we develop, or may be unable to do so on acceptable terms. Even if we are able to establish and maintain arrangements with sufficient third-party manufacturers, reliance on third- party manufacturers entails risks, including: • reliance on the third- party for regulatory compliance and quality assurance; • the possible breach of the manufacturing agreement by the third- party; • the possible misappropriation of our proprietary information, including our trade secrets and know- how; and • the possible termination or nonrenewal of the agreement by the third- party at a time that is costly or inconvenient for us. Third- party manufacturers may not be able to comply with cGMP requirements or similar regulatory requirements outside the United States. The failure of our third- party manufacturers to comply with applicable requirements could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and / or criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. If the third parties that we engage to supply any materials or to manufacture any products for our preclinical tests and clinical trials should cease to continue to do so for any reason, including due to the effects of the COVID- 19 pandemic and the actions undertaken by governments and private enterprises to contain COVID- 19, we likely would experience delays in advancing these tests and trials while we identify and qualify replacement suppliers or manufacturers and we may be unable to obtain replacement supplies on terms that are favorable to us. In addition, if we are not able to obtain adequate supplies of our product candidates or the substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively. For COYA ~~101 we rely on Terumo BCT to manufacture the Terumo Bioreactors, which house the Treg expansion process to generate the billions of Treg cells necessary for the end product. Most of the reagents used in this process can be sourced from multiple manufacturers. For COYA~~ 201, we rely on Terumo BCT to manufacture the Terumo Bioreactors to generate the appropriate number of expanded Treg cells. Since the Treg exosomes are generated from these expanded Treg cells, the bioreactor is a required component of the process. ~~As with COYA 101, most~~ **Most** of the reagents used in the process can be sourced from multiple manufacturers. In addition, COYA 201 requires a tangential flow filtration technology sourced from Repligen. Furthermore, COYA 201 requires a Nanosight technology sourced from Malvern. With respect to COYA 206, we will rely on multiple manufacturers of materials and equipment that are utilized in the manufacturing of COYA 206. For example, to image the exosomes we will rely on Malvern, to measure the size of the exosomes we will rely on Izon, for western blotting we will rely on ThermoFisher, for mass spectrometry we will rely on Applied Biosystems, and for DNA tethering materials we will rely on multiple manufacturers. For COYA 301, we have licensed the biologic cytokine from ARScience Biotherapeutics, Inc. and will rely on its manufacturing of the subject cytokine. For COYA 302, which involves COYA 301 plus a fusion protein, we have entered into ~~a License and Supply Agreement (~~ the ~~"~~ DRL License Agreement ~~")~~ with ~~Dr. Reddy' s Laboratories Limited ("~~ DRL ~~")~~ whereby will in-license DRL' s proposed Abatacept biosimilar to be used in the development and commercialization of COYA 302 in the United States, Canada, Mexico, South America, the European Union, the United Kingdom, and Japan. Identifying an appropriately

qualified source of alternative supply for any one or more of the component substances for our product candidates could be time consuming, and we may not be able to do so without incurring material delays in the development and commercialization of our product candidates. Any alternative vendor would also need to be qualified through a New Drug Application (“ NDA ”) supplement and may need to undergo an FDA inspection before the supplement can be approved, which could result in further delay, including delays related to additional clinical trials. These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing them successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of components and active pharmaceutical ingredients (“ APIs ”) on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, commercialization of our product candidates, and clinical trials of future potential product candidates, may be delayed or we could lose potential revenue and our business, financial condition, results of operation and reputation could be adversely affected. We are dependent on third parties to store our Treg cells and other products and any damage or loss would cause delays in replacement, and our business could suffer. The Treg cells and other products are stored in freezers at third- party biorepositories and will also be stored in our freezers at our production facility. If these materials are damaged at these facilities, including by the loss or malfunction of these freezers or our back- up power systems, as well as by damage from fire, power loss or other natural disasters, we would need to establish replacement Treg cells and exosomes, viral vector, and master and working cell banks of the engineered K562 cells, which would impact clinical supply and delay our patients’ treatments. If we are unable to establish replacement materials, we could incur significant additional expenses and liability to patients whose treatment is delayed, and our business could suffer. We have not yet developed a validated methodology for freezing and thawing large quantities of Treg cells, which we believe will be required for the storage and distribution of our Treg product candidates. We have not yet demonstrated that Treg cells, which can be frozen and thawed in smaller quantities, can also be frozen and thawed in large quantities without damage, in a cost- efficient manner and without degradation over time. We may encounter difficulties not only in developing freezing and thawing methodologies for large scale use, but also in obtaining the necessary regulatory approvals for using such methodologies in treatment. If we cannot adequately demonstrate similarity of our frozen product to the unfrozen form to the satisfaction of the FDA, we could face substantial delays in our regulatory approvals. If we are unable to freeze Treg cells for shipping purposes, our ability to promote adoption and standardization of our products, as well as achieve economies of scale by centralizing our production facility, will be limited. Even if we are able to successfully freeze and thaw Treg cells in large quantities, we will still need to develop a cost- effective and reliable distribution and logistics network, which we may be unable to accomplish. Furthermore, we have not yet demonstrated long- term stability of cryopreserved Treg cells and therefore do not know if we will be able to store the cryopreserved cells for extended periods of time. If we are unable to demonstrate long- term stability, we will need to reduce the manufacturing batch size to ensure that the material we produce will be used before it expires. In that case, the scaling of our production processes will not deliver the efficiencies we expect, and the cost per dose of our product candidates will be substantially higher. For these and other reasons, we have not yet established the long- term stability of our cryopreserved Treg Cells and we may not be able to commercialize Treg cells on a large scale or in a cost- effective manner. If such product is found to be instable, we would be required to conduct more frequent manufacturing runs, which could cause us to incur significant additional expenses. Risks Related to Our Intellectual Property If our license agreement with The Methodist Hospital is terminated, we could lose our rights to key components enabling our Treg Modalities. Key components of the technology utilized in our Treg Modalities have been in- licensed pursuant to an Amended and Restated Patent and Know How License Agreement, (the “ Methodist License Agreement ”), between us and The Methodist Hospital located in Houston, Texas (the “ Methodist ”). Pursuant to the Methodist License Agreement, Methodist granted to us an exclusive, worldwide, royalty- bearing, sublicensable license under specified patents and patent applications related to Treg technology in the field of therapeutics. Pursuant to the Methodist License Agreement, we are also required to pay Methodist, on a licensed product- by- licensed product and country- by- country basis, royalties (subject to customary reductions) ranging from 1 % to 10 % of annual worldwide net sales of such licensed product. The applicable royalty percentage increases as Licensed Products are used to treat from only one to more than three indications and if a given licensed product utilizes only Treg cell therapy or is a combination of both Treg cell therapy and exosomes. Therefore, the lowest tier is paid when there is only a single indication being addressed with a single product. There is only one low double- digit tier with such tier bearing only on combination products where there are three or more indications being served. We are also required to pay a low single digit percentage for certain licensed services. We are required to pay mid- teens royalties on sublicense revenue. The term of the Methodist License Agreement extends until expiration of the last of the patent rights licensed to us by the Licensor, which is currently expected to occur in approximately 2039. The Licensor may terminate the Methodist License Agreement or convert it into a non- exclusive license upon the occurrence or non- occurrence of certain events subject to the terms and conditions therein, such as (i) not “ Actively Attempting to Develop or Commercialize ” (as defined in the Methodist License Agreement) for a continuous period of 6 months anytime beginning October 2, 2025, (ii) breach of obligation to make timely payments or reports by us, (iii) an uncured material breach by us, (iv) the cessation of our business or our insolvency, liquidation or receivership. If the Licensor terminates or narrows the Methodist License Agreement, we could lose the use of intellectual property rights that may be material or necessary to the development or production of our product candidates, which could impede or prevent our successful commercialization of such product candidates and materially adversely affect our business, financial condition, results of operations and growth prospects. Furthermore, our Methodist License Agreement with the Licensor is field- specific and has been granted to us in the field of therapeutics. This Methodist License Agreement permits Licensor to practice the licensed rights, and to allow non- profit academic third parties to practice the licensed rights for certain academic purposes. As such, certain patents in a patent family that is licensed to us by the Licensor have been licensed to at least one other third party. Although these patents should not be overlapping with our licensed patents, there is a risk that inadvertent

overlap may occur, and thus resources may have to be expended to resolve any such overlap and to prevent other licensees from practicing under our licensed patents rights. If any of the foregoing were to occur, it could delay our development and commercialization of our product candidates, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects. Our development and commercialization rights to our current and future product candidates and technology are subject, in part, to the terms and conditions of licenses granted to us by others. Our patent portfolio consists of pending patent applications licensed from third parties, jointly owned with third parties and assigned solely to us based on our ongoing development activities. We are reliant upon certain of these rights and proprietary technology from third parties for the engineering and development of our current and future product candidates. However, these and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we choose to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses. We also engage in collaborations with scientists at academic and non- profit institutions to access technologies and materials that are not otherwise available to us. Although the agreements that govern these collaborations may include an option to negotiate an exclusive license to the institution' s rights in any inventions that are created in the course of these collaborations, we may not be able to come to a final agreement for an exclusive license with an institution. Such licenses and other contracts may be the subject of disagreements with the grantors and / or various third parties regarding the interpretation of such licenses and contracts. The resolution of any such disagreements that may arise could affect the scope of our rights to the relevant technology, or affect financial or other obligations under the relevant agreement, either of which could inhibit our ability to utilize the underlying technology in a cost- effective manner to develop and commercialize our product candidates, which in turn could have materially adversely affect our business, financial condition, results of operations and growth prospects. Under certain circumstances such as a material breach of terms, our licensors could terminate our license agreements. If these in- licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement and defense of patents and patent applications directed to the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced and defended in a manner consistent with our best interests. If our licensors fail to prosecute, maintain, enforce and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be impaired. Additionally, we may be required to reimburse our licensors for all of their expenses related to the prosecution, maintenance, enforcement and defense of patents and patent applications that we in- license from them. Furthermore, our licensors may have relied on third- party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in- licensed. If other third parties have ownership rights to our in- licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could harm our competitive position, and our business. Duration of patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time, and the expiration of our patents may subject us to increased competition. As of the date of this Annual Report on Form 10- K, our patent estate derived from our relationship with The Houston Methodist Hospital included one U. S. non- provisional patent application, five foreign patent applications, and six pending Patent Cooperation Treaty (" PCT ") applications, each co- owned with or in- licensed from The Houston Methodist Hospital. These patent applications are directed to our Treg and exosome compositions and methods of use, methods of Treg and exosome manufacture, and methods of in vivo Treg expansion via combination therapies, among other things. We have filed intellectual property claims on the contents of the exosomes, namely the micro RNAs that are reproducibly represented from batch to batch. Many of these micro RNAs confer anti- inflammatory functionality as a mechanism of action and may explain the exosomes immunomodulatory function. The exosome field is an emerging and new area at present and understanding the functional aspects of the exosomes is an important but evolving regulatory aspect. We have filed intellectual property claims for compositions of matter that teach the reproducible micro RNA contents. To date, no patents have been issued. If any patents issue from or claim priority to these patent applications, the patents are expected to expire in 2040 and 2042, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees. In addition, our patent estate derived from our relationship with ARScience Biotherapeutics, Inc. (described below) included one published patent application and one provision patent application. The patents are expected to expire in 2041 and 2043, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. All of our Houston Methodist Hospital patents have composition and method claims, with the exception of a biomarker patent, which has only method claims. The ARScience Biotherapeutics, Inc. patents have composition, method, and utility claims. **Our patent estate derived from our relationship with Dr Reddy' s Laboratories includes one published patent application This patent, if granted, is expected to expire in 2039, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The Dr. Reddy' s patent has composition, method, and utility claims. our patent estate derived from our relationship with the University of Nebraska includes two provisional patent applications. These patents, if granted, are expected to expire in 2044, without giving effect to any potential patent term extensions or patent term adjustments and assuming**

payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The University of Nebraska patents have use claims. Finally, our patent estate derived from our relationship with Carnegie Mellon included one pending patent application. The patents, if granted, would is expected to expire in 2043, without giving effect to any potential patent term extensions or patent term adjustments and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. The Carnegie Mellon patent has method claims. We ~~plan to file additional patent applications that could potentially allow for further increase of the exclusive market protection for use of COYA 101. However, we~~ can provide no assurance that we will be able to file or receive additional patent protection for ~~COYA 101 or~~ **our** ~~other~~ product candidates. Patent expiration dates may be shortened or lengthened by a number of factors, including terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Our patent protection could also be reduced or eliminated for noncompliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies. In addition, if we fail to apply for applicable patent term extensions or adjustments, we will have a more limited time during which we can enforce our granted patent rights. Given the amount of time required for the development, testing and regulatory review of product candidates, patents protecting such candidates might expire before or shortly after such product candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we have or will obtain patent rights. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent; provided that the patent is not enforceable for more than 14 years from the date of drug approval, which is limited to the approved indication (or any additional indications approved during the period of extension). Furthermore, only one patent per approved product can be extended and only those claims directed to the approved product, a method for using it or a method for manufacturing it may be extended. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authority in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If we are responsible for patent prosecution and maintenance of patent rights in- licensed to us, we could be exposed to liability to the applicable patent owner. If we or our licensors fail to maintain the patents and patent applications covering our product candidates and technologies, we may not be able to prevent a competitor from marketing products that are the same as or similar to our product candidates. Further, others commercializing products similar or identical to ours, and our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case, which could increase competition for our product candidates and materially adversely affect our business, financial condition, results of operations and growth prospects. If any patent protection we obtain is not sufficiently robust, our competitors could develop and commercialize products and technology similar or identical to ours. The market for cell therapy is highly competitive and subject to rapid technological change. Our success depends, in large part, on our ability to maintain a competitive position in the development and protection of technologies and products for use in these fields and to obtain and maintain patent protection in the United States and other countries with respect to our product candidates and our technology. We have sought, and intend to seek, to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and our technology that are important to our business. If we are unable to protect our intellectual property, our competitive position could be materially adversely affected, as third parties may be able to make, use or sell products and technologies that are substantially the same as ours without incurring the sizeable development and licensing costs that we have incurred. This, in turn, would materially adversely affect our ability to compete in the market. The patent position of biotechnology and pharmaceutical companies generally is uncertain, involves complex legal and factual questions and has, in recent years, been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or product candidates or effectively prevent others from commercializing competitive technologies and product candidates. The patent prosecution process is expensive, time- consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may also fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Claim scope in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if the patent applications we license or own do issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative products in a non- infringing manner. Even after issuance, our owned and in-licensed patents may be subject to challenge, which if successful could require us to obtain licenses from third parties, which may not be available on commercially reasonable terms or at all, or to cease the use of the underlying technology, which could materially adversely affect our business. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents, even after issuance, may be challenged in the courts or patent offices in the United States and abroad. Third- party challenges may result in a loss of exclusivity or in our patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to prevent others from using or commercializing similar or identical technology and products, or could limit the duration of the patent protection of our technology and product candidates. Even if our patents are determined to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which could materially adversely affect our ability to develop, manufacture and market our product candidates. There are many patents issued or applied for in the biotechnology

industry, and we may not be aware of patents or patent applications held by others that relate to our business. We cannot guarantee that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of 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 elsewhere that is relevant to or necessary for the development and commercialization of our product candidates in any jurisdiction. For example, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents) and publications in the scientific literature often lag behind actual discoveries. Thus, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications directed to our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to patents directed to such technologies. If third parties have filed such patent applications, an interference proceeding in the United States can be initiated by such third party, or by the USPTO itself, to determine who was the first to invent any of the subject matter recited by the patent claims of our applications. Furthermore, after issuance, the scope of patent claims remains subject to construction as 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, and we may incorrectly determine that our product candidates 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 elsewhere that we consider relevant may also be incorrect, which. If we fail to correctly identify or interpret relevant patents, we may be subject to infringement claims. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay monetary damages, we may be temporarily or permanently prohibited from commercializing our product candidates. We may also be forced to attempt to redesign our product candidates in a manner that no longer infringes third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to the development and commercialization of our product candidates. Claims brought against us for infringing, misappropriating or otherwise violating intellectual property rights of third parties or engaging in unfair competition, would be costly and time- consuming and could prevent or delay us from successfully developing or commercializing our product candidates. Our success depends in part on our ability to develop, manufacture and market our technology and use our technology without infringing the proprietary rights of third parties. As the relevant product industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated. As a result, our technology and any future products that we commercialize could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and / or limit our ability to commercialize our product candidates. We may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties. We employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Accordingly, we may be subject to claims that these employees, or we, have used or disclosed trade secrets or other proprietary information of their former employers. Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third- party proprietary rights, or to establish our proprietary rights. Regardless of whether any such claims that we are infringing patents or other intellectual property rights have merit, such claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend. Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our product candidates while we develop non- infringing substitutes, or may result in significant settlement costs. Litigation can involve substantial damages for infringement (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), and the court could prohibit us from selling or require us to take a license from a third party, which the third party is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties, upfront fees, milestone fees, or grant cross- licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third- party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use, or sale. We may not be able to effectively monitor unauthorized use of our intellectual property and enforce our intellectual property rights against infringement, and may incur substantial costs as a result of bringing litigation or other proceedings relating to our intellectual property rights. Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors' products for potential infringement of our rights. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Any inability to meaningfully monitor unauthorized use of our intellectual property could result in competitors offering products that incorporate our product or service features, which could in turn reduce demand for our products. We may also, from time to time, seek to enforce our intellectual property rights against infringers when we determine that a successful outcome is probable and may lead to an increase in the value of the intellectual property. If we choose to enforce our patent rights against a party, that party could counterclaim that our patent is invalid and / or unenforceable. The defendant may challenge our patents through proceedings before the Patent Trial and Appeal Board, or PTAB, including inter partes and post- grant review. Proceedings to challenge patents are also available internationally, including, for example, opposition proceedings and nullity actions. In patent litigation in the United States, counterclaims alleging invalidity and / or unenforceability and PTAB challenges are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements,

including lack of novelty, obviousness or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the PTAB, even outside the context of litigation. 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 and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and / or unenforceability, we may lose at least part, and perhaps all, of the patent protection on our product candidates. In addition, such lawsuits and proceedings are expensive and would consume time and resources and divert the attention of managerial and scientific personnel even if we were successful in stopping the infringement of such patents. Litigation is inherently unpredictable, and there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions. Furthermore, 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. There is also the risk that, even if the validity of such patents is upheld, the court will refuse to stop the other party on the ground that such other party' s activities do not infringe our intellectual property rights. There could also 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 materially adversely affect the value of our common stock and warrants. Finally, any uncertainties resulting from the initiation and continuation of any litigation could materially adversely affect our ability to raise the funds necessary to continue our operations. We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection. We have a number of international patents and patent applications, and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. However, filing, prosecuting and defending patents relating to our product candidates, including all of our in- licensed patent rights, in all countries throughout the world would be prohibitively expensive. We must ultimately seek patent protection on a country- by- country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries. Furthermore, the protection offered by intellectual property rights in certain countries outside of the United States may be less extensive than those in the United States. Consequently, we may not be able to prevent third parties from utilizing proprietary technology in all countries outside of the United States, even if we pursue and obtain issued patents in particular foreign jurisdictions, or from selling or importing products made using our proprietary technology in and into the United States or other jurisdictions. Such products may compete with our products, and our patent rights or other intellectual property rights may not be effective or sufficient to prevent them from competing. If such competing products arise in jurisdictions where we are unable to exercise intellectual property rights to combat them, our business, financial condition, results of operations and growth prospects could be materially adversely affected. Changes in U. S. patent law or the patent law of other jurisdictions could decrease the certainty of our ability to obtain patents and diminish the value of patents in general, thereby impairing our ability to protect our current and any future product candidates. The U. S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. For example, in recent years the U. S. Supreme Court modified some tests used by the USPTO in granting patents over the past 20 years, which may decrease the likelihood that we will be able to obtain patents and increase the likelihood of a challenge of any patents we obtain or license. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. Those changes may materially adversely affect our patent rights and our ability to obtain issued patents. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Under the Leahy- Smith America Invents Act, or the America Invents Act, 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. The America Invents Act also includes a number of significant changes that affect the way patent applications are 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. 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 materially adversely affect our business, financial condition, results of operations and growth prospects. In addition, the U. S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on 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 weaken our ability to obtain new patents or to enforce patents that we own, have licensed or might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we own or have licensed or that we may obtain in the future, which in turn could materially adversely affect our business, financial condition, results of operations and growth prospects. We may fail to obtain or enforce assignments of intellectual property rights from our employees and contractors. While it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing an enforceable agreement with each

party who in fact conceives or develops intellectual property that we regard as our own. Furthermore, our assignment agreements may not be self- executing or may be breached, and we may be forced to bring or defend claims to determine the ownership of what we regard as our intellectual property, and we may not be successful in such claims. If we fail in bringing or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could materially adversely affect our business, financial condition, results of operations and growth prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees. If we are not able to adequately prevent disclosure of trade secrets and other proprietary information, the value of our technology and products could be materially diminished. Trade secrets are difficult to protect. We rely on trade secrets to protect our proprietary information and technologies, especially where we do not believe patent protection is appropriate or obtainable, or where such patents would be difficult to enforce. We rely in part on confidentiality agreements with our employees, consultants, contractors, outside scientific collaborators and other advisors to protect our trade secrets and other proprietary information. We cannot guarantee that we have entered into such agreements with each party that may have had access to our proprietary information or technologies, or that such agreements, even if in place, will not be circumvented. These agreements may not effectively prevent disclosure of proprietary information or technology and may not provide an adequate remedy in the event of unauthorized disclosure of such information or technology. In addition, others may independently discover our trade secrets and proprietary information, in which case we may have no right to prevent them from using such trade secrets or proprietary information to compete with us. Costly and time- consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could materially adversely affect our business, financial condition, results of operations and growth prospects. Risks Related to Our Securities If we sell securities in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline. We may from time to time issue additional shares of common stock, warrants or other securities convertible into our common stock, at a discount from the current market price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any of our securities sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders and holders of our warrants could experience additional dilution and, as a result, our stock price may decline. Our directors, executive officers and principal stockholders have substantial control over us and could delay or prevent a change of corporate control. **Our** ~~Following our initial public offering, our~~ directors, executive officers, and 5 % stockholders beneficially own approximately ~~10~~ **30** . ~~5~~ **6** % of the voting power of our outstanding common stock. As a result, such entities and individuals will have the ability, acting together, to significantly influence the election of our directors and the outcome of corporate actions requiring stockholder approval, such as: (i) a merger or a sale of our company, (ii) a sale of all or substantially all of our assets, and (iii) amendments to our Certificate of Incorporation and Bylaws. This concentration of voting power and control could have a significant effect in delaying, deferring or preventing an action that might otherwise be beneficial to our other stockholders and be disadvantageous to our stockholders with interests different from those entities and individuals. Certain of these individuals also have significant control over our business, policies and affairs as officers or directors of our Company. Therefore, you should not invest in reliance on your ability to have any control over our Company. The market price for our common stock may be volatile, and your investment in our securities could decline in value. The stock market in general has experienced extreme price and volume fluctuations. The market prices of the securities of biotechnology and specialty pharmaceutical companies, particularly companies like ours without product revenues and earnings, have been highly volatile and may continue to be highly volatile in the future. This volatility has often been unrelated to the operating performance of particular companies. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock: • announcements of technological innovations or new products by us or our competitors; • announcement of FDA approval or disapproval of our product candidates or other product- related actions; • developments involving our discovery efforts and clinical trials; • developments or disputes concerning patents or proprietary rights, including announcements of infringement, interference or other litigation against us or our potential licensees; • developments involving our efforts to commercialize our products, including developments impacting the timing of commercialization; • announcements concerning our competitors, or the biotechnology, pharmaceutical or drug delivery industry in general; • public concerns as to the safety or efficacy of our product candidates or our competitors' products; • changes in government regulation of the pharmaceutical or medical industry; • changes in the reimbursement policies of third party insurance companies or government agencies; • actual or anticipated fluctuations in our operating results; • changes in financial estimates or recommendations by securities analysts; • developments involving corporate collaborators, if any; • changes in accounting principles; and • the loss of any of our key scientific or management personnel. In the past, securities class action litigation has often been brought against companies that experience volatility in the market price of their securities. Whether or not meritorious, litigation brought against us could result in substantial costs and a diversion of management' s attention and resources, which could adversely affect our business, operating results and financial condition. Certain companies with public floats comparable to our public float have experienced extreme volatility that was seemingly unrelated to the underlying performance of the respective company. We may experience similar volatility, which may make it difficult for prospective investors to assess the value of our common stock. In addition to the risks addressed above in "- The market price for our common stock may be volatile, and your investment in our securities could decline in value, " our common stock may be subject to extreme volatility that is seemingly unrelated to the underlying performance of our business. Recently, companies with comparable public floats have experienced instances of extreme stock price run- ups followed by rapid price declines, and such stock price volatility was seemingly unrelated to the respective company' s underlying performance. Although the specific cause of such volatility is unclear, our public float may amplify the impact the actions taken by a few stockholders have on the

price of our stock, which may cause our stock price to deviate, potentially significantly, from a price that better reflects the underlying performance of our business. Should our common stock experience run- ups and declines that are seemingly unrelated to our actual or expected operating performance and financial condition or prospects, prospective investors may have difficulty assessing the rapidly changing value of our common stock. In addition, investors of our securities may experience losses, which may be material, if the price of our common stock declines or if such investors purchase shares of our common stock prior to any price decline. The warrants from our initial public offering are speculative in nature and may not have any value do not entitle the holder to any rights as common stockholders until the holder exercises the warrant for shares of our common stock. The warrants issued in our initial public offering do not confer any rights of common stock ownership on its holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price during a fixed period of time. The holders of the warrants may exercise their right to acquire common stock and pay an exercise price of $ 7. 50 per share of common stock. The warrants became exercisable beginning on the closing of our initial public offering and will expire on the second anniversary of the date of issuance. Until the holder of a warrant acquires shares of our common stock upon exercise of a warrant, the warrant will not provide the holder with any rights as a common stockholder, such as voting rights or the right to receive dividends. Upon exercise of a warrant, a holder will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs on or after the exercise date of the warrant. The warrants issued in our initial public offering may not have any value. The market value of the warrants issued in our initial public offering, if any, is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their imputed offering price. There can also be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants and, consequently, whether it will ever be profitable for holders of the warrants to exercise them. We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. As a public company, and particularly after we no longer qualify as an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur previously. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on U. S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. For example, we expect that these rules and regulations may make it more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors. In addition, these rules and regulations are often subject to varying interpretations, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, once we no longer qualify as an emerging growth company, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. We are an " emerging growth company, " and the reduced reporting requirements applicable to emerging growth companies may make our securities less attractive to investors. We qualify as an " emerging growth company, " as defined in the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to public companies that are not emerging growth companies. These provisions include, but are not limited to: being permitted to have only two years of audited financial statements and only two years of related management' s discussion and analysis of financial condition and results of operations disclosure; an exemption from compliance with the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to Section 404 of the Sarbanes- Oxley Act; not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements; reduced disclosure obligations regarding executive compensation arrangements in our periodic reports, registration statements and proxy statements; and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. In addition, the JOBS Act permits emerging growth companies to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies. We intend to take advantage of the exemptions discussed above. As a result, the information we provide will be different than the information that is available with respect to other public companies. In this Annual Report on Form 10- K, we have not included all of the executive compensation- related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our securities less attractive if we rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities, and the market price of our common stock may be more volatile. We will remain an

emerging growth company until the earliest of (i) the end of the fiscal year following the fifth anniversary of the completion of our initial public offering, (ii) the first fiscal year after our annual gross revenue exceeds $ 1. 235 billion, (iii) the date on which we have, during the immediately preceding three- year period, issued more than $ 1. 0 billion in non- convertible debt securities, or (iv) the end of any fiscal year in which the market value of our common stock held by non- affiliates exceeds $ 700. 0 million as of the end of the second quarter of that fiscal year. We do not anticipate paying dividends on our common stock and, accordingly, stockholders must rely on stock appreciation for any return on their investment. We have never declared or paid cash dividends on our common stock and do not expect to do so in the foreseeable future. The declaration of dividends is subject to the discretion of our board of directors and limitations under applicable law, and will depend on various factors, including our operating results, financial condition, future prospects and any other factors deemed relevant by our board of directors. You should not rely on an investment in our company if you require dividend income from your investment in our company. The success of your investment will likely depend entirely upon any future appreciation of the market price of our common stock, which is uncertain and unpredictable. There is no guarantee that our common stock will appreciate in value. The administrator of our amended and restated 2021 Equity Incentive Plan (the " Amended and Restated Equity Plan ") is authorized to exercise its discretion to effect the repricing of stock options and stock appreciation rights and there may be adverse consequences to our business if the administrator of the Amended and Restated Equity Plan exercises such discretion. Pursuant to our Amended and Restated Equity Plan, we are authorized to grant equity awards, including stock options and stock appreciation rights, to our employees, directors and consultants. The administrator of the Amended and Restated Equity Plan (which is our compensation committee) is authorized to exercise its discretion to reduce the exercise price of stock options or stock appreciation rights or effect the repricing of such awards. Although we do not anticipate needing to exercise this discretion in the near term, or at all, if the administrator of the Amended and Restated Equity Plan were to exercise such discretion without seeking prior stockholder approval, certain proxy advisory firms or institutional investors may be unsupportive of such actions and publicly criticize our compensation practices, and proxy advisory firms may recommend an " against " or " withhold " vote for members of our compensation committee. In addition, if we are required to hold an advisory vote on named executive officer compensation (known as the " say- on- pay " vote) at the time of, or subsequent to, any such repricing, it is likely that proxy advisory firms would issue an " against " recommendation on our say on pay vote and institutional investors may not be supportive of our say- on- pay vote. If proxy advisory firms or institutional investors are successful in aligning their views with our broader stockholder base and we are required to make changes to the composition of our board and its committees, or if we need to make material changes to our compensation and corporate governance practices, our business might be disrupted and our stock price might be negatively impacted. Even if we are able to successfully rationalize the exercise of such discretionary power, defending against any " against " or " withhold " recommendation for members of our compensation committee, any " against " recommendation on our say on pay vote or public criticism could be distracting to management, and responding to such positions from such firms or investors, even if remedied, can be costly and time- consuming. In addition, if the administrator of the Amended and Restated Equity Plan does determine to reprice stock options or stock appreciation rights, even absent negative reactions from proxy advisory firms and institutional investors, management attention may be diverted and we could incur significant costs, including accounting and administrative costs and attorneys' fees. We may also be required to recognize incremental compensation expense as such result of a repricing. These actions could cause our stock price to decrease and experience periods of increased volatility. The rights of the holders of our securities may be impaired by the potential issuance of preferred stock. Our amended and restated certificate of incorporation (the " Amended Charter ") contains provisions that gives our board of directors the ability to designate and issue preferred stock in one or more series. As a result, the board of directors may, without stockholder approval, issue preferred stock with voting, dividend, conversion, liquidation or other rights which could adversely affect the relative voting power and equity interest of the holders of common stock. Preferred stock, which could be issued with the right to more than one vote per share, could have the effect of discouraging, delaying or preventing a change of control of us. The possible impact on takeover attempts could adversely affect the price of our securities. Although we have no present intention to designate any series, or issue any shares, of preferred stock, we may do so in the future. If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline. The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. We currently do not have research coverage by securities industry and financial analysts. We may not receive any research coverage by equity research analysts. Equity research analysts may elect not to initiate or to continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we obtain research coverage by such securities or industry analysts, if one or more of the analysts who cover us downgrade our stock, our stock price may decline significantly. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Anti- takeover provisions in our organizational documents and Delaware law might discourage or delay attempts to acquire us that you might consider favorable. Our Amended Charter, Amended and Restated Bylaws (the " Amended Bylaws ") and Delaware law contain provisions that could have the effect of rendering more difficult, delaying or preventing an acquisition deemed undesirable by our board of directors. Our corporate governance documents include provisions: • classifying our board into three classes; • authorizing " blank check " preferred stock, which would be issued by our board of directors without stockholder approval and may contain voting, liquidation, dividend, and other rights superior to our common stock; • limiting the liability of, and providing indemnification to, our directors and officers; • limiting the ability of our stockholders to call and bring business before special meetings; • requiring advance notice of stockholder proposals for business to be conducted at meetings of our stockholders and for nominations of candidates for election to our board of directors; • controlling the procedures for the conduct and scheduling of board of directors and stockholder meetings;

and • providing our board of directors with the express power to postpone previously scheduled annual meetings and to cancel previously scheduled special meetings. These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. As a Delaware corporation, we are also subject to provisions of Delaware law, including Section 203 of the Delaware General Corporation law, which prevents certain stockholders holding more than 15 % of our outstanding common stock from engaging in certain business combinations without approval of the holders of substantially all of our outstanding common stock. Any provision of our amended and restated certificate of incorporation, bylaws or Delaware law that has the effect of delaying or deterring a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock. Our Amended Charter provides that the Court of Chancery of the State of Delaware is the sole and exclusive forum for substantially all disputes between us and our stockholders and federal district courts will be the sole and exclusive forum for Securities Act claims, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees. Our Amended Charter provides that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of fiduciary duty owed by any of our current or former directors, officers, or other employees to us or to our stockholders; (iii) any action asserting a claim arising pursuant to the Delaware General Corporation Law (the " DGCL "), the Amended Charter or the Amended Bylaws or as to which the DGCL confers exclusive jurisdiction on the Court of Chancery of the State of Delaware; or (iv) any action asserting a claim governed by the internal affairs doctrine of the law of the State of Delaware, provided that the exclusive forum provisions will not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction. Our Amended Charter further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts are the sole and exclusive forum for the resolution of any complaint asserting a right under the Securities Act, subject to a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. The choice of forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage such lawsuits against us and our directors, officers, and other employees. Further, the choice of forum provisions may result in increased costs for a stockholder to bring a claim. Alternatively, if a court were to find the choice of forum provisions contained in our Amended Charter to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations, and financial condition. Provisions in our organizational documents regarding exculpation and indemnification of our directors and officers may result in substantial expenditures by us and may discourage lawsuits against our directors and officers. Our Amended Charter and Amended Bylaws, to the maximum extent permissible under Delaware law, eliminates the personal liability of our directors and officers to us and our stockholders for damages for breach of fiduciary duty. These provisions may discourage us, or our stockholders through derivative litigation, from bringing a lawsuit against any of our current or former directors or officers for any breaches of their fiduciary duties, even if such legal actions, if successful, might benefit us or our stockholders. In addition, our Amended Charter and Amended Bylaws provides that we will, to the fullest extent permitted by Delaware law, indemnify our directors and officers for costs or damages incurred by them in connection with any threatened, pending, or completed action, suit, or proceeding brought against them by reason of their positions as directors and officers. We also entered into indemnification agreements with each of our directors and executive officers. See " Certain Relationships and Related Party Transactions- Agreements with Directors and Officers- Indemnification Agreements. " Although we expect to purchase directors' and officers' insurance, these indemnification obligations could result in our incurring substantial expenditures to cover the cost of settlement or damage awards against our directors or officers. We ratified certain actions pursuant to Section 204 of the Delaware General Corporation Law and filed Certificates of Validation with the Secretary of State of the State of Delaware. As of February 1 and 2, 2022 respectively, our Board and our stockholders, ratified certain actions (the " 2020 Ratifications ") pursuant to Section 204 (" § 204 ") of the Delaware General Corporation Law (the " DGCL "), which allows a Delaware corporation to ratify a defective corporate act retroactive to the date the corporate act was originally taken. The Ratification was adopted in order to correct certain failures of authorization with respect to the (i) merger of Nicoya Health, Inc. with and into the Company as of December 22, 2020 (the " Merger "), and (ii) amendment and restatement of the Corporation' s certificate of incorporation filed with the Secretary of State of the State of Delaware (the " Secretary of State ") on December 22, 2020 (the " A & R Charter ") (collectively, the " 2020 Corporate Acts ") and thereby remove any uncertainty and confirm the valid issuance of (a) 1, 887, 453 shares of putative common stock of the Company to the former stockholders of Nicoya Health, Inc. pursuant to the Merger effective December 22, 2020, and (b) 7, 361, 744 shares of putative Series A preferred stock to the investors participating in that certain Series A Financing effective on December 22, 2020 (collectively, the " 2020 Issuances "). Consequently, in accordance with § 204, our Board ratified the 2020 Corporate Acts and the 2020 Issuances, and approved the submission to (i) the stockholders of the Company for ratification and approval of each of the 2020 Corporate Acts and the 2020 Issuances; and (ii) upon receiving stockholder ratification and approval, the Secretary of State of the State of Delaware of a Certificate of Validation regarding the Merger, and a separate Certificate of Validation regarding the A & R Charter. Our stockholders ratified the 2020 Corporate Acts and the 2020 Issuances on February 2, 2022. Similarly, on February 16, 2022, our Board ratified certain actions (the " 2021 Ratifications ") pursuant to § 204 in order to correct certain failures of authorization with respect to the (i) appointment and removal of certain members of our Board that occurred between March 30, 2021 and June 6, 2021 (the " Director Designations "); (ii) approval of our 2021 Equity Incentive Plan on February 5, 2021 (the " Equity Plan Adoption "); and (iii) certain option grants under the 2021 Equity Incentive Plan on April 10, 2021, May 17, 2021 and June 7, 2021 that resulted in the issuance of options exercisable for up to an

aggregate of 45, 650 putative shares of common stock at an exercise price of $ 1. 09 per share (the " Option Grants "), and thereby remove any uncertainty regarding the composition of our Board as well as confirm the valid issuance of the Option Grants. Consequently, in accordance with § 204, our Board ratified the Director Designations, the Equity Plan Adoption and the Option Grants, and approved the submission to the stockholders of the Company for ratification and approval of each of the Director Designations and the Equity Plan Adoption, which our stockholders ratified on February 24, 2022. Although we believe we have fully complied with the procedures and requirements of § 204, there can be no assurance that (i) claims that the 2020 Corporate Acts, the 2020 Issuances, the Director Designations, the Equity Plan Adoption, and / or the Option Grants or putative stock ratified in connection with the 2020 Issuances and / or the Option Grants are void or voidable due to the identified failure of authorization, or (ii) claims that the Delaware Court of Chancery should declare in its discretion that the ratification pursuant to § 204 not be effective or be effective only on certain conditions or other claims related thereto, will not be asserted, and, if asserted, that any such claims will not be successful. Under § 204, these claims must be brought within 120 days from (A) the filing of the applicable Certificate of Validation in the case of 2020 Corporate Acts and 2020 Issuances; (B) the date the stockholders ratify the Director Designations and Equity Plan Adoption in the case of the Director Designations and Equity Plan Adoption; and (C) the date the Board approved the 2021 Ratifications in the case of the Option Grants. If any of the ratifications pursuant to § 204 were not effective, then the 2020 Corporate Acts, the 2020 Issuances, the Director Designations, the Equity Plan Adoption, and the Option Grants, as applicable, would be invalid and, as applicable, we could have liability to holders of the common stock and / or the Series A preferred stock corresponding to the 2020 Issuances and the grantees under the Option Grants, as applicable, including being subject to monetary damages and rescission rights. ~~77~~ **71**